Submissions Received in Response to the Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond

Updated: 02/19/2016

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Introduction

On November 12, 2015, The Centers for Medicare & Medicaid Services (CMS) released the Request for Comments: Enhancements to the Star Ratings for 2017 and beyond (original request available here: http://go.cms.gov/partcanddstarratings). Respondents were requested to post their submissions via a web based tool.

CMS received 143 separate submissions through the web tool. An additional 7 documents were sent to the Star Ratings mailbox (PartCandDStarRatings@cms.hhs.gov). Some of those additional documents had also been submitted through the web tool.

To ensure we had a complete submission from each unique submitting organization, CMS read each of the submissions and parsed out any duplicates that came from the same unique submitting organization. The final count of unique submitting organizations was 89. A table listing all of the unique submitter organization names is provided in Attachment A. The following table contains a breakdown of the number of submissions from each type of submitter that participated.

Submitter Type	Submissions
Advocacy Group	3
Consultant	4
Other	8
Part C/D Plan Sponsor	57
Pharmaceutical Manufacturer	5
Trade/Professional Organization	12
Total	89

Not all submitters responded to each of the topic/sub-topics presented in the request for comments. We have provided a breakdown by topic/sub-topic of the number of submissions that applied to the topic/sub-topic in Attachment B.

The remainder of this document contains the responses from each unique submitter in each of the topic/sub-topics. We have followed the same topic/sub-topic format as the original request document. Under each topic of those topics/sub-topics are listed the submitting organization and their response.

A. Changes to Measures for 2017

1. Improvement measures (Part C & D)

Submitter	Response
American College of Mohs Surgery	Please see the supporting document for some general comments about the Star Ratings.
American Pharmacists Association	General Comments: APhA thanks CMS for the opportunity to offer our comments regarding enhancements to the Star Ratings in 2017. APhA's member pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians are committed to continuous quality improvement. In our efforts on quality standards, APhA works closely with the Pharmacy Quality Alliance (PQA). Although APhA is submitting separate comments, we would also support any comments PQA offers on this RFI.
America's Health Insurance Plans	CMS is proposing to use a contract's 2014 CAHPS measure score as the baseline for the 2017 improvement calculation if the contract's 2015 CAHPS measure score moved to very low reliability with the exclusion of enrollees with less than 6 months of continuous enrollment. It is unclear how CMS plans to handle cases where the reliability was also very low for a contract's 2014 CAHPS measure score. We recommend that CMS provide this clarification.
Anthem, Inc	Anthem recommends that CMS adopt the following changes to the improvement measure in order to ensure that it rewards plans that improve their quality, while not adversely impacting consistently high performing plans. MA plan Star Ratings should be calculated separately for Part C and Part D with and without the improvements measures to first determine if the corresponding quality improvement (QI) measure should be included in the overall Star Rating calculation. Currently, the "hold harmless" methodology accounts for both QI measures together; however, this can adversely impact a plan's consistent high performance in either of the Part C or Part D sections. For example, Plan A received a 5 Star for Part C improvement. Their historical performance for Part D has always been 4 Stars. Thus, year-over-year improvement is minimal. As such, Plan A received a 3 Star for Part D improvement, which negatively effects the plans overall rating. As a result, Anthem proposes the following revision for MA-PD contracts: 1. There are separate Part C and Part D improvement measures (C29 and D07) for MA-PD contracts. a) C29 is always used in calculating the Part C summary rating of an MA-PD contract b) D07 is always used in calculating the Part D summary rating for an MA-PD contract c) Either or both measures will be used when calculating the overall rating in step 3 2. Calculate the summary ratings without including the improvement measure a) Part C Summary Rating without improvement measure b) Part D Summary Rating without improvement measure 3. Calculate the Part C and Part D summary ratings with the improvement measure a) Part C Summary Rating with improvement measure b) Part D Summary Rating with improvement measure 4. Determine for each Part C and Part D if

Submitter	Response
	the improvement measure should be included based on summary scores (i.e., which is higher, 2a or 3a, and 2b or 3b) 5. Calculate the overall rating for MA-PD contracts based on determination in step 4 above Also, all MA plans that are subject to the improvement measure should be allowed to benefit from it. We do not support any proposal that would limit the application of the improvement measure to only those plans with Star Ratings greater than 2.5 Stars (or other minimum threshold). Limiting the measure to only plans with more than 2.5 Stars goes against the objective of the improvement measure in encouraging and rewarding improvements in performance, particularly among lower rated plans. This is important because plans with 2.5 Stars may have a disproportionate share of members who are low income, low health literacy, or otherwise vulnerable and more difficult to reach. As a result, these plans may be struggling to make strides in the Star Ratings and should not be further disadvantaged by being excluded from the improvement measure if they are demonstrating improvements in quality year-over-year. Lastly, Anthem requests that CMS remove the Consumer Assessment of Healthcare Providers & Systems (CAHPS) survey and Health Outcome Survey (HOS) measures from the improvement factor calculation given their subjectivity. Survey data are based on perceptions and thus are not a true reflection of plan performance or outcomes. Plans should not be judged on perceptions, but rather factual evidence.
Blue Cross Blue Shield of Michigan	This comment relates to the introduction, not the improvement measures. As an introduction to this section, CMS outlined its general policies regarding specification changes to Star Ratings measures. CMS indicates that if a change is announced during the measurement period that significantly impacts the numerator or denominator, the measure will be moved to the display page for at least one year. BCBSM greatly appreciates this general guidance regarding specification changes, but requests further clarification regarding the definition of "significant" as it relates to numerator and denominator changes and moving a measure to the display page. Further clarification will help BCBSM plan and prepare for future changes, bringing additional stability and predictability to the Stars program.
BlueCross and BlueShield Association	CMS proposes to update the measures that are included in the Improvement Measures, while maintaining the methodology by which they are calculated. BCBSA and Plans understand that CMS proposes to make the following changes to the included measures: (1) CMS proposes to include – based on at least two years of data – Part C measures for Breast Cancer Screening, Complaints about the Health Plan, Plan Makes Timely Decisions about Appeals, and Call Center – Foreign Language Interpreter and TTY Availability; and Part D measures for Call Center – Foreign Language Interpreter and TTY Availability, Appeals Upheld, Complaints about the Drug Plan, and

Submitter	Response
	Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR). (2) CMS proposes to remove the Part D measure of High Risk Medication (HRM), in accordance with CMS's proposal to move the HRM measure to the Display Page for 2017. (3) For those Medicare Advantage Organizations (MAOs) whose Consumer Assessment of Healthcare Providers and Systems (CAHPS) measure score has moved to very low reliability with exclusion of certain enrollees, CMS proposes to use the contract's 2014 (as opposed to 2015) CAHPS score as the baseline in the Improvement Measure. BCBSA and Plans appreciate CMS's efforts to update the Improvement Measures in conjunction with other changes made to the Star Ratings. Plans have significant concerns, however, with the Part C and D measures of Call Center – Foreign Language Interpreter and TTY Availability. For example, several Plans commented that CMS used an inappropriately small number of calls to the call center or no calls to the call center in developing the data for evaluative performance. One Plan noted that its call center is set up to reject calls that come from unidentified telephone numbers, resulting in the rejection of CMS secret shopper calls and thus a materially inaccurate data set for evaluating performance. Use of inappropriately small data sets that are statistically invalid reduces the reliability of the measure. Accordingly, BCBSA and Plans recommend that CMS revise the Part C and D measures of Call Center – Foreign Language Interpreter and TTY Availability to increase the sample size and also consider modifications to the manner in which CMS collects data. Additionally, BCBSA and Plans recommend that CMS consider revising the nature of calls made, in order to more accurately reflect the beneficiary population being served. For example, CMS could make calls to test the availability of various language interpreters in frequencies proportional to the number of people aged 65 and older who speak such languages. CMS could also take into account geographical differences among beneficiary populations, and make test calls to those regions in accordance with those differences. If such changes are not made, we recommend that the measures not be included in the Improvement Measures, so as to avoid use of unreliable metrics in Plans' performance evaluation and again in the Improvement Measure. Separately, BCBSA and Plans request that CMS reconsider the current policy behind the application of the Improvement Measures. According to the Medicare 2016 Part C & D Star Rating

Submitter	Response
	Technical Notes, the Improvement Measures for high-performing MA-PD contracts are only applied to the contract if the contract's overall rating, including both the Part C and the Part D Improvement Measures, is better than its overall rating without either Improvement Measure. Plans believe that CMS should also consider including the Part C Improvement Measure or the Part D Improvement Measure when such measures independently are better than the contract's overall rating. Under this approach, CMS could compare the contract's overall rating for Part C both with and without the Part C Improvement Measure, and could compare the contract's overall rating for Part D both with and without the Part D Improvement Measure. CMS could use the higher rating for Part C and the higher rating for Part D. Those higher ratings could then be combined to form the contract's overall MA-PD rating. As such, a high-performing MA-PD contract would be allowed to benefit from any improvement in Part C, Part D, or Parts C and D metrics. Recommendations: BCBSA and Plans recommend that CMS revise the Part C and D measures of Call Center – Foreign Language Interpreter and TTY Availability to increase the metric's sample size. BCBSA and Plans recommend that CMS better tailor the calls made to the beneficiary population served. Alternatively, we request that CMS not include the Part C and D measures of Call Center – Foreign Language Interpreter and TTY Availability in the Improvement Measures. BCBSA and Plans recommend that CMS allow MA-PD contracts to benefit from improvements in Part C, Part D, or both Parts C and D by including the Improvement Measure for any score that benefits the contract.
BlueCross BlueShield of Tennessee	BCBST agrees with CMS' decision to keep the improvement methodology used in previous years, specifically to only include those measures with at least two years of data for calculating the 2017 improvement measures. Since the improvement measures are the most heavily weighted metrics and are designed to encourage plan improvement with patient experience, access, and intermediate outcomes, BCBST requests that CMS provide further insight on: 1) how the proposal to use 2014 scores as the baseline for contracts with low reliability CAHPS measure scores will likely impact industry performance and 2) how CMS expects this proposal will or will not support consistency in measuring plan sponsors' improvement across metrics. BCBST requests clarification on how CMS will measure plans with contracts obtaining very low reliability CAHPS measure scores beyond the 2017 ratings and for contracts who receive this score for consecutive years. Disagree with inclusion of the call center measures in the QI calculation id methodology for the call center measures is not revised and adjusted (refer to section

Submitter	Response
	G.8. Measurement and Methodological Enhancements for more information). One additional consideration is that CMS apply the Quality Improvement score to a plan's overall rating only if it does not decrease the score.
Centene Corporation	Centene Corporation requests more detail before full comment. Specifically, what is the procedure in the event that a plan has not previously reported on CAHPS measures and the 2015 score is deemed unreliable? Would such measures then be excluded from the Quality Improvement Measure calculation or would the unreliable measurement from 2015 be used in the measure calculation? Additionally, we would propose that using a previous rating years' CAHPS measure score as a proxy for measures with very low reliability would not provide an accurate reflection of more recent efforts that may have been made to impact CAHPS performance. Under such circumstances, we would propose that measures with very low reliability be excluded from the Quality Improvement Measures so as not to risk introducing validity concerns in an effort to combat poor reliability. Additional comments, Andy Slavitt Acting Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Room 445-G Hubert H. Humphrey Building 200 Independence Ave SW Washington, DC 20201 RE: Request for Comment: Enhancement to the Star Ratings for 2017 and Beyond Dear Mr. Slavitt: Thank you for the opportunity to comment on the RFC issued on November 12 regarding potential changes to the Star Ratings system for 2017 and beyond. Centene commends the Agency for considering refinements and we are eager to work with you as the process unfolds. As you will see in the attachment, our assessment is qualified in some areas because we feel we need more information in order to respond in more detail. We look forward to providing additional thoughts as CMS provides further clarification and we hope our initial response is helpful in the meantime. With this caveat, we are offering brief comments in the following areas of the RFC: • Changes to measures for 2017 • Removal of measures from Star Ratings • Impact of socioeconomic and disability status on Star Ratings • Display measures • Potential new measures for 2018 and beyond • Changes to existing Star Ratings and display measures and potential future changes Founded as a single health plan in 1984, Centene Corporation (Centene) has established itself as a national leader in the healthcare services field. Today, Centene's managed care organizations work with over 4.8 million members across 23 states. Centene provides health plans through Medicaid, Medicare and the Health Insurance Marketplace and other Health Solutions through our specialty services companies. We believe quality healthcare is best delivered locally. Our local approach enables us to provide accessible, high quality and culturally sensitive healthcare services to our members. Centene is pleased to provide these initial comments and to work further with CMS once additional clarification is available in the areas we

Submitter	Response
	highlight. Thank you again for the opportunity to comment and if you have any questions, please contact Lisa Brubaker, Senior Vice President of Complex Care, at either (314) 445- 0091or lbrubaker@centene.com. Sincerely, Jonathan Dinesman Senior Vice President, Government Relations
Cigna	Reward factor - we recommend CMS reward plans that achieve a Summary Rating at or above the 95th percentile the highest reward factor, 0.4. If under the 95th percentile, then CMS would utilize the current Reward Factor methodology. We believe this change will ensure CMS will appropriately assign the highest reward factor to plans that achieve 5 Stars in the majority of measures and eliminate the risk of Reward Factor being impacted by a rating degradation in one measure.
Commonwealth Care Alliance	CCA supports this methodology.
EmblemHealth	1. CMS should share the prospective star measures including changes to the inclusion/exclusion and methodology well in advance of the measurement year that they apply to. This will allow health plans to adjust their programs and provider incentives to align them with the star measures and thereby achieve the improvement that CMS intends to achieve by including the measures in the star rating. 2. CMS should research for regional variations as well as variations in performance across urban and rural areas, and adjust the final rates accordingly. 3. The provider specific CAHPS metric scores show wide variations depending on geography. For example - patient expectations may differ between urban and rural areas as is evident from the wide variation in metro and national benchmarks on Press Ganey patient satisfaction metrics.
Fresenius Health Plans	Thank you for the opportunity to comment on the impact of disability and specifically ESRD on Star Ratings. As an MA organization focused exclusively on caring for ESRD beneficiaries through C-SNPs, we are concerned that the current star rating methodology is not a true reflection of the performance and experience of our patients. We recommend that CMS considers excluding ESRD beneficiaries from the star measure calculations or alternatively creating ERSD-specific measurements to put in place of star rating for ESRD C-SNPs. Further, we welcome the opportunity to dialogue around ESRD-specific measures and rating methodology. As ESRD SNPs require a unique model of care because of the special needs of these beneficiaries, the applicable measurements should also reflect the special needs of these beneficiaries (which includes where and how services are provided). While the ultimate star rating applies to the entire contract, sponsors with beneficiaries who are not special needs are able to absorb the impact of the special needs beneficiaries, while C-SNP contracts are not. It is unfair and not meaningful to compare the top 1-2% sickest population to the entire Medicare population. In addition, we ask CMS to provide special consideration to the following proposed measure changes: • Breast

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	Cancer Screening: Mammography guidelines now suggest not pursuing mammography in women whose life expectancy is less than 10 years. This makes a lot of sense given the unintended consequences of mammography (quite a few of biopsies or second imaging procedures for what turn out to be false positive mammograms-which in addition to the trauma and expense cause undue anxiety for the patient). By way of reference, USRDS quotes 5 year survival rates for PD & HD patients of around 35%. The 10 year survival is very low. • Colorectal Cancer Screenings: This is a quality of life question for ESRD beneficiaries. Compared with the general population, the ERSD population has a substantially reduced life expectancy, which does not support universal screening for colon cancer, but to screen instead for acquired cystic kidney disease due to elevated risk for renal cell carcinoma in this population. • Annual Flu Vaccine: The receipt of a flu shot is reported on the Health Outcomes Survey. We recommend measurement be based on claims data to ensure accurate numbers. A majority of ESRD patients will received flu vaccines at the Dialysis Center and not at their PCP office or pharmacy.
Health Care Service Corporation	HCSC supports CMS' proposal to use the 2014 CAHPS measure score (for 2015 Star Ratings) instead of 2015 as the baseline for the 2017 improvement calculation if a contract's CAHPS measure score moved to very low reliability with the exclusion of the enrollees with less than 6 months of continuous enrollment for the 2015 survey administration.
Health Net, Inc.	Disagree w/ CMS using prior years results for any low-reliability measures as they will not reflect performance improvement efforts put in place by the Plan for current rating period.
HealthPartners	HealthPartners recommends that CMS modify the methodology for applying improvement measures to allow the inclusion of either the Part C or the Part D quality improvement measure if including only one of the measures would improve the plan's overall score. We believe this approach supports CMS' hold harmless provision.
HealthPlus	The Call Center - Foreign Language Line and TTY Availability measure does not have enough transparency in the reporting of healthplan performance to justify inclusion in the Improvement measure. The data collection methodology, vendor consistency and outcomes reported to healthplans needs to be more detailed and reliable for healthplans to understand improvement opportunities. Additional Comment: The Complaints about the Health Plan measure is not recommended for inclusion in the Improvement measure due to the variances of membership sizes across healthplans and the often small number of complaints that could influence significance of improvements or declines. Or consider a miminum threshold of complaints for a healthplan to eligible for Star rating purposes.
Humana	Humana respectfully requests that CMS exclude CAHPS measures from the calculation of the improvement measure that were low

Submitter	Response
	reliability in 2015 CAHPS as a result of the CMS sampling error
Medica Health Plans	Medica supports the continued methodology for Improvement Measures. Medica believes that the weighting for these measures is too high and should be reduced from 5 weights to 3 weights. Medica does not support differentiating baselines used for some plans and not for others based on low reliability of data for CAHPS. All plans should use the same baselines and same new comparison numbers. Or, plans should be held harmless for any adverse impact to their ratings based on this differentiation. Additional Comment: Medica supports keeping this measure in the display area. We are concerned about the word 'treatment' in the survey as we believe most beneficiaries would not describe exercises as treatment, yet they are effective in the management of urinary leakage. CMS should consider changing the question wording to 'treatments or exercises' to make the question clearer for the beneficiaries surveyed. Medica supports the addition of outcomes measures provided the analyses can demonstrate a benefit to beneficiaries.
Molina Healthcare Inc.	Molina Healthcare agrees with the proposed changes to the 2017 improvement measure set. We support CMS's decision to include additional measures with two years of data to the Improvement Score. To move forward, we ask that CMS maintain the same Improvement Score calculation methodology that was used in the 2016 Star Ratings. This approach allows for consistent application over time. In addition, we encourage CMS not to consider using a contract's 2014 CAHPS measure score as the baseline for the 2017 improvement calculation in situations where the contract's CAHPS measure score moved to very low reliability with the exclusion of the enrollees with less than six months of continuous enrollment for the 2015 survey administration. We are concerned that plans may be disadvantaged by use of dated 2014 CAHPS measure scores. It is also unclear what CMS might do if the 2014 CAHPS measure scores also are unreliable.
North Texas Specialty Physicians	The hold harmless clause should be extended to all regardless of the plans star rating. The intention of these measures were to assist low performing plans to increase their rating. If you are going to use these measures for all plans lower than 4 stars then the weighting of the measures needs to be lowered to be in line with other measures. For plans that were impacted by the significant cut point changes this year to then have 5x weight improvement measures "hit" it was if they were double penalized
PCMA	1. Improvement Measures (Part C & D) – PCMA believes measures that were of low reliability in the 2015 CAHPS survey as a result of the CMS sampling error should be removed from the calculation of the 2017 improvement measures. We also disagree with the inclusion of MTM Program Completion Rate for CMR as an improvement measure as noted in the Appendix. This characterization places additional weight on a process measure within the rating system. PCMA requests that CMS develop

Submitter	Response
	outcomes measures for MTM rather than continuing to rely on a flawed process measure in the Star Ratings. PCMA Recommendation: PCMA recommends that CMS exclude measures from the calculation of the 2017 improvement measures that were of low reliability in the 2015 CAHPS survey due to the CMS sampling error. PCMA requests that the MTM Program Completion Rate for CMR not be listed as an improvement measure.
PrescribeWellness	We support the CMR rate measure and appreciate the recognition by CMS that development of outcomes-based MTM companion measures is needed. Recognition of identifying and resolving drug therapy problems on an on-going basis should be considered.
Senior Whole Health	We would support using CAHPS scores from the survey conducted in 2014 as the baseline for the improvement measures associated with CAHPS. We are troubled by the low reliability of the CAHPS scores sourced by the 2015 survey administration.
SNP Alliance	1. Improvement measures (Part C & D) We share CMS' concern about using CAHPS measure scores that are determined to be of low reliability as the basis for calculating the 2017 improvement measures. Although we do not have an alternative to CMS' proposal to use the 2014 CAHPS measure score (used in 2015 Star Ratings) in these situations, we are concerned that extending the timeframe for calculating the improvement measures from one to two years may be problematic in situations in which the population enrolled in a given contract changes significantly over time. This is more likely to happen the longer the length of time between the baseline and the current year. We are concerned that the longer the intervening period, the greater the likelihood that the improvement score may not be an accurate measure of improvement.
UnitedHealthcare	UnitedHealth appreciates the consideration given to make the CAHPS data usable after the removal of the non-eligible members from the sample; however, the suggested substitution would use baseline data that is much older than the current Star year 2017 data. UHG recommends that the baseline data remain not-rated for the improvement score so that its exclusion can remain neutral.

2. Reviewing Appeals Decisions/Appeals Upheld measures (Part C & D)

Submitter	Response
Anthem, Inc	Anthem agrees with CMS that the Appeals Upheld measure should be modified so that if a re-opening occurs and is decided prior to May 1, 2016, the reopened decision would be used in the measure calculation. We believe that by including reopened decisions into the calculation, CMS will further pursue consistency with the Part C Reviewing Appeals Decisions measure. However, Anthem recommends that CMS further extend the timeframe for re-openings for both Parts C and D measures from May 1 to the first six to eight months of the year, as this would lead to even greater consistency across the program. Regardless of the final timeframe utilized, Anthem recommends that any reopened cases after the CMS

Submitter	Response
	deadline be included in the following year's data. More broadly, Anthem requests that CMS consider adjusting the Appeals Upheld measure to account for the volume of cases appealed to the Independent Review Entity (IRE) as a percentage of a plan's total coverage determination and re-determination cases. This adjustment would provide evidence that a plan is effectively managing prior authorizations (PAs) and properly evaluating coverage requests based on their established clinical criteria. We similarly request that CMS consider adjusting this measure to account for the common occurrence of members or physicians submitting different or additional information to the IRE compared to what was originally submitted to the plan. This discrepancy alone could account for the IRE making a different determination than the plan, when the plan would have made the same decision as the IRE if the same information were made available to the plan. Anthem also requests that CMS adjust the threshold for contracts to be excluded from the Appeals Upheld measure from ten total cases reviewed by the IRE to a number of cases determined by a set proportion of each contract's membership. While ten cases is a significant threshold for small plans, it is disproportionately low for multi-region plans.
BlueCross and BlueShield Association	CMS proposes to modify the collection time period for data used to calculate the Reviewing Appeals Decisions and Appeals Upheld measures. Specifically, CMS proposes to extend the time frame to include cases that are reopened and decided by May 1st of the following year, as opposed to April 1st. BCBSA and Plans understand that this would mean that any reopenings decided after the May 1st deadline would be excluded, and the original decision result would be used. BCBSA and Plans support CMS's efforts to include additional revisited decisions in these measures and appreciate CMS's efforts to make them more reflective of Plan performance. Plans also encourage CMS to consider whether extending the deadline even further, perhaps to include the first six to eight months of the year, would increase the value of the metric by allowing CMS to include additional cases. As CMS is revising the measure, BCBSA and Plans also request that the Agency consider excluding those cases for which the Independent Review Entity (IRE) obtains new or different information than was available to the Plan when the initial decision was made. These cases are out of the Plans' control and should not be counted against their Ratings. (See Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.) Recommendations: BCBSA and Plans support CMS finalizing this measure as proposed and encourage the Agency to consider whether to further extend the time frame beyond the proposed May 1st deadline. BCBSA and Plans request that CMS exclude from the Appeals

Submitter	Response
	Upheld measures those cases for which the IRE obtains new or different information. (See Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.)
BlueCross BlueShield of Tennessee	BCBST is in agreement with this proposed change as it will likely only improve the accuracy of the data used to calculate the score.
Cambia Health Solutions	Supportive of this change as this will capture more cases originated in the measurement year
Clover Health	Clover Health supports the recommendation to capture reopen decisions through May 1st, 2016.
CVS Health	SilverScript supports the recommendation to capture reopen decisions through May 1st, 2016.
HealthPartners	We support CMS modifying the measure specifications to extend the timeframe for counting a reopened decision. We encourage CMS to extend the timeframe further to be able to use a reopened decision occurring prior to July 1, 2016.
Humana	We have examples where providers submit new relevant details concerning medical necessity to the Independent Review Entity (IRE) that they failed to present to the plan during prior authorization and/or the grievance and appeals process. We believe that cases where the IRE does not support a plan's determination based on evidence that was withheld, for whatever reason, from the plan at the time of the determination, should not be included in underlying Stars appeals measures.
Kaiser Permanente	Kaiser Permanente supports this proposed change, as it will help ensure fair consideration for appeals filed in the fourth quarter of the year.
Medica Health Plans	Medica supports this change from April 1 to May1.
PCMA	2. Reviewing Appeals Decisions/Appeals Upheld measures (Part C & D) – CMS proposes to modify these measure specifications for the 2017 Star Ratings so that if a Reopening occurs and is decided prior to May 1, 2016, the Reopened decision would be used. PCMA Recommendation: PCMA supports this modification.
SCAN Health Plan	A.2 Changes to Measures for 2017 - Reviewing Appeals Decisions/Appeals Upheld measures (Part C & D). Modify measure specs to include re-opening decisions up to May 1, 2016 (change from April 1). SCAN Comment: Agree with change.
SNP Alliance	2. Reviewing Appeals Decisions/Appeals Upheld measures (Part C & D) We concur with CMS' proposal to modify these measures' specifications.
UCare	UCare feels that the suggested modifications to the measure specifications would impede the health plan's ability to get information timely for appeals data and result in a shorter time to review appeals decisions.
UnitedHealthcare	UnitedHealth agrees with the extension of the reopen decision date to May 1st for appeals and recommends moving it back one more month to June 1st. UHC estimates that the change could add up to an additional 7% of reopen decisions, resulting in more complete and

Submitter	Response
	accurate data, and would still allow enough time to calculate rates and cutpoints before the plan preview periods.
Universal American	In addition to the proposed reporting timeframe change for reopened decisions, the plan respectfully requests that MAXIMUS provide the same reports to the plans they provide to CMS to simplify tracking and monitoring activities. In the alternative, to reduce the potential for human error, the plan requests that MAXIMUS update their website to allow a download of the timeliness/uphold rate data rather than requiring plans to cut and paste the information page by page.

3. Contract Enrollment Data (Part C & D)

Submitter	Response
America's Health Insurance Plans	CMS is proposing to change the current time period (January – December) for pulling enrollment data from the Health Plan Management System (HPMS) to February through January for the following measures: Complaints about the Health/Drug Plan, Part D Appeals Auto-Forward, and the three Part C Care for Older Adults measures. The average enrollment over a twelve month period is used in the calculations for these Stars Ratings measures. Given that HPMS enrollment numbers available in a given month reflect data from the prior month, the change would ensure that the enrollment data used in the calculations for these Star Ratings measures accurately reflect contract enrollment numbers for the relevant measurement period. We therefore support the proposed change. We also recommend that a conforming change be made in the Star Ratings technical specifications to specify that enrollment data will be pulled from HPMS during this time period.
Anthem, Inc	Anthem supports CMS in modifying contract enrollment numbers for the Part C and D Complaints about the Health/Drug Plan measure and the Part D Appeals Auto-Forward measure to reflect an average of the Health Plan Management System (HPMS) enrollment from February through January of the measurement year.
Blue Cross Blue Shield of Michigan	CMS is proposing to modify enrollment numbers to reflect an average of the HPMS enrollment from February through January of the measurement year (compared to January through December). BCBSM supports this change, so long as the enrollment files pulled for the measurement period does not include enrollment from two separate plan years.
BlueCross and BlueShield Association	CMS proposes to adjust the enrollment data used in the following measures: (i) Part C and D Complaints about the Health/Drug Plan, (ii) Part D Appeals Auto-Forward, and (iii) Part C Care for Older Adults (3 measures). Instead of basing the measures on the average of the HPMS enrollment files from January through December, CMS proposes to use the average of the enrollment files from February through January.

Submitter	Response
	In general, BCBSA and Plans support this change, as the HPMS enrollment numbers reflect accurate data from the prior month. As such, using data from February of Contract Year 1 through January of Contract Year 2 will give a more accurate count of members who were enrolled from January through December of Contract Year 1. Plans ask CMS to confirm that the reliance on the average of enrollment files for the modified 12-month period is consistent with the data collection periods for the affected metrics, particularly the three Part C measures for Care for Older Adults. Recommendations: BCBSA and Plans recommend that CMS adjust the enrollment data as proposed for the Part C and D measure of Complaints about the Health/Drug Plan and the Part D measure of Appeals Auto-Forward. BCBSA and Plans request that CMS re-evaluate the appropriateness of the change in enrollment data relative to the data collection period for the three Part C measures of Care for Older Adults.
BlueCross BlueShield of Tennessee	BCBST agrees that modifying the membership timeframe will allow CMS to capture a more accurate picture of enrollment for calculating measures that rely on this information.
Cambia Health Solutions	Supportive of this change as it will reflect more accurately the measurement year enrollment. Would like clarification from CMS on whether the effective date of enrollment for January to December will be used, with the data being pulled February - January
Centene Corporation	We have a question in regard to CMS' proposal to modify the contract enrollment numbers used to reflect an average of the HPMS enrollment for purposes of calculating the three Part C "Care for Older Adults" measures. Because these are HEDIS measures, the measurement period for them is the calendar year January through December. If the enrollment numbers are modified to reflect an average of HPMS enrollment from February through January, we wonder if the enrollment average used for the denominator of the measure will be in sync with the HEDIS data used for the measure's numerator.
Cigna	We agree with CMS' enrollment proposed change.
Clover Health	Clover Health fully supports the recommended adjustment to include enrollment values between February and January to calculate average enrollment, as this will improve the accuracy of the information used to calculate a plan's Star Rating.
CVS Health	SilverScript supports the recommended adjustment to leverage enrollment values from February – January to calculate average enrollment, as this will improve the accuracy of the information used

Submitter	Response
	to calculate a plan's Star Rating.
Fresenius Health Plans	We recommend that the data timeframe be February to December, meaning that the January timeframe be excluded, due to the fact that the January data could contain an overlap of benefit plan years, risking to skew the results.
Health Care Service Corporation	CMS states, "Additionally, plan-level enrollment is pulled for the three Part C "Care for Older Adults" measures." CMS further states, "We propose going forward to adjust the twelve months from January to December to February through January of the relevant measurement period." While HCSC supports the proposal to shift the twelve-month period for the Part C and D "Complaints about the Health/Drug Plan" and the Part D "Appeals Auto-Forward" measures, it is unclear how this shift would apply to "Care for Older Adults." The "Care for Older Adults" measures are HEDIS measures and HEDIS measures have prescribed data collection and reporting period specifications. It does not appear that the HEDIS specifications align with the CMS proposal. HCSC recommends that the "Care for Older Adults" measures be omitted from this proposal.
Kaiser Permanente	Kaiser Permanente supports this proposed change. We also recommend the following: - We recommend that CMS use the same contract enrollment data processes for all measures that require enrollment data as part of the rating methodology (both for Star Ratings and Display Page measures). - We request that CMS identify the date on which the agency will upload the enrollment numbers monthly to the CMS website. The enrollment data posted on the website is used regularly by plan sponsors for monthly internal tracking and monitoring purposes.
Medica Health Plans	Medica has some concern about this change and how it relates to the timing of the HEDIS data collection timeframe. Specifically, we are concerned that the data will be asynchronous by one month.
Molina Healthcare Inc.	Molina Healthcare requests that CMS clarify how the three Part C "Care for Older Adults" measures will be calculated. Because these are HEDIS measures, the measurement period is the calendar year between January and December.
PCMA	3. Contract Enrollment Data (Part C & D) – CMS proposes to adjust the twelve months from January to December to February through January of the relevant measurement period. PCMA Recommendation: PCMA supports this adjustment.
SNP Alliance	3. Contract Enrollment Data (Parts C & D) We have a question in regard to CMS' proposal to modify the contract enrollment numbers used to reflect an average of the HPMS enrollment for purposes of calculating the three Part C "Care for Older Adults" measures. Because these are HEDIS measures, the measurement period for them is the calendar year January through December. If the enrollment numbers are modified to reflect an average of HPMS enrollment from February through January, we wonder if the enrollment average used for the denominator of the measure will be in sync with the HEDIS data used for the measure's numerator.

Submitter	Response
UCare	UCare seeks clarification of the Care for Older Adults (COA) measures. COA measure time frames do not appear to be in alignment with HEDIS measure time frames.
UnitedHealthcare	UnitedHealth supports CMS' proposal to compensate for data lag in its market share enrollment tables. UnitedHealth finds, however, that the proposed solution overcorrects the data lag and results in inclusion of partial enrollment from January of the year following the measurement year (see January 2015 CMS market share enrollment compared to February-December 2014 for H2001 as example). UnitedHealth therefore recommends that the enrollment averages be calculated using only February-December of the measurement year, an average of 11 months, and to simply exclude the January enrollment that has been unstable and inaccurate.
VIVA Health, Inc.	The Plan supports the recommended adjustment to leverage enrollment values from February – January to calculate average enrollment, as this will improve the accuracy of the information used to calculate a plan's Star Rating. The Plan does ask CMS to note that the HEDIS timeframes associated with the Care for Older Adult measures is a calendar year. The Plan requests that CMS clarify what the potential impact of the time period shift on the COA measures will be.

4. Transition from ICD-9 to ICD-10 (Part C & D)

Submitter	Response
America's Health Insurance Plans	CMS indicates that the Pharmacy Quality Alliance (PQA) is reviewing its measure specifications with diagnosis-related requirements as they transition from ICD-9 to ICD-10. CMS further notes that PQA plans to update their measure specifications and that the agency will test and adopt changes implemented by PQA as appropriate for Part D Star Ratings and display measures. CMS also indicates that the National Committee for Quality Assurance (NCQA) has incorporated the ICD-10 codes in the 2016 Healthcare Effectiveness Data and Information Set (HEDIS). We note that NCQA has also indicated recently their plans to continue to monitor the impact of the ICD-9 to ICD-10 transition and to make adjustments to benchmarks and thresholds for HEDIS measures, as necessary. We recommend that as in the case of PQA, CMS monitor NCQA activity during this transition period and consider changes as appropriate for relevant Star Ratings and display measures.
Anthem, Inc	We thank CMS for providing an update on the measure stewards' work to review measure specifications with diagnosis-related requirements in light of the transition from ICD-9 to ICD-10. Anthem appreciates the National Committee for Quality Assurance's (NCQA's) efforts to incorporate both ICD-9 and ICD-10 codes for some 2016 Healthcare Effectiveness Data and Information Set (HEDIS) measures. We ask that CMS work with the Pharmacy Quality Alliance (PQA) to implement a similar transition.
BlueCross and	BCBSA and Plans appreciate CMS's efforts to transition the Star

Submitter	Response
BlueShield Association	Ratings from ICD-9 to ICD-10, and we agree that CMS should look to the revisions from the Pharmacy Quality Alliance (PQA) and the National Committee for Quality Assurance (NCQA) for guidance on the measure changes. BCBSA and Plans caution that ICD-10 is significantly more complex and allows for more diagnoses than ICD-9. As such, it is unclear how the transition will affect the Star Ratings. Given this uncertainty, BCBSA and Plans request that CMS provide Plans with a hold harmless period for claims data submitted as changes are being implemented. Recommendations: BCBSA and Plans request that CMS provide additional information and clarity on the impact that transitioning to ICD-10 will have on the Star Ratings. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment) In the interim and while the transition is underway, BCBSA and Plans encourage CMS to consider whether there should be a hold harmless period for claims data submitted during a certain timeframe (e.g., the fourth quarter of 2015).
Commonwealth Care Alliance	CCA looks forward to receiving more information from CMS. We agree that both ICD-9 and 10 codes need to be used during the transition period.
Healthfirst	We recommend that CMS, in conjunction with NCQA/PQA, continue to monitor the impact of the ICD-10 transition on measures and adjust benchmarks appropriately.
Independent Care Health Plan	It is re-assuring to know that CMS is concerned with the preservation of data integrity during the ICD9-to-ICD10 transition period. Murphy's Law requires that "if it can go wrong, it will go wrong." Look-back periods will overlap different combinations of ICD9 and ICD10 periods. It is presumed by this section that the cross-walk will be carefully monitored so that numerators are not missed or that denominators are not wrongly populated (for which numerator production cannot occur by definition). We continue to find examples of coding errors that mistakenly populate denominators: i) hospital coders reading the medical record and coding for diabetes when there is no diabetes; ii) home health agencies coding for rheumatoid arthritis when osteoarthritis is the correct diagnosis. Coding errors themselves serve to undermine the integrity of the data in addition to the ICD9-to-ICD10 complications. We continue to see evidence where numerator data is withheld as proprietary when plans need it as performance evidence. Recommendation: Strengthen regulatory support to ensure consistent accuracy and

Submitter	Response
	availability of performance sensitive information.
Kaiser Permanente	All plan sponsors have expended significant resources preparing for and executing the transition from ICD-9 to ICD-10 codes. There will certainly be challenges in adopting the new codes in HEDIS and other reporting. Nevertheless, with respect to the conversion to ICD-10, NCQA has clearly and unambiguously stated its intent "to continue to monitor impacts in measures and adjust benchmarks and thresholds as necessary" (NCQA Academy, HEDIS Update and Best Practices, November 4, 2015), and we request that CMS engage similarly in monitoring and adjusting for the impact of ICD-10 transition for purposes of the Star Ratings.
Medica Health Plans	Medica has some concern about the timing of the PQA analysis completion causing a shortened time frame for plans to adequately evaluate and comment on any changes or impact to Part D measure performance.
Molina Healthcare Inc.	Molina Healthcare encourages CMS to work with the National Committee for Quality Assurance and the Pharmacy Quality Alliance to determine the impact of performance measurement rates reported in 2016 and beyond based on the ICD-10 transition. As a result of the transition, we expect that benchmarks may change and they will need to be modified.
PCMA	4. Transition from ICD-9 to IDC-10 (Part C & D) – CMS indicates it will test and adopt changes to measure specifications with diagnosis-related requirements implemented by PQA for the Part D Star Ratings and display measures. PCMA urges CMS to bear in mind that diagnosis codes typically are not provided on medication prescriptions and that neither PDP sponsors nor community pharmacies have direct access to a patient's medical records. Measure specification changes involving the inclusion of diagnosis codes that arise from the transition to ICD-10 should not be applied to prescription transactions in the PDP context. PCMA Recommendation: PCMA recommends that CMS, in its review of PQA measure specifications with diagnosis-related requirements, take into account the lack of access to and use of diagnosis codes for prescription drug transactions in the PDP context
SNP Alliance	4. Transition from ICD-9 to ICD-10 (Part C & D) We ask that CMS work to ensure that PQA implements a transition process similar to what NCQA is using for HEDIS.
UCare	UCare seeks clarification on the time frame for the ICD-9 to ICD-10 transition period. NCQA plans to monitor the impacts of the ICD-10 transition on HEDIS measures and adjust benchmarks accordingly. Will CMS make similar adjustments?
VIVA Health, Inc.	The Plan requests that CMS take the same approach as NCQA and utilize ICD-9 and ICD-10 codes during the transition period for all measures impacted.

5. Appeals Upheld measure (Part D)

Submitter	Response

Submitter	Response
Blue Shield of California	There is a potential negative impact if hospice patients are not excluded from the 2016 Star ratings since these services and medications are paid out of CMS hospice benefits, which would involve providers that may not be contracted with the plan.
BlueCross and BlueShield Association	CMS proposes to include appeal cases for beneficiaries enrolled in hospice in the 2017 (and future years) Star Ratings Appeals Upheld measure. Although BCBSA and Plans appreciate CMS's efforts to base the Star Ratings measures on as much data as possible, thus increasing the accuracy of the metrics, we are concerned that the data from hospice-enrolled beneficiaries is unreliable and not reflective of Plan performance. Once a beneficiary enters hospice, their benefits are bifurcated such that their hospice benefits are managed and paid under Original Medicare, while Plans are responsible for their non-hospice related pharmacy and medical benefits. This creates significant confusion, and claims may not always account for the operational challenges and appeals of organizational coverage determinations. As such, BCBSA and Plans recommend that appeal cases for beneficiaries enrolled in hospice continue to be excluded from the Appeals Upheld measure.
BlueCross BlueShield of Tennessee	BCBST disagrees with this proposed change asks that CMS continue to exclude appeal cases for beneficiaries enrolled in hospice from this measure. BCBST is concerned that plans could be negatively impacted as they may not have the visibility to hospice status at the time of the initial review due to the lag in timing of receipt of hospice indicators and/or retroactive changes to hospice status as sent on the TRR.
Healthfirst	Plans have strict timeframes to make redetermination decisions and cannot reopen their decisions if additional information is received after an enrollee files a request for an IRE reconsideration, or if the adjudication time frame at the coverage determination or redetermination levels have expired (and the plan is required to forward the enrollee's request to the IRE). A plan has 72 hours for an expedited case and 7 days for a standard appeal. While the IRE is generally held to the same adjudication timeframes as previously highlighted, if additional information is needed from a prescriber, the IRE is allowed to extend the adjudication timeframe to obtain this information. In our experience, the IRE is often able to obtain additional information from the prescriber because of this extended time frame. A plan, however, is not afforded this and thus if a prescriber is unable to provide the information needed to render a decision within the adjudication timeframe, the plan must deny based on the information provided in order to prevent cases from being auto-forwarded to the IRE. We recommend that CMS not penalize plans for appeals that were overturned when providers provided

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	"new" information to the IRE, which was not originally submitted by the provider at the time of the Plan's original coverage determination or redetermination and after reasonable efforts were made by the Plan to obtain missing information from the provider. We urge CMS to align the time frames and processes for plan sponsors and IREs so that there is a more equitable evaluation of plan sponsor decisions.
Medica Health Plans	Medica supports this change as outlined in the 2016 Call Letter.
PCMA	5. Appeals Upheld Measure (Part D) – The exclusion of appeal cases for beneficiaries enrolled in hospice during 2014 from the 2016 Star Rating Appeals Upheld measure will not be continued for the 2017 measure. PCMA Recommendation: PCMA supports this decision.
SCAN Health Plan	A. 5 Changes to Measures for 2017 - Appeals Upheld Measure (Part D). Cases for members enrolled in hospice will not be excluded from the measure for 2017 Star Ratings. SCAN Comment: Agree with change.
Triple S Advantage, Inc	TSA suggests not including appeals from members in hospice. The services for members in hospice are not under those provided by the MA, in addition there is still much confusion among members and their caregivers over how are services provided when a member is in hospice. Appeals from members in hospice do not relate to services rendered by the MA; including those in the calculation may result in a rate which does not represents the true compliance of the MA.

6. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D)

Submitter	Response
Alliance of Community Health Plans	ACHP recommends that CMS ensure consistency in the CMR measure by allowing plans to count towards their CMR rate the members who are enrolled through a plan's use of expanded eligibility and who meet other plan-specific targeting criteria. The current calculation uses the cohort of MTM enrollees who meet the specified targeting criteria per CMS requirements. However, it is a matter of fairness to make sure that plans that choose to expand MTM eligibility to a larger population get credit for all of their members who complete a CMR. We share CMS' preference to move towards the development and endorsement of outcomes-based MTM measures. We believe that outcomes such as decreased admissions, readmissions, and adverse drug events would better reflect the effectiveness of a MTM program.
American Pharmacists Association	APhA strongly supports the development of meaningful measures for medication therapy management services and is encouraged by CMS' addition of the CMR completion rate to the 2017 Part D Star ratings. APhA commends CMS' continued efforts to identify outcomes-based MTM measures that can serve as companion measures to the CMR completion rate as more robust MTM

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	measures are needed to effectively measure the value of MTM services. APhA is supportive of CMS' approach of adding a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and Data Validation score. .
Anthem, Inc	Anthem remains concerned about the inherent inconsistency in the MTM Program Completion Rate for CMRs measure from plan to plan, which leads to inappropriate comparisons between plans. Under the current flexibility afforded plans in designing their MTM programs, plans may structure MTM programs to be more or less inclusive, in accordance with CMS guidelines. Therefore, the "denominator" or total number of MTM-enrolled beneficiaries may be quite different from plan to plan. We are concerned about the impact that varying plan MTM eligibility criteria will have upon the relative performance for this measure. Additionally, Anthem believes that the population served and the plan type used by the MA plan should be taken into account when plans are evaluated. For instance, a staff-model HMO pharmacy would have consultation access to most members at point of sale and, thus, could have direct impact on the completion rate. In contrast, Special Needs Plans (SNPs) that serve dual eligible members would have more significant difficulties reaching their members—as evidenced by CMS' research on the impact of low-SES status on Star Ratings performance. In light of these concerns, Anthem continues to recommend that CMS establish predetermined standard MTM eligibility criteria, that different populations served be averaged separately for metric cut points and scoring, and that CMS include a qualifier on this metric for plans that have more expansive MTM programs. This would ensure that such plans are not unfairly disadvantaged by affording their members access above and beyond what is required by law. In addition, Anthem encourages CMS to consider making the denominator the number of Part D eligible individuals or to make MTM qualification rate a Star Ratings measure. The CMR rate and qualification rate together provide a composite picture of the CMR portion MTM program as a "process measure." We recommend that CMS define a threshold for acceptable CMR completion rates, as well. Anthem also notes that the CMR completion rate is only one of many measurable aspects of plan sponsors' MTM programs. To that end, we support efforts to develop outcomes-based MTM measures for the Star Ratings and recommend that CMS consider other ways of evaluating the quality of care provided through MTM programs. For example, we suggest that CMS consider measuring rates of targeted medication review (TMR), interventions, and member education, as well as member satisfaction. Moving forward, we encourage the Agency to follow a transparent process that emphasizes plan input for outcomes-based measure development. Finally, Anthem supports CMS' proposal to implement additional data integrity checks. We believe these checks—in addition to the

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	recommendations made above—will safeguard against improper attempts to bias the data used for the MTM CMR measure. We do, however, underscore the critical need for CMS to provide stakeholders with detailed information regarding these data integrity checks well in advance of their implementation so that we can appropriately plan and prevent disruptions to our established processes. (Anthem's complete comments on CMS' MTM data integrity checks proposal are included in the Data Integrity section).
Blue Shield of California	Rate for 5 Star is 76%. Overall % of enrollment should be taken into consideration. There should be a minimum % of enrollment. Better regulation around how it's completed is needed – form vs. face-to-face. Currently, completion is measured by a form. Unclear on the purpose for the files. Plans will have completed the DVA prior to receiving this information. Is the report to be used to adjust CMR rate?
BlueCross and BlueShield Association	CMS proposes to add a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and Data Validation score, since exclusions are applied to the Plan-reported MTM data. Although BCBSA and Plans appreciate this transparency, we believe that the MTM Program Completion Rate for CMR measure has significant problems and recommend that CMS revisit the entire measure. BCBSA and Plans believe that this measure does not reflect Plan performance and thus should not be included in the Star Ratings. (See also Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.) First, BCBSA and Plans believe that the MTM Program Completion Rate for CMR measure does not reflect Plan performance because it is based on beneficiary choices or other circumstances outside of Plans' control. Beneficiaries' participation in an MTM program is voluntary, and the MTM program may be just one of several medication oversight programs available to them. Accordingly, beneficiaries may choose to "opt-out" of their Plans' MTM programs. Measuring Plans' performance on a voluntary benefit metric – especially when other opportunities may be available to beneficiaries that serve the same function – does not reflect Plan performance or provide useful information to beneficiaries. Second, BCBSA and Plans maintain that the MTM Program Completion Rate for CMR measure focuses inappropriately on the completion of a specific form, as opposed to the actual care received by each beneficiary. Plans offer various types of MTM and similar disease management and care coordination programs, and not all programs necessarily require the completion of the CMR. Measuring

Submitter	Response
	performance based only on the completion of the CMR does not accurately reflect Plans' performance and efforts on MTM more generally. Moreover, BCBSA and Plans note that it may not be appropriate to assume that a beneficiary received adequate MTM just because his or her file includes a completed CMR form. Accordingly, BCBSA and Plans encourage CMS to revisit the MTM measure and develop a more useful, outcomes-based metric of Plan performance and beneficiary value. Separately, BCBSA and Plans generally support CMS's efforts to implement additional data integrity checks on the MTM Program Completion Rate for CMR measure. As noted above, Plans have varying types of MTM programs, and BCBSA and Plans are concerned that the measure incentivizes Plan Sponsors to create fairly restrictive MTM program eligibility criteria. In this way, Plan Sponsors are able to maintain a high percentage of participants that have completed the CMR. We note that, while an MA-PD contract needs to achieve a 76% score for a 5-star rating, Plans understand that the industry average is significantly lower, suggesting wide variation in MTM programs. As such, BCBSA and Plans encourage CMS to consider such tactics when the Agency conducts additional data checks. Finally, BCBSA and Plans request that CMS provide additional information about what is considered biased data in the context of the MTM Program Completion Rate for CMR measure and what CMS means by additional data integrity checks. (See Section C of this Appendix for a more general discussion of biased data.) For example, Plans are concerned that persuading members to remain in the MTM program for 60 days may be considered a tactic that renders the data biased. Recommendations: BCBSA and Plans urge CMS to exclude the MTM Program Completion Rate for CMR measure from the Star Ratings, as it does not reflect Plan performance. (See also Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.) If CMS retains the measure, we support CMS's provision of detailed files listing a contract's denominator, numerator, and Data Validation

Submitter	Response
	score. If CMS wants to include a measure of MTM efforts, BCBSA and Plans recommend that CMS develop an outcomes-based measure that does not focus on the completion of one particular form. BCBSA and Plans encourage the Agency to look at the eligibility criteria used for each MTM program and consider whether variations in this criteria correlate to higher or lower scores and therefore undermine the validity of the measure. BCBSA and Plans request that CMS provide additional information as to what data the Agency considers biased in the context of the MTM Program Completion Rate for CMR measure.
BlueCross BlueShield of SC	The current calculation for the Star measure "MTM Program Completion Rate for CMR" excludes members who are enrolled in the program for less than 60 days. In the memo, CMS discusses their concern around plans encouraging members to opt-out of the program within this 60-day window, and says they will implement "additional data integrity checks". We suggest that CMS make MTM a level playing field and remove the current opt out exclusion from the denominator, with the exception of members who opt out in the first 60 days due to disenrollment or death and newly qualified MTM members who qualify for MTM services within the last 60 days of the program year. Plans must still offer MTM services to members who qualify in the last 60-days of the program year, but we believe plans should not be evaluated on CMR completion rates for these members.
BlueCross BlueShield of Tennessee	BCBST supports CMS with their efforts in making the CMR Completion Rate numerator and denominator more transparent to plan sponsors during the plan preview period. BCBST is concerned that because participation in the MTM program is voluntary the current measurement is not a true reflection on the plan's ability to affect improved outcomes. For this reason BCBST encourages CMS to develop and adopt use of a replacement measure that focuses on the outcomes of the MTM program. BCBST recommends that CMS consider applying a performance standard to this measure and moving it to the display measure page. If CMS choses to continue using this measure in the star ratings program, BCBST recommends that CMS reconsider the current incentive program guidelines and allow plans to offer incentives to enrollees for completion of the CMR which would help plans to achieve a better response. Please clarify what is meant by "bias the data". Please describe how the 2016 star ratings cut points were assigned for this measure. They do not seem to align with the national averages for this measure.
Cambia Health Solutions	We would welcome the detailed file. As for outcomes based measures, we would appreciate CMS sharing the potential outcomes based measures that are being considered and when such measures may be implemented.
Centene Corporation	Centene Corporation looks forward to providing substantive comment on any outcome-based MTM measure currently under

Submitter	Response
	development, and requests that CMS provide adequate time for review and comment when development is completed. We believe it is critical to involve Special Needs Plans in the development process for these measures. The provision of medication therapy management services and use of prescription drugs present unique challenges to SNP populations, and these should be considered and addressed in the development process.
Cigna	We thank CMS for giving the plans a detailed file during the plan preview period to validate the rate for this measure. We recommend that CMS not consider moving this to a heavier weighted "outcome" measure because plans with high LIS membership can have a higher qualification rate for MTM and this population can be more difficult to connect with to complete a CMR.
Clover Health	Clover Health finds valuable CMS's provision of detailed files on HPMS in order for plans to review and confirm their Medication Therapy Management (MTM) data. We support moving away from MTM process measures and looks forward to inclusion of outcomes-based MTM measures in the Star Ratings Program in the future.
Commonwealth Care Alliance	CCA supports the idea of outcomes-based MTM measures and encourages CMS to consider dually eligible beneficiaries as it creates outcome measures.
CVS Health	SilverScript appreciates CMS's provision of detailed files on HPMS in order for plans to review and confirm their Medication Therapy Management (MTM) data. SilverScript supports the movement away from MTM process measures and looks forward to inclusion of outcomes-based MTM measures in the Star Ratings Program in the future. In the interim, we recommend CMS evaluate changes to the MTM Comprehensive Medication Review Completion Rate (CMR) measure methodology. Small, geographically focused plans and plans with unique arrangements with provider networks have historically been able to achieve a higher completion rate with a substantially lesser degree of effort than large plans that span multiple regions. Additionally, within our data, we've found regional variations in CMR completion rate. Our CMR completion rate ranges between 6.1% – 43.6% depending on the region the plan is serving. Contracts with low enrollment can target a very small population of beneficiaries and achieve a high CMR completion rate. For example, if a 500 beneficiary plan has 100 members that qualify for the MTM program based on the plan's criteria, the completion of CMR's for only 50 members will result in a CMR rate of 50%. However, plans with higher enrollment across multiple geographies require extensive efforts to achieve a comparable CMR rate. As the absolute number of targeted beneficiaries increases across different geographies, the complexity of achieving a comparable CMR completion rate increases as well. Additionally, plans with lower enrollment tend to have a closer affiliation with the member due to their geographical focus near the member's home. For example, a plan that has a regional focus is more likely to have an affiliation with

Submitter	Response
	an ACO. This affiliation could increase the plan's ability to reach the member and prescriber to conduct a CMR, which would offer an advantage over plans that do not have this unique arrangement. We are concerned that the focus on volume of CMR's completed incentivizes plans to narrow their targeting criteria for patients who should receive this service. We are also concerned that misaligned incentives that reward volume could result in lower quality of CMRs being performed in order to achieve the rates desired. To solve for the issues raised above, we recommend CMS consider adjustment to the measure to evaluate true differences in plan performance. CMS could consider adjustments based on plan size, targeting criteria, overall health of the population, and geographical location to solve for differences in number of members who qualify for the measure and a plan's ability to complete the CMR. The 2016 thresholds provided by CMS indicate significant shifts in plan performance as compared to prior years. Previous data would have been significantly skewed by outliers in the cluster analysis used to determine the Star thresholds. Historical industry data indicates that a large majority of the industry achieved a 30% or less CMR completion rate in prior years. • 2014 Star Ratings: 382/452 MAPD contracts (who received a score on this measure) or 85% achieved a MTM CMR completion rate of 30% or less. • 2015 Star Ratings: 374/470 MAPD contracts (who received a score on this measure) or 80% achieved a MTM CMR completion rate of 30% or less. • 2016 Star Ratings: MAPD contracts achieving a CMR completion rate of 30% would receive a 2 Star Rating. Based on this information, we recommend CMS evaluate changes to the measure methodology and the cluster analysis used to determine the thresholds, to more fairly evaluate plan performance on the MTM CMR completion rate measure. Again, we also support the replacement of this measure with outcomes-based MTM metrics, such as the two metrics that PQA is currently developing, "Patient Satisfaction Survey following Comprehensive Medication Review" and "MTM-Part D: Specific Drug Therapy Problem (DTP) Resolution." We feel that outcomes measures such as these are better aligned with the quality of care provided to beneficiaries through an MTM interaction.
Essence Healthcare	We suggest excluding members who have opted out of the Medication Therapy Management (MTM) program from the denominator for CMR rate. Several of our members are long-standing and have had several CMRs in the past. Generating interest in completing this again is difficult in this patient population and several of them opt out of the MTM program all together. We employ several methods to solicit CMR participation including welcome letters, outbound calls to members, and outreach from member's primary care physician recommending a CMR. We have also taken steps to improve our scripting on the outbound calls to attempt to garner more interest in the CMR. Since we are not allowed to call members who have opted out for a CMR, they should

Submitter	Response
	not be included in the denominator of CMR eligible members. We suggest defining standard definitions and guidelines for what qualifies as a CMR. After talking to other health plans, their definitions of CMRs each varied. There is guidance around the parameters for member eligibility and also a standard template for the member mailing after the CMR but further guidance around what qualifies as a CMR is needed. We would like CMS to research the following possible confounder and address as deemed appropriate: Are health plans with more stable membership (i.e. low turnover, minimal year over year growth) and with the same members being identified as Medication Therapy Management Program (MTMP)-eligible year over year likely to have a lower CMR completion rate because of CMR burn-out?
Health Net, Inc.	Request that any proposed Star measures be included on display page for a minimum of two rating periods. Have concerns that Plans who service low-SES members will be impacted by this measure due to transient nature of this population and difficulty in reaching to conduct review.
Healthfirst	We urge CMS to take into account the proportion of members that qualify for a CMR when calculating this measure. Plans with higher proportions of MTM-eligible members are disadvantaged by this current star measure. Healthfirst has the most stringent eligibility criteria in accordance with CMS regulations for enrollment in the MTM program (at least 3 chronic conditions and 8 Part D drugs). Even with these eligibility criteria, there are approximately 40,000 Healthfirst Medicare members (one-third of the plan's membership) who qualify for the MTM program, demonstrating the disease complexity of Healthfirst Medicare members. Unfortunately, this is another example of a measure in the star ratings program in which performance disparities are driven by individual member characteristics as opposed to plan quality. Factors impacting Healthfirst in achieving higher CMR completion rates include: ? Many of our eligible members are low-income subsidy/dual-eligible members. These populations are very difficult to reach as many can be transient, leading to frequent address and phone number changes. ? Tremendous resources are required to achieve ever-higher CMR rates due to our high proportion of eligible members, high proportion of non-English speaking members, and greater clinical complexity of our MTM-eligible members. Since CMS is currently working to address measure-level performance differences driven by individual member characteristics and has proposed interim Star Rating changes to account for some of these differences, we urge CMS to consider including this measure in the proposed options to address the observed impact of SES on quality scores. Alternatively, we recommend that CMS remove this measure from the Star Ratings and move it to the display page while CMS explores modifying the specifications of this measure to take into account the variation in MTM eligibility across plans (i.e., high

Submitter	Response
	proportion MTM-eligible vs. low proportion MTM-eligible plans). Additionally, we would support this measure changing from a process-based measure, to one that is outcome based (e.g., resolution of drug therapy issues through the MTM program). Additionally, we request an exclusion of long term care (LTC) beneficiaries from the CMR completion rate. Per OBRA-87 requirements, a licensed pharmacist must perform a monthly Drug Regimen Review (DRR) for a resident of a long term care facility, and any concerns identified must be reported and acted upon by the attending physician or director of nursing. The main differences between the CMR and the DRR include the responsible party for payment of the program and the number of eligible beneficiaries (all residents vs. 'targeted' residents). From a clinical perspective, since the DRR and CMR are duplicative, we continue to suggest that CMS remove the requirement to offer a CMR to LTC beneficiaries.
Humana	Humana is concerned with the inclusion of CMR as an improvement measure. The 2016 CMS Quality Strategy emphasizes outcomes, using the term 44 different times. We believe that continuing to place additional weight on a process measure within the Rating System is inconsistent with the shared goal of focusing on outcomes. Humana is concerned that the CMR measure does not take into account the number of members eligible, but focuses only on the completion rate. Based on our experience, we do not believe that the CMR completion rates are an effective way to measure the performance of MTM programs. Contracts that have a low number of patients who qualify will require a much lower number of CMRs to achieve high scores, while contracts with high numbers of qualifying patients will require a higher number of CMRs, and therefore, a relatively greater effort internally and with external partners to meet measure goals. In addition, due to the ability of health plans to select criteria for inclusion, plans could choose conditions that minimize the eligible patient population rather than include high-prevalence, chronic conditions that can potentially greatly improve member health. Finally, we note that through October of 2015, Humana has completed nearly 50% more CMRs than the same time period in 2014, a fact that unfortunately may not be reflected within proposed improvement measure calculations. Humana recommends removal of CMR as an improvement measure and recommends CMS pursue outcomes-based measures in this domain.
Independent Care Health Plan	"Plans," of course, are not "contracts." Should "plan-reported MTM data" not be rephrased more correctly as "contract-reported MTM data?" Some of the difficulty in getting a true picture of how DSNP plans compare is the confusion that arises from blending plan scores within a contract that includes regular Medicare Advantage members or FIDESNP members. Within H2237, for example, the FIDESNP plan by itself is scoring above 4.0 stars whereas the D-SNP plan is not; averaged together the contract score impacting both is 3.683. Scoring plans separately would allow CMS and consumers compare

Submitter	Response
	D-SNP plans more accurately without contract-averaging distortions. The current CMS policy is that D-SNPs cannot be scored at the plan level and SNP plans within a contract cannot be given their own contract number. Contract-averaging is leaving the impression that some D-SNP plans are performing at a higher level than they really are and some FIDESNPs (as in the case of the H2237 FIDESNP) are performing at a lower level than they really are. The current policy creates an error in funding and an error in consumer information. Recommendation: Score D-SNP and FIDESNP plans separately without contract-averaging.
Innovacare	In order for a plan to achieve 4 stars or better it will be required to achieve a Comprehensive Medication Review rate of close to 50%. This will be particularly challenging for plans such as ours with a higher number of beneficiaries (we have approximately 80,000 SNP members). We also have a high proportion of dual-eligible SNP members, with whom making the necessary telephone contact is especially difficult. We believe that CMR cut points should be better aligned with the national average of approximately 30% for MAPD plans and 15% for PDP plans, or otherwise adjusted to take into consideration challenging population profiles.
Martin's Point Health Care	Martin's Point appreciates that detailed Medication Therapy Management (MTM) data files will be provided to Plans on HPMS as we believe this will allow review and confirmation of data. We additionally support moving away from MTM process measures and feel that moving toward including outcomes-based MTM measures will better represent the quality of a Plan's MTM reviews. We would suggest that while CMS evaluates moving toward outcomes based measures for MTM, there is reassessment of the Comprehensive Medication Review (CMR) measure to address concerns that, as the measure stands today, incentives reward volume and could result in lower quality of the CMRs being performed in order to achieve the desired rates.
Medica Health Plans	Medica supports the study of CMR related measures and outcomes from these reviews that add value to our eligible beneficiaries. Medica would like CMS to consider a companion measure based on member input around length of time spent in the CMR, and member satisfaction with the review.
Molina Healthcare Inc.	Molina Healthcare requests that CMS make available specific and detailed documentation that outlines the process to be used for data integrity checks. The process should include validation of the counts for the measures to determine rates, and also the content and structure of the MTM programs. We ask that plans have the opportunity to comment on the process before it is finalized.
North Texas Specialty Physicians	Criteria for inclusion in the MTM program should be standardized for all plans. The current system encourages manipulation of the program to lessen the amount of members in the MTM EP. In addition, when you allow plans to decide how eligibility for the program will be determined and then compare all plans to each other

Submitter	Response
	to determine cut points there is an inherent disadvantage to those that are true to the intentions of the MTM program
OutcomesMTM	CMS commented that this measure represents an initial measure of the delivery of MTM services, and that CMS looks forward to the development and endorsement of outcomes-based MTM measures as potential companion measures to the current MTM Star Rating. OutcomesMTM seeks to retain the quality-improvement intent of the Comprehensive Medication Review (CMR) and has been advocating for a companion, quality-focused measure to this new 2016 Star Rating Measure since 2012. OutcomesMTM recommends CMS adopt one or more quality measures to the CMR completion rate measure. Three such measure concepts have been developed by OutcomesMTM, in collaboration with the National MTM Advisory Board, and introduced to the Pharmacy Quality Alliance in 2015 for further evaluation and specification: -Average number of prescriber recommendations per CMR -Average number of drug therapy changes per CMR -Percentage of prescriber recommendations made during a CMR that result in a drug therapy change
PCMA	6. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) Measure (Part D) – CMS will add a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and Data Validation score. CMS acknowledges the CMR rate measure is an "initial" measure of the delivery of MTM services and that CMS looks forward to the development of outcomes-based MTM measures. CMS indicates it will implement additional data integrity checks to safeguard against attempts to bias the data used for this measure. PCMA supports the provision of detailed files on HPMS and the movement away from process measures to outcomes for MTM. However, PCMA continues to have concerns with this Star Rating. The CMR Completion Rate is a process measure that is highly dependent on member behavior (e.g., participation in a CMR is voluntary), and does not accurately reflect plan performance. The current focus on the volume of completed CMRs encourages plans to narrow their targeting criteria for members who should receive this service and could lead to lower quality CMRs in order to achieve a desired completion rate. We suggest that CMS consider weighting this measure by enrollment prior to benchmarking plans against one another. PCMA previously recommended that the CMR Completion Rate not be added to the Star Ratings. The addition of this measure appears to have adversely affected 2016 PDP Star Ratings. In the 2016 Star Ratings Fact Sheet, CMS attributes a marked decline in the 2016 average PDP Star Ratings, in part, to the addition of three new measures not used in the prior year, including the CMR Completion Rate. As CMS acknowledged, given the smaller number of measures for PDPs, these changes have a more significant impact. PCMA thinks CMS should consider changes in the CMR measure methodology that would more fairly evaluate plan

Submitter	Response
	performance on MTM interactions with beneficiaries. PCMA Recommendation: PCMA urges CMS to consider changes in the CMR Completion Rate measure methodology and step up its efforts to develop measures that accurately reflect the clinical outcomes of MTM services.
Pfizer	Description of the Issue or Question: CMS is proposing to add a detailed file during each Health Plan Management System (HPMS) preview period to list each contractor's underlying denominator, numerator, and Data Validations score since exclusions are applied to the plan-reported Medication Therapy Management (MTM) data. CMS will also be implementing additional data integrity checks to safeguard against inappropriate attempts to bias the data used for the completion rate for Comprehensive Medical Reviews (CMR) measure. Suggested Revisions/Comments: Pfizer supports CMS' approach to include additional details to the Comprehensive Medical Reviews (CMR) measure, as well as the intention to audit MTM programs. This updates will ensure proper measurement and use of MTM programs, improving quality of care provided to patients. We applaud CMS for adding MTM CMR reviews as a way to drive completion of these annual reviews (and note that for high-risk patients on multiple therapies, conducting a CMR every six months would be more appropriate). CMR reviews are often forwarded to prescribers (as required) and this information could be very valuable to coordinate and optimize care. We also urge CMS to consider options for how to integrate CMR annual review information into a patient's medical record, including future efforts to evolve EHR standards/meaningful use criteria.
PhRMA	CMS proposes to add a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and Data Validation score, as well as implementing additional data integrity checks to safeguard against inappropriate attempts to bias the data used for this measure. PhRMA supports the additional detail that is proposed to be added during each HPMS plan preview period. Ensuring that beneficiaries are taking the right drug at the right dose is critically important to achieving optimal health outcomes, and MTM and the use of CMRs are important tools to ensure that beneficiaries are being treated appropriately, regardless of setting. We acknowledge that the measure for Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) provides a good foundation for the assessment of CMR, but also support CMS's position that measure development, endorsement, and evaluation of MTM should continue to advance to ensure the quality of MTM programs and activities.
SCAN Health Plan	A.6 Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D). CMS will add a detailed file during each HPMS plan preview period to list each contract's underlying denominator, numerator, and

Submitter	Response
	Data Validation score since exclusions are applied to the plan-reported MTM data. SCAN Comment: SCAN Supports - This will allow plan sponsors to more accurately project the final CMR rate if the denominator that CMS has calculated is known.
SNP Alliance	6. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D) We appreciate CMS' proposal to add a detailed file during the HPMS plan preview period listing each contract's underlying denominator, numerator, and Data Validation score allowing for additional data integrity checks. With respect to the current MTM Program Completion Rate for CMR measure, consistent with previous SNP Alliance comments, we remain concerned about the inconsistency inherent in this measure from plan to plan due to the current flexibility afforded plans in designing their MTM programs. Plans may structure MTM programs to be generously inclusive or more restrictive, within CMS guidelines, with respect to member eligibility. As a result, we ask CMS to consider that different populations served be averaged separately for metric cut points and scoring, and that CMS include a qualifier on this metric for plans that have more expansive MTM programs. Our objective is to ensure that plans are not unfairly disadvantaged by affording their members access to MTM above and beyond what is required by law. With respect to CMS' plans for future development and endorsement of outcomes-based MTM measures as potential companion measures to the current MTM Star Rating, we appreciate these efforts but feel strongly that plans must have time to review and comment on any proposals for outcome-based MTM measures. Even more, to the extent that CMS will be developing such outcome measures, we believe it is critical to involve Special Needs Plans in the development process for these measures. The provision of medication therapy management services and use of prescription drugs present unique challenges to SNP populations, and these should be considered and addressed in the measure development process. We also encourage CMS to continue to work with stakeholders to identify alternative tools and measures that incentivize and reward plans for prioritizing the quality and effectiveness of CMRs rather than simply the quantity completed.
Tenet Healthcare	The plan encourages the movement toward outcomes based MTM measures for the Stars Program. We feel the current process measurement that evaluates MTM CMR completion rate rewards for quantity which could have a negative impact on the quality of the interaction.
Triple S Advantage, Inc	TSA suggests a more delimited process for this measure. Currently, all MAs have a different process, sources and methodology. Having a clear guidance for all plans to follow, may result in a more cohesive process. This may ensure that all Plans are working accordingly to comply with this measure. Before adding outcomes measures, a pilot of the different possible service delivery models could be

Submitter	Response
	beneficial, to determine which model will achieve the outcomes. Currently there is a lot of variability in the delivery of the service, making it difficult to measure outcomes. Also need to assess member access to services (person to person, telephonic) when incorporating the requirement of outcomes measures.
UCare	UCare has concerns with this measure modification, specifically with our D-SNP contract. This is a difficult population for us to engage, influenced by cultural issues, and poor contact information. Poor outreach success with these members impacts ability to do well in this measure. Furthermore, outcome methodology to measure this would be very complex and burdensome to produce.
UPMC Health Plan	UPMC is and always has been a strong proponent of initiatives designed to promote the continued efficacy and safety of our beneficiaries' medication regimens, and has remained supportive of the CMS Medication Therapy Management (MTM) requirements since their inception. While we support the use of the Comprehensive Medication Review (CMR) Completion Rate measure, we are concerned about its reliability given substantial variability in the quality of CMRs completed. Here at UPMC, we take pride in performing thorough and high-quality CMRs; particularly for individuals with multiple chronic conditions who are often on complex medication regimens. Our CMR process provides a comprehensive review of an individual's prescription and over-the-counter medications with the goals of providing individuals a better understanding of the purpose of their medications, reducing the risk of negative side effects and complications, and finding ways to save on out-of-pocket drug spending. With this support as a backdrop, we note that the current MTM Star Rating measure is more heavily weighted toward the overall completion of CMRs rather than the thoroughness of the evaluation itself. We encourage CMS to continue to work with stakeholders to identify alternative tools and measures that incentivize and reward plans for the quality and effectiveness of CMRs rather than simply the number completed.
VIVA Health, Inc.	The Plan agrees with CMS's provision of detailed files on HPMS in order to review and confirm our Medication Therapy Management (MTM) data. The Plan supports the eventual addition of an outcomes-based MTM metric to the process measure. The Plan requests that any move towards an outcomes-based MTM measure allow for plan comment and adequate lead time for measure preparation and modeling of its potential impact. The Plan requests that plans have at least two years of experience managing outcomes-based MTM metrics (closing adherence gaps, resolving drug-drug interactions, appropriate disease state management, etc.) prior to placing an outcomes measure in the star ratings. In the interim, The Plan recommends CMS evaluate changes to the MTM Comprehensive Medication Review Completion Rate (CMR) measure methodology. The Plan expends significant effort and resources towards CMR achievement. The Plan has thousands of

Submitter	Response
	members eligible for CMR completion as of 12/3/15. Due to the percentage based calculation of this measure, the Plan and other larger plans may be disadvantaged over smaller plans in measure achievement. The Plan has also noted that in 2016 Star ratings nationally, the number of plans achieving national average has decreased as compared to prior years, and the 3 Star cut point does not reflect the majority of plans' performance percentages. The 2016 cut points were likely impacted by smaller outlier plans that may have an easier path to five star achievement. We request CMS consider weighting this measure by enrollment prior to benchmarking plans against one another. Additionally, The Plan has a substantial LIS/Dual and Disabled population, which presents additional barriers to completion CMRs as well as achievement of the current process measure due to challenges such as: inadequate member transportation, telephonic outreach, lower health literacy, and additional complex co-morbidities. We also request that CMS include this measure in the analytical adjustments to address the LIS/DE/disability effect.
WellCare	WellCare supports CMS' proposed methodological changes for the MTM measure. Providing each contract its denominator, numerator, and data validation score increases the transparency into how this measure will be calculated. We ask CMS to provide ample time during the plan preview period to allow plans to review the data in order to assure its accuracy and submit feedback.

B. Removal of Measures from Star Ratings

1. Improving Bladder Control (Part C)

Submitter	Response
Aetna	Aetna also supports the removal of the Bladder Control measure from the Star Ratings Program. There are adequate concerns from a clinical and methodological standpoint with this measure, as CMS details in the HPMS memorandum, to warrant removal from the Star Ratings Program.
Anthem, Inc	Anthem supports the removal of this measure from the 2017 Star Ratings as it is based on survey data, making it inherently subjective. We recommend that CMS include the Bladder Control measure on the display page for both 2017 and 2018 to give plans sufficient time to review data and performance. Overall, Anthem recommends that CMS seek to remove all survey-based metrics from the Star Ratings program.
Blue Cross Blue Shield of Michigan	CMS will not report this measure in the 2017 Star Ratings, since NCQA changes required revising the underlying survey questions in the Health Outcomes Survey (HOS). BCBSM supports both the changes being made to the measure, as well as keeping this measure on the display page for the 2016 and 2017 Star Ratings.
BlueCross and	CMS proposes to keep the Improving Bladder Control measure on

Submitter	Response
BlueShield Association	the Display Page for the 2017 Star Ratings, as the NCQA recently made changes to the metric that impact the data collected in 2015. BCBSA and Plans support keeping this measure on the Display Page. Recommendations: BCBSA and Plans support CMS's proposal to keep the Improving Bladder Control measure on the Display Page for the 2017 Star Ratings and request that CMS also consider keeping the measure on the Display Page for the 2018 Star Ratings so that Plans have sufficient time to review their data and performance.
BlueCross BlueShield of Tennessee	BCBST supports exclusion of this measure from the 2017 star ratings. Please clarify whether the intent is for this measure to remain on the display measure page indefinitely or if it is CMS' intent to bring it back into as a star measure in the 2018 star ratings.
Commonwealth Care Alliance	CCA is concerned that respondents will not realize that "treatment" does not always involve medication or surgery and could involve other management protocols that they will not interpret as "treatment". CCA suggest that the questions be reworded prior to including this measure in Star Ratings.
Fresenius Health Plans	We support the removal of this measure and appreciate CMS' consideration of ESRD patients in doing so, as the majority of ESRD beneficiaries are anuric, so measuring a response for urinary leakage is not be meaningful for our beneficiary population.
Health Alliance	Improving Bladder Control- The request for comments states that this revised HOS measure will be reported on the 2017 display page. Based on current star reporting methodology, HOS data with the revised questions would not be available until the 2019 Star Display page. The question was revised in the 2015 HOS survey. Data from the baseline survey will be available for 2017 Star reports but the complete Cohort measure (2015-2017) will not be available until the 2019 Star reporting period.
Healthfirst	We ask that CMS notify plans prior to the next draft Call Letter if the Improving Bladder Control measure will be included for the 2018 Star Ratings as the HOS survey fielded in 2016 will impact the 2018 Star Ratings for this measure. In the previous 2016 Enhancement Memo and Draft Call Letter, CMS states that "The revised questions will be first collected in 2015. As a result of these changes, there will be no data for this measure for the 2016 and 2017 Star Ratings." There is no language in the current 2017 Enhancement Memo confirming whether this measure will be included in the 2018 Star Rating or remain on the 2018 Display Page.
HealthPartners	HealthPartners believes that bladder control is a discussion component that needs to be measured. Rather than focusing exclusively on the receipt of treatment, we recommend the questions

Submitter	Response
	be expanded to include discussion of management of this problem with health care providers.
Molina Healthcare Inc.	Molina Healthcare questions whether the Improving Bladder Control measure is a useful indicator to measure Star Rating performance especially for a Special Needs Plan. It is difficult for a Special Needs Plan member to improve bladder control due to complex medical and behavioral health conditions. We ask that CMS discuss the validity of this measure with health plans and other stakeholders to ensure that this measure continues to be reliable to evaluate comparative plan performance.
PhRMA	CMS is proposing temporary removal of the Improving Bladder Control measure to reflect changes to the Health Outcome Survey (HOS). PhRMA remains concerned about the removal of a question addressing treatment receipt. While we appreciate the addition of an outcome indicator to assess the impact of urinary incontinence on quality of life for beneficiaries, we believe that the question about receipt of treatment should be retained so that changes in quality of life can be better correlated to treatment choice.
SNP Alliance	1. Improving Bladder Control (Part C) Consistent with prior SNP Alliance comments, we believe it is not appropriate to expect improvement of bladder control for a number of the members being served in SNPs due to their age, or medical or functional conditions. As a result, the focus of the HOS question (#45 in 2015 HOS) on treatment for urine leakage is problematic. In some cases, health care providers will discuss ways in which this problem can be effectively managed as opposed to treated. Rather than focusing exclusively on the receipt of treatment, the question should be expanded to include discussion of management of this problem with health care providers. Until this measure is modified consistent with concerns expressed above, we recommend it remain on the display page and not return to the Star Ratings. However, if CMS decides to return the measure to Star ratings, we request that this not be done until 2019 at the earliest to provide for adequate experience with the revised measure.
UnitedHealthcare	UnitedHealth agrees with CMS' recommendation to keep Improving Bladder Control as a display measure for 2017 Stars. This is appropriate due to significant measure rewording beginning with the 2015 survey. However, UnitedHealth requests that CMS clarify whether the revised Improving Bladder Control measure is expected to be included in the Star year 2018 ratings.

2. High Risk Medication (Part D)

Submitter	Response
Academy of Managed Care Pharmacy (AMCP)	AMCP appreciates CMS' recommendation to remove the High Risk Medication (HRM) measure from the Star Ratings and move it to the display page for 2017. AMCP appreciates CMS' recognition of the American Geriatrics Society's recommendation that the Beers Criteria not be applied in a punitive manner and the recognition that

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	identification as a HRM is not a contradiction to use, but rather an encouragement to avoid use without first considering the clinical risks and benefits to the individual patient. AMCP applauds CMS for focusing on ensuring the right patients have access to the right medications. In the future, if CMS implements further changes to the HRM list for purposes of Stars Ratings, AMCP requests that CMS provide advance notice to plans of potential changes to the HRM drug list and that the updated list only be incorporated in the measure after plans have had access to it. AMCP has previously commented on the inclusion of updated Beers criteria in this measure and urged CMS to allow plans sufficient lead-time prior to formulary design bid submissions.
Aetna	Aetna supports removal of the High Risk Medication (HRM) measure from Star Ratings and believes the rationale provided by CMS is reasonable and valid. As stated, without additional clinical non-PDE data that sheds light on the benefits/risks analysis, the current view of HRMs is limited and inconsistent with the full AGS-recommended medication list. Furthermore, the recent finding that there appears to be SES-related associations with the measure does indicate the need to further understand such potential impact and explore mechanisms to equalize such impacts for those plans with proportionally larger DE/LIS populations. In cases where patients are stable without adverse events of the medication, physicians often choose to keep patients on the therapy. In conditions such as insomnia, given lack of clinically viable alternatives available in the market, discontinuing therapy on a stabilized patient might pose higher risk than benefit of the drug. Aetna supports physician flexibility in making decisions appropriate for providing optimal care to their patients.
AHCCCS	AHCCCS supports CMS' assertion that high risk medication use is under direct provider control and should not be used in a punitive manner, especially since drug plans do not have access to the full array of clinical data.
Ahold USA	I endorse this change. Trying to get pharmacists to change HRM physician prescribing after the medication has been ordered is reactive and not likely endorsed by prescribers. HRM prescribing should be proactive and the burden should not be on the pharmacy but the prescriber.
Alliance of Community Health Plans	ACHP supports the removal of the High Risk Medication (HRM) from the star ratings and its placement on the display page for 2017. We also agree with CMS that avoiding potentially inappropriate medications for beneficiaries is important for quality of care, and we encourage CMS to consider the HRM measure for the star ratings in the future upon making specification changes.
American Pharmacists Association	APhA is in agreement with CMS' proposal to move the High Risk Medications in the Elderly (HRM) measure from a Star Ratings measure to a Display Measure in 2017. The need to incorporate updates to the Beers' Criteria, the efforts to better understand the

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	unintended consequences when plans lack access to clinical data, and the need to analyze the associations between low-income status and the use of high-risk medications in the elderly are all important reasons to move the HRM measure to display status.
Anthem, Inc	Anthem strongly opposes the removal of the HRM measure from the 2017 Star Ratings. This measure is an important vehicle for the improvement of patient safety and quality of life—it provides credibility to the interventions implemented by the health plans for the benefit of our members. We understand that CMS' proposed removal of this measure is based on several factors, including the American Geriatrics Society's (AGS') position that the addition of a drug to the HRM list is not a contraindication to use but an encouragement to avoid use in the senior population without consideration of risks and benefits for an individual, and that some "Avoid" medications are included in the HRM measure, while others are not. However, Anthem is concerned by this rationale—the intent of the HRM measure is not to eliminate use of all high risk medications, but to minimize their use. Across our membership, we have seen a significant reduction in the use of HRMs, which indicates the measure is working and that members are getting safer and more appropriate therapy for their conditions. To that end, Anthem would only support the complete removal of this measure if outcomes analyses were conducted that showed that members on HRMs have equivalent safety-related outcomes compared to members on the alternatives to the HRMs. To our knowledge, however, this type of analysis has not been completed. The improvements made to-date at the patient level, the impact made to prescribing habits at the physician level, and the value-add from a patient-safety perspective at the plan level will all be at risk if the HRM measure is removed. Physicians will no longer be tied to a performance measure that encourages safer prescribing habits in regards to the Beers Criteria, allowing for an increase in the utilization of these potentially unsafe medications. This will put the patient at risk. It will also put the plans at a direct disadvantage by undermining the several years' worth of efforts to reduce utilization, impact prescribing trends, and improve member safety and quality of life. Lastly, removal of the HRM measure would send the wrong message to providers and reduce the credibility of all clinical measures moving forward. Anthem believes it would be more appropriate for CMS to retain the HRM measure—with its existing methodology—for 2017, and to include on the 2018 display page a simulation of how plans perform under a contemplated new methodology. This would provide plans with the ability to monitor HRM interventions and subsequent performance on the measure before CMS moves forward with implementing a material change to the HRM measure.
Association for Community Affiliated	ACAP strongly supports CMS' proposal to remove the High Risk Medication (HRM) measure from its Part D methodology. ACAP

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Plans	plans share many of the concerns that CMS highlighted with the measure, including unintended consequences of drugs appearing on the HRM list. In addition, ACAP encourages CMS to also remove two additional measures: D2, Appeals Auto forward, and D10, Medication Plan Finder Accuracy from its methodology. CMS has stated that it will remove a measure if there is little to no room for improvement and a lack of variability in the scores. Measures D2 and D10 meet these criteria. According to CMS' 2016 Star Ratings fact sheet, the average D2 score is 4.5, the highest of any Part C or Part D measure. Greater than three out of every four MA-PD contracts earned a 5-Star Rating for this measure (285/373). The D10 measure is defined in technical guidance as "A score comparing the prices members actually pay for their drugs to the drug prices the plan provided for this Website (Medicare's Plan Finder Website). Higher scores are better because they mean the plan provided more accurate prices." Though the average D10 score is not nearly as extreme as that of D2, the 2016 Technical Notes reveal a lack of variability across plans for this measure, diminishing its significance to consumers. The cut points that separate a 3-Star Rating form a 5-Star Rating are minimal: A 3-star plan scores between 97 and 99 on the adjusted accuracy index while a 5-star plan scores 100. 453 of the 478 (95 percent) contracts scored between 98 and 100 on the measure and 87 percent were rated 3 or 4 on the measure. ACAP supports the removal of High Risk Medication measure and urges CMS to also retire the D2 and D10 measures.
BIO	BIO supports the proposal to remove the High Risk Medication (HRM) measure from the Star Ratings and move it to the display measures for 2017. We agree that avoiding the utilization of potentially inappropriate medications for Medicare patients is an important quality of care metric, but that the HRM measure for Part D beneficiaries addresses this issue only tangentially. Moreover, this measure may be inadvertently applied in a punitive manner, disadvantaging plans that enroll certain types of patients who require therapies on the HRM list. As CMS notes in the RFC, therapies on the HRM list are not contraindicated for use in the Medicare population, but instead, placement on the list is meant to denote the need for clinicians to take particular care in weighing the benefits and risks of utilization in this population. The decision to prescribe the therapy should be made based on the clinical circumstances of an individual patient, circumstances not comprehensively described by prescription drug event (PDE) data, on which the HRM measure is based. Thus, even when an HRM-listed therapy is the most clinically appropriate treatment for an individual Medicare beneficiary, this measure may penalize the plan in which the beneficiary is enrolled by negatively impacting its Star Rating. When moved to the display measures, the HRM measure will still be reported to providers on a monthly basis, such that its potential to inform, but not unduly influence, clinical behavior will persist. For these reasons, BIO urges

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	CMS to finalize the RFC proposal to remove the HRM measure from the Star Ratings and move it to the display measures for 2017.
Blue Cross and Blue Shield of Minnesota	In general, BCBSMN agrees with the broad-based request to provide accurate measurement technical specifications on a prospective basis to plans to allow plan resources to be used in the most effective and efficient manner possible. However, when clinical guidelines change to be no longer consistent with Star measures, this rationale should not be supported. Ultimately, the goal of the Star Ratings must continue to be the Triple Aim – specifically, improving patient outcomes – not prioritizing health plan activities. For example, JNC8 guidelines were released in February 2014 which contradicted the treatment assessed in the Diabetes Treatment measure. CMS accordingly excluded that measure from the 2015 Star Ratings. Similarly, in the High Risk Medication measure, there are clinical concerns that implementation could create unintended consequences, which may not be the best choice for an individual member's circumstances. While our plan has also invested considerable resources in this measure, and we perform well, clinical quality should take precedence over other concerns. Additional Comment: BCBSMN supports the CMS recommendation to further review D-SNP enrollment on HRM measure performance.
Blue Cross Blue Shield of Michigan	CMS is removing the High Risk Medication (HRM) measure from the Star Ratings and moving it to the display page for 2017. BCBSM supports removing the measure from Star Ratings given concerns that the measure may inadvertently encourage utilization of non-HRM medications even in cases where the non-HRM medication is not the optimal course of treatment for a member's particular clinical circumstance. If CMS considers moving the HRM measure from the display page back to the Star Ratings in the future, BCBSM urges CMS to implement any changes made by the Pharmacy Quality Alliance (PQA) well in advance of the Medicare Advantage and Part D formulary and bid submission deadlines for the upcoming Calendar Year. Plans will need time to analyze and respond to the changes, such as removing drugs from the formulary or adding prior authorization criteria, which may impact the formulary and bid submission. In addition, BCBSM asks that hospice patients be excluded from the measure's denominator. Hospice patients have complex medical needs, and certain HRMs may provide substantial comfort that may override any associated risk for that particular patient.
Blue Shield of California	We would like to request that CMS consider removing the RY2018 ratings as plans have worked to decrease HRM utilization for RY2017 (MY2015). If removed in RY2017 then appeals associated with these products should also be removed from their related measures
BlueCross and BlueShield Association	CMS proposes to move the HRM measure to the Display Page for 2017. BCBSA and Plans understand that the removal of this measure from the Star Ratings is based on several factors, including

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	the American Geriatrics Society's position that the addition of a drug to the HRM list is not a contraindication to use but an encouragement to avoid use in the senior population without consideration of risks and benefits for an individual, and the fact that some "Avoid" medications are included in the HRM measure, while others are not. As such, BCBSA and Plans agree with CMS's suggestion that the HRM measure may not be the most accurate reflection of Plan performance or of value to individual beneficiaries. We continue to believe that the HRM measure is not necessarily tied to better clinical care and that any measure of HRM use should recognize that the decision to prescribe an HRM should be based on the individual physician's assessment of the risks and benefits for a particular patient. Plans also note that this measure tends to penalize Plans with pay-for-performance arrangements with prescribers. Nonetheless, BCBSA and Plans emphasize the detriment to Plans with CMS's abrupt change in course regarding this metric. BCBSA and Plans have repeatedly objected to this metric, but CMS ignored these comments and retained the metric. Accordingly, Plans have made significant investments in improving their performance on the HRM measure, and the proposed change in course – moving this measure to the Display Page in 2017 – will mean that Plans' efforts and resources on the measure will be unrecognized. Moreover, Plans note that they may now need to adjust their operations, including making changes to their utilization management programs, formularies, and prior authorization requirements. In the future, BCBSA and Plans encourage CMS to be more cautious before abruptly adding or moving a measure to the Display Page or the Star Ratings. If CMS decides to retain the MTM measure on either the Display Page or the Star Ratings, BCBSA and Plans encourage the Agency to consider excluding members in hospice care from the measure. These members have substantially different medical needs, which further complicate implementation of the HRM list. Recommendations: BCBSA and Plans generally agree that the HRM measure does not provide value to beneficiaries and perhaps does not deserve to be included in either the Star Ratings or on the Display Page. If CMS

Submitter	Response
	retains the HRM measure on either the Display Page or in the Star Ratings in future years, BCBSA and Plans recommend that members in hospice care be removed from the measure. We encourage CMS to consider making the removal of the measure more gradual so as to recognize and potentially reward Plans' efforts to perform well on the HRM measure.
BlueCross BlueShield of SC	Thank you for removing the HRM measure. This measure certainly has ran its course in that those that were being prescribed the medication inappropriately were offered clinical alternatives and either switched or the physician indicates the risk outweigh the benefits. We totally appreciate not having to be graded on the same group of members year over year where the HRM benefits outweigh the risks to them.
BlueCross BlueShield of Tennessee	BCBST supports CMS' proposed recommendation to move the HRM measure to the display page for 2017 due to the 2015 changes to the Beers Criteria released by the American Geriatrics Society. BCBST encourages CMS to work with plans to better understand the association between dual eligible/low income status and HRM as the measure should not be affected by non-clinical beneficiary characteristics. Lastly, BCSBT recommends that CMS engage plan sponsors when determining adoption for the 2019 display page (using 2017 data) to ensure that sufficient time is available to make updates to align with the PQA changes and associated formulary and bid timelines.
Cambia Health Solutions	We are supportive of moving the HRM measure to display measure. 1. The AGS drug list has been updated more frequently in recent years with significant changes. To incorporate significant changes in HRM will warrant a year of display measure regardless of the other reasons stated in the RFC. 2. Providers have been educated and encouraged to use HRMs judiciously over the years. Many are aware of the risks and benefits that need to be considered. 3. As stated in the RFC, not all the drugs in the AGS list were considered HRM. There could be unintended consequences encouraging use of unsafe drugs that were not included in the HRM drug list (e.g. benzodiazepines). However, we believe this is one of the measures that has the most benefits for patients. We would caution that this move may have the effect of de-prioritizing the measure. Perhaps CMS can consider being more selective with the list.
CareSource Management Group	We support CMS' proposal to remove the High Risk Medication (HRM) measure from its Part D methodology. Also, we encourage CMS to remove two additional measures: D2, Appeals Auto forward, and D10, Medication Plan Finder Accuracy from its methodology. CMS has stated that it will remove a measure if there is little to no room for improvement and a lack of variability in the scores. Measures D2 and D10 meet these criteria. According to CMS' 2016 Star Ratings fact sheet, the average D2 score is 4.5, the contracts earned a 5-Star Rating for this measure (285/373). The D10 measure is defined in technical guidance as "A score comparing the

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	prices members actually pay for their drugs to the drug prices the plan provided for this Website (Medicare's Plan Finder Website). Higher scores are better because they mean the plan provided more accurate prices." Though the average D10 score is not nearly as extreme as that of D2, the 2016 Technical Notes reveal a lack of variability across plans for this measure, diminishing its significance to consumers. The cut points that separate a 3-Star Rating form a 5-Star Rating are minimal: A 3-star plan scores between 97 and 99 on the adjusted accuracy index while a 5-star plan scores 100. 453 of the 478 (95 percent) contracts scored between 98 and 100 on the measure and 87 percent were rated 3 or 4 on the measure.
Centene Corporation	Centene Corporation requests that CMS consider efforts already expended on ensuring adequate star measure performance for measurement year 2015, and include this measure in rating year 2017 and consider removal for in the 2018 rating year. Centene asks that notification regarding future measure removal occur prospectively, prior to the beginning of a new measurement year as opposed to retrospective removal.
Cigna	CMS' implementation of HRM as a Star measure accomplishes the goal of promoting patient safety, is a good quality of care measure for our elderly populations, and improves member health outcomes. In this proposal, CMS is considering the removal of HRM from the 2017 Star Rating because plans do not have clinical information to render adequate decisions. This is evidenced by the HRM National Average (7% MAPD, 11% PDP). We disagree with CMS' proposal and recommend keeping this measure as a Star measure because it achieves CMS' goals, supports member safety and reduces adverse events due to high risk medications. Our model supports physicians with robust medication education and provides physicians options for alternatives for patients. With this information our physicians make informed clinical decision for their patients. There are times that a high risk medication is indicated because the clinical benefit outweighs the risk of the medication and our model supports physicians making those decisions. The removal could undermine initiatives that support quality of care and patient safety. We also recommend that CMS remove HOSPICE patients from this measure.
Clover Health	Clover Health supports CMS's recommendation to remove the High Risk Medication (HRM) measure from the Stars page, as the plan is not best positioned to evaluate the appropriateness of therapy based on the individual patient's condition. We recommend CMS keep the HRM measure on the display page and move forward with updates to align with the revised Beer's criteria. We appreciate advanced notice of the potential changes to the High Risk Medication (HRM) drug list. Since plans are currently working on their 2017 bid; therefore, the revised drug list would need to be available for immediate distribution in order to adjust formulary decisions, allow time for PA edit decisions and P&T approval.
Commonwealth Care	CCA supports the exclusion of this measure from Star Ratings.

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Alliance	
CVS Health	SilverScript supports CMS's recommendation to remove the High Risk Medication (HRM) measure from the Stars page, as the plan is not best positioned to evaluate the appropriateness of therapy based on the individual patient's condition. We recommend CMS consider delaying the movement to the Display page until the 2018 Star Ratings. CMS should allow plans sufficient notice prior to adjusting measures included in the program. Unexpected removal of a triple weighted measure significantly impacts the overall importance of other measures within the Star Ratings program. This impact is magnified for PDPs since there are fewer measures factored into the plan's overall score. Implementation of this change in the 2018 Star Ratings program would allow plans sufficient time to adjust their communication strategies to beneficiaries, pharmacies and physicians as well as their planning around Star measure performance. We recommend CMS keep the HRM measure on the display page for 2018 Stars and beyond and also move forward with updates to align with the revised Beer's criteria. We appreciate advanced notice of the potential changes to the High Risk Medication (HRM) drug list, as formulary is an effective strategy to help manage HRM utilization. Plans are currently working on their 2017 bid; therefore, the revised drug list would need to be available for immediate distribution in order to adjust formulary decisions, allow time for PA edit decisions and P&T approval.
EmblemHealth	Tracking and monitoring high-risk medications is crucial in the Medicare population, especially the elderly. If the measure is removed from the core star measure set, health plans and providers would stop monitoring this important clinical issue. As far as having access to clinical information for evaluating the appropriateness of the drug is concerned, health plans can put systems in place requiring providers to submit supporting documentation to justify the use of the drug in the elderly population.
Essence Healthcare	Notice of removing a STAR metric, such as High Risk Medication Use, in the last few months of the measurement period may unintentionally reward plans that are not focusing on an important quality opportunity, like ensuring our seniors are prescribed the safest medication option. One of the stated goals of the STAR program is "Providing incentives for MA and Part D quality improvement" and removal of measures late in the measurement period may reward apathy versus action that is a critical differentiator in developing an effective quality improvement program at the health plan level. We recommend that CMS not remove the High Risk Medication Use measure for 2017 STAR.
Fresenius Health Plans	Due to the fact that many ESRD patients become Medicare C-SNP eligible due to his/her health condition, rather than age, this measure is not conducive to measuring the ESRD SNP population, as this measurement would not be applicable to many beneficiaries in our population. We recommend either a carve out for the ESRD

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	population or for there to be ERSD-specific measurements put in place for ESRD SNPs.
Group Health Cooperative	High Risk Medication (Part D) Group Health supports removing the high risk medication (HRM) measure from the Star Ratings to the display page for 2017, but encourages CMS to return HRM to the ratings as soon as possible. Group Health does believe that health plans serve an important role in discouraging use of HRMs and that encouraging safe medication prescribing is an important tenant of high quality care and should therefore be included in the Star Ratings.
Health Care Service Corporation	HCSC supports moving the HRM measure to the Display measures; however, we recommend that CMS make this move in 2018 instead of 2017. Many MAOs, including HCSC, have invested considerable resources in this measure during 2015 in an effort to improve the rating for 2017. If CMS were to move forward with a retrospective specification by not counting the rating in 2017, it would not reflect the resources MAOs have invested to date. We recommend that CMS continue to strive to make prospective requirements and in the case of the HRM measure, make the proposed change in 2018 rather than 2017. In addition, the most recent AGS 2015 Update cited "The 2015 AGS Beers Criteria are applicable to all older adults with the exclusion of those in palliative and hospice care." CMS should update the specifications in the measure to exclude members in Hospice care from the denominator.
Health Net, Inc.	Retirement of Star measures should be made by CMS prospectively to allow time for process changes/messaging to Providers. Request that CMS delay retiring the HRM until the 2018 Rating period.
Healthfirst	We do not support the removal of this measure for 2017 Stars. With fewer than 30 days left in the measurement period for this measure, the removal of the High Risk Medication measure from the Star Ratings would be a retrospective change to the program. Retrospective changes are problematic for incentive-based programs like the Star Ratings that aim to change the behavior and activities of incentivized parties because it effectively changes the rules of the program after the measurement period has ended. The Star Ratings program aims to “drive organizations and sponsors toward higher quality and more efficient care” by awarding bonuses to plans that perform well on the suite of measures included in the Star Ratings; changing the program measures after the end of the measurement period undermines the integrity of the program and reduces plans’ confidence in investing time and resources into improving on Star Ratings measures. Furthermore, Healthfirst uses formulary management tools, such as utilization management edits and higher tiering placement, to minimize inappropriate HRM use, but this does not prevent or deny the appropriate patient from obtaining the medication. We agree that all High Risk Medications should be evaluated for use on a patient-specific basis, taking into account the risks and benefits for that particular patient. We do not expect or

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	encourage providers to stop prescribing these medications as a whole, and believe this measure helps us work with providers to stop inappropriate utilization, minimizing safety concerns and risks for our elderly population. We have been able to effectively curb the overutilization of these medications, especially Ambien. Additionally, in a population like ours, with a large proportion of LIS members and where health literacy is a concern, we believe this measure has helped to minimize the risk of serious health issues and/or injury in our elderly population.
HealthPartners	Due to the most recent AGS updates, HealthPartners supports CMS' proposed removal of the HRM measure from the 2017 Star Ratings and move to the display page. We will continue to work with PQA and NCQA regarding concerns with use of the Beers List. We note the Beers criteria identify a drug has risks, but it is not a black and white list. The list should not be used exclusively as it suggests potential risk only.
Humana	Humana supports the overarching goals of the 2016 CMS Quality Strategy. The number one goal of that strategy is to "make care safer by reducing harm caused in the delivery of care" which includes reducing "inappropriate and unnecessary care." We believe this is an area where MA and Part D Stars can be strengthened. Currently there is a lack of balance between measures focused on providing care and those measures focused on protecting beneficiaries from inappropriate and unnecessary care. This imbalance would be exacerbated by the removal of the High Risk Medication (Part D) measure as CMS has proposed. Humana recommends that CMS prioritize creating a balance between measures incentivizing care and measures incentivizing the reduction of inappropriate and unnecessary care. One area that should receive consideration is the overuse of antibiotics, which has been well documented in the literature. See for example, Gonzales R, Malone DC, Maselli JH, Sande MA. Excessive antibiotic use for acute respiratory infections in the United States. Clin Infect Dis. 2001 Sep 15;33(6):757-62 and Zoorob R, Sidani MA, Fremont RD, Kihlberg, C. Antibiotic use in acute upper respiratory tract infections. Am Fam Physician. 2012;86(9):817-822. NCQA and NQF have already conducted measurement work in this area, albeit with a under-65 population. For background, see http://www.qualitymeasures.ahrq.gov/content.aspx?id=48611. Additional Comment: Humana supports the continued utilization of HRM. As noted in the 2015 CMS Call Letter, the goal of this measure is to reduce potentially inappropriate use of these medications by beneficiaries over the age of 65, when there may be safer drug choices available. Furthermore the 2015 Call Letter states, the goal is to not achieve a zero percent HRM rate as it is understood some of these medications may be clinically necessary. Humana strives to provide evidence based messaging, not only for our members, but for provider partners as well. The importance of this measure allows

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	for continuous improvement of members' medical conditions and avoidance of Adverse Drug Events. Through formulary management, we are afforded the opportunity to have safety edits in place not to preclude provider's clinical judgment but aid in identifying safer alternatives. Our formulary alternatives are equally and therapeutically as efficacious and align with the American Geriatric Society 2015 Beer's Alternatives List.1 As a health plan we welcome the opportunity to work in concert as a member of the healthcare team to ensure improved and continued patient safety. Reference 1. Hanlon, Joseph T., Todd P. Semla, and Kenneth E. Schmader. "Alternative Medications for Medications in the Use of High?Risk Medications in the Elderly and Potentially Harmful Drug–Disease Interactions in the Elderly Quality Measures." Journal of the American Geriatrics Society (2015).
Independence Blue Cross	Removing this measure from the Star measures may result in increased falls and overmedication use resulting in admissions/readmissions and poor outcomes. Recommend continuing to keep this as a Star measure for the benefit of beneficiaries.
Independent Care Health Plan	We encourage this move for a number of reasons: i) we believe the measure inherently conflicts with another measure – "Getting Needed Prescription Drugs" – in that members (and prescribers) prefer medications on the Beers list are not able to get them under the "High Risk Medication" measure; a high score on the later measure could produce a low score on the former measure; ii) the Beers list was not intended to be absolute, but rather precautionary; the HRM measure tends to eliminate member-centric clinical decision-making and patient-preferences (because a medication works) from the equation. Recommendation: Redesign the measure further before even listing on the display page.
Innovacare	While we suppport the view of AGS that the High Risk Medication measure is not intended to be punitive for the patient, the removal of this measure for RY2017 at this point, when substantial efforts have already been made by plans to achieve a positive result, would be punitive for plans. Accordingly, if the HRM measurement is to be removed, we believe it should be removed effective RY 2018, and not RY 2017. We also believe ta\hat excessive exposure of geriatric populations to HRMs is in fact of concern, and alternative approaches rewarding plans that demonstrate the successful ability to avoid HRMs should be considered rather than simply removing the measure altogether. As a matter of fact, some protocols may include effective transitions to other medications that are not only safer for the elderly, but also of a lower cost.
Kaiser Permanente	Kaiser Permanente supports moving the HRM measure to the Display Page given the recent updates to the Beers Criteria. We agree with the American Geriatrics Society (AGS) statements regarding the intent of the Beers Criteria. Specifically, "the intent is not to apply the criteria in a punitive manner" and "the addition of a

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	drug to the HRM list is not a contraindication to use, rather an encouragement to avoid use in the senior population without consideration of risks and benefits based on individual patient considerations." We are concerned about the potential unintended consequences of assigning a Star Rating to a measure that is highly dependent on the member's clinical circumstances. For example, from a clinical perspective, we have significant concerns about estrogens being on the Beers Criteria list. Presently, estrogens contribute to a high percentage of failures on the HRM measure and we have difficulty gaining endorsement on this drug category as a high-risk medication from both our physician leads and our members. The "unintended consequences" of listing estrogens as an HRM can include compromising the quality of life for female members who otherwise would benefit from taking these drugs.
Medica Health Plans	Given the timing for our improvement work and corresponding ratings' timeframes, Medica would like CMS to consider the impact of moving measures to display one year later. For example, this year CMS proposes to move the HRM measure to display. This does not allow plans to determine final comparisons with other plans and the related star ratings, even though a given plan may have put a great deal of effort into the particular measure being moved to display. This disrupts the cycle of improvements and incentives. The move to display for this measure should occur in 2018 star ratings since the new definitions did not apply for beneficiaries in 2015 and it certainly was important to limit High Risk Medications during the period. Medica does support the adjustment of the measure based on the new medication list and specifications endorsed by the American Geriatrics Society, and study on the new definitions can continue as planned without undue impact to plans and beneficiaries. Potential changes to star ratings based on LIS and Disability status should be considered in total as there are SNP plans that scored 4 stars or higher on this measure as it was defined in 2014-15 for 2016 star ratings, supporting their overall plan ratings.
Molina Healthcare Inc.	Molina Healthcare appreciates the Agency's proposal to move this measure to the 2017 Display Page. However, we are concerned that the Agency is considering removing this measure at the end of the current measurement year. We support the continued inclusion of the measure in Star Ratings due to the clinical importance of appropriate medication use by health plan members. If CMS continues to move forward with placing this measure on the 2017 Display Page, we ask that CMS move as quickly as possible to address the deficiencies in this measure. CMS could take action by excluding certain medications from this measure for specified types of beneficiaries (e.g. persons with SPMI) or, alternatively, by identifying those factors that are linked to appropriate use of high risk medications and adjusting the measure for these factors, either through risk adjustment, stratification, or like plan comparisons. We also recommend, consistent with the most recent American

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	Geriatrics Society 2015 Update, that beneficiaries in hospice care should be excluded from this measure's denominator. We also ask that CMS apply all changes to the Star Rating system and Display Pages – such as changes to technical specifications and the removal of measures — on a going forward basis. The final set of measures that will be included in the Star Ratings and on the Display Page should be finalized by the start of the measurement period. In addition, modifications to existing measures and/or introduction of new measures should be made before the measurement period begins. This transparency is critical for plans to meet the goal for performance that CMS expects and to ensure beneficiaries are able to rely upon the Star Ratings as a true indicator of quality when selecting a plan. If CMS moves forward with the current proposal, we recommend that CMS hold plans harmless from any negative impact that may result from removal of this measure from Star Ratings in 2017.
OutcomesMTM	OutcomesMTM supports the removal of the HRM measure from the Star Ratings for 2017 based on the guidance from the American Geriatrics Society (AGS) to not apply the criteria in a punitive manner. We also support continual monitoring of HRM use in the Medicare population via the display page to ensure removal from the Star Ratings does not have unintended consequences for patient safety.
PCMA	2. High Risk Medication (Part D) –The High Risk Medication (HRM) measure calculates the percent of beneficiaries 65 and older who received two or more prescriptions for the same HRM drug with a high risk of serious side effects in the elderly. CMS notes this is difficult to evaluate in a drug plan without access to full clinical information. CMS intends to remove the HRM measure from the Star Ratings and move it to the display measures for 2017. As noted in the 2015 Call Letter, the goal of this measure is to reduce potentially inappropriate use of HRMs by beneficiaries 65 and over when there may be safer drug choices available. Furthermore, the goal is not to achieve a zero percent HRM rate as it is understood some of these medications may be clinically necessary for certain individuals. PCMA believes that CMS should support underlying Stars measures and prescribing provider measures that track overuse and inappropriate use. We recommend that CMS reconsider its removal of the High Risk Medication (Part D) measure until such time as it is replaced with other measures that examine overuse and inappropriate use of prescription drugs. PCMA also requests that CMS provide advance notice to plans of potential changes to the HRM drug list and that the updated list only be incorporated in the measure after plans have had access to it. PCMA has previously commented on the inclusion of updated Beers criteria in this measure and urged CMS to allow plans sufficient lead-time prior to formulary design bid submissions. PCMA Recommendation: PCMA recommends that CMS revise the timeline for removing the HRM

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	measure from the Star Ratings from 2017 to 2019, to allow sufficient time to develop the new overutilization measures being considered for 2018 and beyond. We also request that CMS provide advance notice of potential changes to the HRM drug list.
Pfizer	Description of the Issue or Question: CMS is proposing to remove the High Risk Medication (HRM) measure used in Part D from the calculation of Star Rating and move it to the display measures for 2017 and beyond. The agency acknowledges the position of the American Geriatrics Society (AGS) that the Beers Criteria should not be applied in a punitive manner. In particular, it is difficult for drug plans to consider whether use/non-use is appropriate based on individual patient considerations because plans do not have access to full clinical information on the patient. However, because avoiding potentially inappropriate medications in older adults remains important for quality of care, the HRM measure will be moved to the 2017 display page and may be considered for the Star Ratings again in the future. Suggested Revisions/Comments: Pfizer supports CMS' decision to remove the High Risk Medication (HRM) measure from the Star Ratings program for 2017 and beyond. We are encouraged that CMS has acknowledged some of the concerns about using a list of drugs included in the AGS Beer's Criteria as part of a quality measure in a program that is designed to financially both incentivize and penalize health plans. For example, the AGS has stated: "The Beers Criteria are a valuable tool for clinical care and quality improvement but may be misinterpreted and implemented in ways that cause unintended harms." "Many clinicians misunderstand the purpose of the criteria, mistakenly believing that the criteria deem all uses of the listed drugs to be universally inappropriate. Health systems have often reinforced this perception, implementing quality improvement and decision support systems that implicitly consider any use of these medications to be problematic. In addition, some payors have adopted prior authorization requirements for Beers Criteria medications, which may be misapplied by the payor and/or misinterpreted by the prescribing clinician. Implementation of the criteria in inflexible, dogmatic ways can breed resentment and lack of faith in the recommendations. Moreover, they can negatively affect quality of care by restricting access to medications included in the criteria that are being used in appropriate ways and create troublesome and unnecessary burdens for prescribers." The AGS describes their criteria as a "warning light" to identify medications that have an unfavorable balance of benefits and harms in many older adults, but makes clear that there are situations in which use of medications included in the criteria can be appropriate. It is difficult to translate those nuances into an appropriate quality measure. Although the original intent of the HRM measure was not to achieve a zero percent HRM rate, as implemented in the Star Ratings program it does encourages plans to strive for a zero percent rate in order to perform better and benefit from the incentives under the

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	program. In addition, in the proposed rule, CMS noted an association between dual eligible/low income status (LIS) and high-use of HRMs. In an effort to better ensure that the HRM list is not used as a vehicle to penalize plans for unintended consequences for this very unique population, Pfizer further applauds CMS on their recommendation to remove this measure. Steinman, M, Beizer, J, DuBeau, C, Laird, R, Lundebjerg, N, and Mulhausen, P. How to Use the American Geriatrics Society 2015 Beers Criteria—A Guide for Patients, Clinicians, Health Systems, and Payors. Journal of the American Geriatrics Society, 2015.
PhRMA	CMS proposes to remove the high risk medication measure from the Star Ratings for 2017. PhRMA appreciates CMS' consideration that the addition of a drug to the American Geriatric Society Beers Criteria is not a contraindication, but rather encouragement to avoid use in the senior population without consideration of the associated risks and benefits. PhRMA believes that medications should be used appropriately and safely, and we support measures that further this goal. Accordingly, we support removal of the measure from the Star Ratings and encourage CMS to continue to explore alternate measurement approaches that reflect appropriate high risk medication use in patient-specific circumstances.
PQA	PQA supports CMS's proposal to remove the HRM measure from the Star Ratings and move it to the display measures for 2017. There has been a substantial decrease in the measure rate over the last several years. While the medications in the HRM measure should be avoided in most elderly patients, there will be instances where use of the HRM is the best choice for particular patients. Without more clinical information available, encouraging PDPs to decrease an already low measure rate may cause unintended consequences. PQA has nearly completed its review and update of the HRM measure based on the AGS 2015 update of the Beers Criteria. The updated measure will be finalized in early 2016. As the measure steward, PQA intends to better understand the association between certain socio-economic factors and/or clinical factors and HRM use. PQA agrees that the HRM measure should be monitored as a Display measure and considered for the Star Ratings in the future.
PrescribeWellness	We support moving HRM to display measure due to issues identified, but recognize that use of high-risk medications in the elderly is significant and need to be addressed to ensure quality care, especially in the elderly.
Rite Aid Corporation	We are opposed to the removal of the HRM measure this late in the measurement period. The HRM measure does not fit the criteria for immediate removal as described in section A of this Memo. While AGS published updated Beers Criteria during the measurement period, PQA has not yet endorsed the new list, therefore the AGS publication does not significantly impact the denominator or population covered for the current measurement period. Since PQA has announced that they are in the process of updating this measure

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	and anticipating finalization in early 2016, the change to the measure has been announced in advance of the 2016 measurement period and the HRM measure should be moved to the display page for 2018 instead of 2017.
RxAnte	RxAnte supports moving the High Risk Medication (HRM) measure from the Star Ratings to the display page for the 2018 measurement year. Without the ability to document patient exclusions for appropriate HRM use, this measure could limit access for patients in need of certain therapies. RxAnte does not support removing the HRM measure from the 2017 Star Ratings. As CMS obviously knows, Star Rating removal typically happens due to changes in clinical guidelines that significantly affect the numerator or denominator or a plateau in high performance for a measure. This appears not to be the case for this measure, as this measure was still clinically relevant during the 2015 data period and will continue to be recognized through the Patient Safety Analysis website indicating it is still a clinically relevant measure. This is not how the previous AGS Beer's List update was handled in 2011, and activities for decreasing HRM use have already occurred in 2015 for the 2017 Star Ratings for performance on this measure since there was no forewarning. RxAnte supports moving HRM to the display measure for 2018 measurement year, but not for the 2017 measurement year.
SCAN Health Plan	B.2 Removal of Measures from Star Ratings - High Risk Medication (Part D). The HRM measure will be removed from the Star Ratings and moved to the display measures for 2017. The HRM measure may be considered for the Star Ratings again in the future. If measure updates are endorsed by PQA ahead of 2017 formulary deadlines in June 2016, then CMS may consider adoption for the 2019 display page (using 2017 data). SCAN Comment: SCAN supports removal of the HRM measure for the 2018 Star Ratings; however, recommends that the HRM measure be counted for the 2017 Star Ratings. This would be in alignment with the CMS principle of providing advanced notice to plans prior to making changes to the Star Ratings. Advanced notice is needed for proper allocation of resources devoted to what CMS deems as quality measures. Plans have already allocated an extensive amount of time, staff, and financial resources to minimize the HRM rate in 2015. Achieving this represents quality efforts as previously defined by CMS and should be included in the quality star rating measure for 2015 date of service (2017 Star Rating).
Senior Whole Health	We would encourage CMS to be more definitive about how long the HRM measure would be on the display page. The first sentence says it would be moved for 2017 (we assume this includes Stars '17, which would have been sourced out of CY '15 data.) This does not tell us that it will remain on the display page, so in means plans will have to continue their focus on this measure for CY '16 / Stars 18. There is mention made of the 2019 display page in the last paragraph, but it is unclear whether the measure could become a

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	Star measure between now and then. CMS should commit to moving it to the display page for a defined time period, and should notify plans well in advance if it intends to move it back to being a Star measure.
SNP Alliance	2. High Risk Medication (Part D) CMS' rationale for proposing the HRM measure be moved to the display page is consistent with arguments that the SNP Alliance has made repeatedly with respect to the HRM measure, i.e. that the measure does not sufficiently allow for clinical context in its administration and that performance on this measure may be impacted by members' socio-demographic characteristics independent of plan performance. For these reasons, we agree that the measure should move to the display page but feel it is inappropriate to do so until 2018. We believe that it would be much fairer to plans that have invested heavily in efforts to improve performance on this triple weighted measure at the direction of CMS to delay removal of the HRM measure from the Star Ratings until 2018. Having CMS change course at this juncture when the performance period is over is fundamentally unfair to plans that done their best to respond to CMS' stated priorities. Plans should be rewarded for the work they have done in response to CMS' direction. In addition, provider contracts are in place that include pay –or- performance incentives related to this measure; to remove the measure in 2017 is challenging for this reason as well.
Tenet Healthcare	While we support CMS's recommendation to move the High Risk Medication measure to the Display page, we would request this move be implemented for the 2018 stars measure(2016 data). The plan has put forth tremendous effort and invested heavily in resources to improve the quality of care for our Medicare beneficiaries through personalized member education and provider outreach. The coordination of care between case management and providers to decrease the utilization of inappropriate medications in older adults has been a focus point this year for the plan. To change the weighting of this rating after the year is over puts small plans who have invested their limited resources in this area at a disadvantage.
Triple S Advantage, Inc	TSA agrees with moving the measure to Display and suggests retiring the measure all together, given all the factors which affect it and are not under the Plan's scope.
Tufts Health Plan	B.2. High Risk Medication (Part D) We echo CMS' assessment of the unintended consequences of the High Risk Medication measure, and we support the measure's move from the Star Ratings to the Display Page.
UnitedHealthcare	UnitedHealth agrees that the intent of the High Risk Medication (HRM) measure should not be to apply the criteria in a punitive manner and that the addition of a drug to the HRM list is not a contraindication to use; rather, it is an encouragement to avoid use in the senior population based upon a consideration of risks and benefits based on individual patient considerations. However, UnitedHealth would like to point out that this decision has a

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	retroactive impact on plans, in that we have invested in improving our performance on this measure. Because of these investments, our preference would be that the HRM measure remain a Star measure for 2017 before moving to a display measure in 2018. If CMS proceeds with removing the HRM measure from Star Ratings, UnitedHealth recommend that CMS a) keep this as a display measure until CMS reassesses how best to monitor quality for this measure, and b) if CMS is considering HRM to be a Star measure in the future, that consideration be placed on ensuring that the drugs that are considered high risk medications are truly high risk in the elderly and not be bound by CMS formulary rules and regulations (e.g. avoid adding the following medications to the HRM list since management may become more challenging for plans: i) Protected class medications ii) CMS requirement to keep on the formulary e.g. Benztropine, guanfacine iii) no good alternatives and providers are able to assess drug safety using drug levels e.g. digoxin iv) essential class per P&T (e.g. methyldopa)). Finally, as CMS considers moving this measure to a display measure, CMS may see an initial increase in HRM utilization as members previously paying cash for the HRM may start using their Part D benefit again. UnitedHealth will continue internal efforts on ensuring appropriate HRM utilization in its members.
VIVA Health, Inc.	The Plan respectfully requests that CMS include the HRM measure in 2017 Star ratings and move the measure to the display page for the 2018 Star ratings. Despite the noted issues in the CMS call for comments, the Plan believes that efforts expended towards HRM management in calendar year 2015 and prior years have positively impacted the quality of our members' health and this positive impact outweighs the concerns noted. The Plan has invested significant time and resources towards educating and engaging both our Member and Provider community in the effort to decrease inappropriate HRM use. We are concerned that the retrospective decision to exclude this as a Star measure for 2017 will negatively impact Plan credibility with our Members and the engaged Providers. Clinically valid issues and imperfections within Star measures are not unexpected. Most measures do not fully account for clinically valid reasons members should not or could not comply with the recommendations. For example, members included in an adherence measure whose physicians switch to a different therapeutic drug class are still included in the denominator. Specific common scenarios include members who are switched from a Statin to a Fibrate class of drugs after an initial fill, and members initially prescribed an ACE or an ARB to treat high blood pressure being moved to a Calcium Channel or Beta Blocker due to intolerance. These members remain in the denominator for Star ratings purposes inappropriately, and Plans must accept this negative consequence. The Plan is encouraged when measure stewards acknowledge these imperfections and make recommended changes based on feedback

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	a considered evaluative process. However, when Plans have expended significant resources towards measure achievement in good faith reliance on CMS's earlier decision to include this measure, we believe the negative impacts to Plans resulting in such late retrospective decisions outweigh the intended positive impact of the change. These types of retrospective decisions can lead to instability in Plan's administrative resource allocations towards the overall Quality Program, as well as negatively impact Member and Provider relations. The Plan appreciates CMS's acknowledgement of the impact of socio-economic status on this measure and requests that in addition to keeping the measure for Star year 2017, CMS include this measure in the analytical adjustments to address the LIS/DE/disability effect. The Plan appreciates advanced notice of the potential changes to the High Risk Medication (HRM) drug list. We request that the revised drug list be made available for immediate distribution in order to adjust formulary decisions, allow time for PA edit decisions and P&T approval.
WellCare	WellCare supports the removal of the High Risk Medication (HRM) measure from the Star Ratings. We agree with the American Geriatric Society's statements that the measure should be used as an educational tool and to dissuade inappropriate use, but that the criteria should not be applied in a punitive manner. Additionally, WellCare appreciates CMS' recognition of the "significant association between dual eligible/ low income status and HRM use." We support CMS' recommendation that measure developers review the measure further to better understand the association. WellCare looks forward to the results of that review and encourages CMS to keep this measure on the display page until the review concludes. Additionally, WellCare asks CMS to clarify if the Agency examined all measures in the data set or all measures the Agency believes are under provider control to determine an association between dual eligible/ low income status and measure performance. If so, we ask CMS to release the findings of that study.

C. Data Integrity

C. No Subtopics

Submitter	Response
Academy of Managed Care Pharmacy (AMCP)	AMCP appreciates CMS' intent to perform rigorous data validation of Part D sponsors' Medication Therapy Management (MTM) programs to ensure accuracy, reliability, and the quality of Comprehensive Medication Reviews (CMRs) performed. While AMCP believes that the proposed audits are a step in the right direction to understand how different practice models play a factor and how positive results can be replicated across Part D sponsors, there are several outstanding questions that CMS must address prior to finalizing this proposed change. Outstanding questions that must be addressed

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	include: • How will CMS utilize audit data to determine if a different bar and/or measures should be implemented for integrated versus non-integrated systems? • How will CMS ensure fairness and consistency in audit guidelines and interpretations? • Will these audits occur in addition to Data Validation, or in lieu of Data Validation? • How will CMS audit plans who achieve a 100% on Data Validation, if at all? • How will the audit requirements impact the amount of process related data that needs to be uploaded to CMS? • How will CMS utilize audit data to move from process orientated measures to outcomes/quality orientated measures for MTM, inclusive of CMRs, in the future? • How will CMS account for the variation among plans in %-MTM eligible patients and how the variable inclusion criteria may affect CMR completion rates? • What is the anticipated audit burden on Part D sponsors, especially for smaller Part D sponsors that may not have designated staff for auditing purposes?
AHCCCS	In full support of CMS safeguarding against perverse incentives for Part D sponsors who submit biased or erroneous data.
Alliance of Community Health Plans	ACHP has significant concerns with CMS' intention to review and apply any relevant MTM program audit findings that could demonstrate sponsors' MTM data were biased, outside of the Data Validation results. CMS had stated at its 2015 Medicare Advantage and Prescription Drug Plan Fall Conference that the new MTM audit program would be in a pilot stage for 2016 and findings would not apply to final audit results. The reasoning for this was to give plans an opportunity to provide feedback and for CMS to make needed adjustments to the MTM audit protocol as necessary. We believe it would be not be appropriate to apply MTM audit findings in the pilot stage to penalize plans, and we are concerned that plans could be penalized twice for certain measures – once if there are data issues under the program audit and again under the Data Validation results. We urge CMS to not apply the MTM program audit findings until the audit protocol is final. ACHP recognizes the importance of accurate and reliable data for measures reported in the star ratings and CMS's ongoing efforts to identify new vulnerabilities where inaccurate data could exist. Given the potentially significant impact on star ratings of receiving a rating of "1," we request that CMS provide specific information on which data validation findings, under what circumstances, would result in reductions, and to which measures. We also recommend CMS establish a process through which plan sponsors can discuss with CMS, and potentially resolve, data problems.
America's Health Insurance Plans	Under the agency's current data integrity policy, a contract's measure rating is reduced to 1 star if it is identified that biased or erroneous data have been submitted by the plan. However, we continue to believe and recommend that CMS provide greater clarity regarding the applicability of its data integrity policy to Star Ratings by developing transparent and objective criteria and provide plans

Submitter	Response
	with the opportunity to review and comment on the criteria. While CMS provides examples of cases subject to the agency's policy, those examples are not sufficiently clear or inclusive. As an example, CMS notes that the policy applies to "a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements" or "a contract's failure to adhere to Plan Finder or PDE data requirements." However, the meaning of "failure to adhere to" is not defined. In addition, in the Request for Comments (RFC) document, CMS is proposing to apply its data integrity policy to findings from Medication Therapy Management (MTM) program audits. Yet according to CMS' October 20, 2015 guidance on the 2015/2016 program audits, the MTM program audit protocol will first be pilot tested in 2016, and the results of the pilot "do not count against a sponsor and do not factor into the audit score." Given that CMS is starting the pilot-testing of the new MTM program audit protocol in 2016, we seek clarification regarding the timing of the agency's plans to include MTM program audit findings in its data integrity review activities.
Anthem, Inc	Anthem supports CMS' high standards and agrees that it is appropriate to take reasonable steps to ensure data integrity in the Star Ratings. We continue to believe that distinguishing between generally well-functioning plans that may have an occasional data error versus plans that have significant, material errors due to major systemic issues is critical when assessing and rating plans based on the integrity of their data. While CMS has reserved the right to assign a rating of 1 Star when there are issues with Plan data, we recommend that MAOs be entitled to the same level of accountability from CMS or its vendors (i.e., we urge the Agency to ensure that contracted vendors are held accountable and to the same level of data validation for things like CAHPS and external audits for the Call Center TTY or Foreign Language Interpreter monitoring measure). When CMS or its contractors are responsible for issues with data accuracy, accountability for those errors should be imputed directly to CMS in the same way that CMS imputes errors made by a sponsor's contractors to the sponsor. To establish parity, CMS should assign to MAOs the most favorable Star "5" and/or permit the MAO the option of utilizing the prior year's Star Rating for the measure. Anthem recommends that CMS assign a rating of "5" to the MAO for any measures for which CMS determines it has bad data that was due to the Agency's or its vendor's actions (or inactions). CMS should hold itself to the same strict standards with comparable implications that it applies to MAOs for failing to provide reliable data. CMS' decision to assign ratings at the lowest possible Star Rating ("1") in this instance would logically compel an assignment of the highest possible rating ("5") to sponsors as a result of CMS' failure to administer these measures properly. CMS should accept that responsibility and adjust the Star Ratings in a manner that will negate the harm that CMS' actions have caused to MAOs. In the alternative, Anthem recommends that CMS give

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	MAOs the opportunity to request that their preceding year's Star Rating apply to the current year. CMS would only make this adjustment to the Star Ratings of plans who request it. This option allows for a reasonable proxy of the measures, based on reliable data. Anthem believes that it is appropriate to presume—in the absence of more recent, reliable data—that the performance of the MAO on these measures remains the same. Finally, Anthem supports CMS' continued efforts to ensure that the Star Ratings program does not create perverse incentives for sponsors. Specifically, Anthem applauds CMS' proposal to include a review of Part D sponsors' MTM programs in the Agency's program audits. As described previously in this comment letter, we are concerned that the current structure of the MTM program, including its reporting requirements, could lead to the submission of biased data, decreasing the validity of the measure. The implementation of the data integrity checks would greatly lessen these concerns—though Anthem recommends that CMS incorporate data integrity checks into the established Data Validation process. Doing so would streamline the overall process and ensure that all plans are appropriately reviewed.
Blue Cross and Blue Shield of Minnesota	BCBSMN recommends that CMS distinguish between unintentional and knowing/willful submission of inaccurate data that have a material impact to the measure result. Further, CMS should consider adjusting the timing of the data validation and/or audit process so that plans are provided with the opportunity to correct unintentional mistakes in the data. For the MTM/CMR rate, BCBSMN believes that this measure focuses inappropriately on completion of a form as opposed to actual care received by a member. To that end, we support the creation of a MTM outcome measure. For the current MTM/CMR, it will be very difficult – if not impossible – to validate the accuracy of opt-out data through additional audits. Instead, BCBSMN suggests that CMS make MTM a level playing field and remove the current opt-out exclusion from the denominator, with the exception of members who opt out in the first 60 days due to disenrollment or death and newly qualified MTM members who qualify for MTM services within the last 60 days of the program year. Plans must still offer MTM services to members who qualify in the last 60 days of the program year, but we recommend plans not be evaluated on CMR completion rates for these members.
BlueCross and BlueShield Association	BCBSA and Plans appreciate CMS's commitment to ensuring that the data used in the Star Ratings is reported and accurate, and thus reflects actual Plan performance. We believe, however, that Plans are unfairly impacted by CMS's policy of reducing measures to a one-star rating for data integrity issues. Moreover, such a reduction decreases the value of the Star Ratings as a source of information to beneficiaries, who rely on the ratings as indicators of actual Plan performance on the metrics themselves.

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	CMS is continuing its policy to reduce a plan's score on a measure to a one-star without taking into account why or how the submitted data for that measure was inaccurate. For example, one Plan noted that its Star Rating on a measure was reduced to a one-star because three out of 80,000 data submissions contained minor errors. BCBSA and Plans maintain that this application of the policy undermines the purpose of the Star Ratings. Reducing a Plan's rating on a particular measure due to such errors skews the Star Ratings inappropriately. Instead, BCBSA and Plans believe that CMS should distinguish between the knowing and willful submission of inaccurate data and those mistakes in data submission that result from immaterial and unintentional administrative errors. Additionally, BCBSA and Plans recommend that CMS provide Plans an opportunity to correct immaterial, unintentional deficiencies. For example, the CMS audit process, which can identify errors in data, is currently conducted after the measure data is collected. Conducting audits of data prior to collections for Star Ratings purposes would allow Plans to correct any unintentional data mistakes uncovered by the audit. BCBSA and Plans believe that such measures will increase the accuracy and reliability of the data used in the Star Ratings. Finally, BCBSA and Plans recommend that CMS exclude from this policy any findings and issues from audits with new protocols. For example, findings from the first round of MTM audits should not be considered in evaluating the integrity of Plan data or used as the basis to reduce the Plan's Star Ratings measure. Recommendations: BCBSA and Plans urge CMS to distinguish between the knowing and willful submission of inaccurate data and the submission of data which includes unintentional, immaterial errors and mistakes. BCBSA and Plans request that CMS consider allowing Plans the opportunity to correct unintentional mistakes in the data, which may require adjusting the timing of the data validation and/or audit process.

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	BCBSA and Plans request that CMS exclude from its data integrity policy the findings from audits conducted pursuant to new protocols.
BlueCross BlueShield of SC	We recommend that CMS establish a work group to address MPF Star and display measures, including PBM, plan sponsor and CMS experts to deep dive into this important measure and develop a recommendation that will provide the intended member protection. CMS has acknowledged that the industry has concerns with the MPF measure as it relates to Average Wholesale Price (AWP), AWP and MAC change frequently and create the situation where the PDE can be higher or lower than the MPF depending on if the AWP / MAC rate increases or decreases between MPF submissions to CMS. The PBM updates AWP and MAC pricing on a weekly basis whereas MPF updates are completed every two weeks per the CMS requirement. The majority of CMS identified MPF errors analyzed were related to claims impacted by the update schedule for AWP or MAC. We are also concerned with the addition of a frequency calculation. In looking at just one of the client contracts the PBM found that 60% of the claims identified, by CMS, on that file had a difference between the PDE and the MPF of $1.00 or less. 17% of the file had a difference between the PDE and MPF of 5 cents or less. If CMS moves forward including a frequency calculation a .01 difference will be weighted the same as a $100.00 difference. We agree with CMS that utilizing percentage as a part of the calculation will not provide the needed outcome. We would recommend that if CMS moves ahead with the addition of frequency, that any claims below a determined de minimis amount (e.g. $1.00) be excluded from the calculation thereby focusing on the higher dollar discrepancies. We have concerns about the display measure "PDE being less than the MPF." During our monitoring it became clear that besides the issues related to AWP and MAC changes taking place between MPF submissions, "Lower of Logic" creates situations where the member pays less than what is displayed on the MPF. The PBM's adjudication system uses "Lower of Logic" when determining what price to use for the drug. Regardless of brand or generic it will select the lowest price of four fields: 1. Usual and customary (U&C) submitted by the pharmacy on the point of sale transaction 2. Submitted price submitted by the pharmacy on the point of sale transaction 3. Average Wholesale Price (AWP) minus the contracted rate negotiated with the pharmacy (brand drugs) 4. Maximum Allowable Cost (MAC) for that drug, (applicable generic drugs) AWP minus contracted rate and MAC rates are submitted to CMS on the price files. Any time that the adjudication system selects either the U&C or submitted price the PDE will automatically be reflecting a lower price than what was submitted on the Price File (e.g. Walgreens $4.00 generics). We recommend that CMS take this into consideration and eliminate any claims where the U&C or Submitted price were used to adjudicate the claim prior to doing their calculation.

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BlueCross BlueShield of Tennessee	BCBST supports CMS' commitment to protecting the integrity of the Star Ratings data. Please define what CMS would consider as biased data. Should CMS add the MTM program into the performance audits, please define the reasonableness standards by which plans would be held accountable.
Cigna	As a MAPD plan, we make every effort to maintain CMS' operational and compliance requirements. At times, although we are a highly rated plan, we fail to achieve 100% accuracy. We support CMS' efforts to ensure accuracy and data integrity. We recommend CMS consider a tiered approach to Star Rating decreases in the event of unintentional biased or erroneous data submission. Also, plans that self-disclose operating discrepancies should be recognized for their integrity and willingness to report operational issues. We are not proposing that CMS reward plans that self-disclose, but instead, use a tiered approach when assigning a Beneficiary Access and Performance Problem Star Rating and/or a CAM CMP score.
Clover Health	Clover Health appreciates CMS's continued focus on the important topic of risk adjustment for socioeconomic and disability factors to determine the extent to which these factors impact a plan's performance on the Medicare Star measures. Similarly, we suggest that CMS provide specific examples for each of the suggested approaches to increase the understanding of CMS' proposed methodologies and how beneficiaries' and plans' data would be used through the risk adjustment process. Historical data, such as 2013 data, could be used in order to compare plans' performance using the current Star ratings methodology instead of the 2017 approaches proposed, which will in turn provide a more realistic result.
Health Care Service Corporation	CMS states that the agency's "policy is to reduce a contract's measure rating to 1 star if it is determined that biased or erroneous data have been submitted. This would include cases where CMS finds mishandling of data, inappropriate processing, or implementation of incorrect practices by the organization/sponsor have resulted in biased or erroneous data. Examples would include, but are not limited to: a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements; a contract's failure to adhere to Plan Finder or PDE data requirements; …" HCSC supports CMS' proposal to pursue data accuracy, appropriate processing, and implementation of correct practices to avoid the use of biased or erroneous data and to promote fairness in the evaluation of contracts. However, we recommend CMS utilize a reasonableness standard when reviewing data, processes and implementation practices and determining that a contract has failed to adhere to requirements. When the vast majority of data are submitted correctly, and appropriate and accurate protocols and practices are in place, but a rare human error or anomaly in submission of data occurs, we believe this should not be treated the same as situations in which a significant percentage of errors occur or protocols are not established to ensure accuracy. For example, if a MAO submits

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	millions of PDE claims for a contract and 3 or 4 PDEs are in error, it does not seem reasonable to reduce the entire contract's rating to 1 star. A reasonableness standard could address such situations while promoting fair and consistent administration of the Part C and Part D programs. Additional Comment: The Comment box will not open for Section: D. Impact of Socio-economic and Disability Status on Star Ratings, so I am including under Data Integrity Comment: CMS proposes "two options for interim analytical adjustments to address the LIS/DE/disability effect: a Categorical Adjustment Index or Indirect Standardization." HCSC appreciates CMS' ongoing initiatives to improve the Star Rating system and address the correlation between lower performance on some of the Star Ratings and the enrollment of dual eligible and/or disabled members. We agree that any adjustments to the Ratings should be data driven and that the adjustment methods should be transparent to enable MAOs to translate CMS' findings into actionable quality improvement steps. The presentations and additional information that CMS has provided after the release of the proposal have been very helpful in clarifying the proposed options. It would be helpful to include the additional details CMS has conveyed verbally or in slides in the proposal to ensure an accurate understanding of the details. To promote transparency, HCSC recommends that CMS provide additional information prior to finalizing a proposal so that we can provide a more meaningful response on the issues. Specifically we request that CMS provide step-by-step analyses of each model using current contract data. This would enable us to evaluate the details of the methodology, the relative impact of the two models, the data that will be available for review each year, and how we might use the data to drive provider performance. It would be most helpful if this additional information could be provided prior to the 45-day notice to permit a more concerted review. It is not clear if the proposed options adequately address some issues that we believe contribute to lower Star ratings such as the effects of living in a low-income community, the presence of multiple chronic conditions, and low education level. Given the complexity of the proposals and the need for MAOs to incorporate the final proposal into their Star Rating and provider strategies, HCSC also recommends that CMS delay implementation until at least 2018. Typically when CMS makes a change in the ratings, MAOs are provided with time to make adjustments and plan for the change. It is too late to impact 2015 measures for 2017 ratings and any solution implemented before 2018 will not permit sufficient time for MAOs to plan for the potential consequences of the new adjustment.
Health Net, Inc.	Request that data integrity issues identified by CMS and result in reducing a Contract's measure to 1 star be limited to systemic issues vs. single episode. Also request that CMS review the clarity of guidelines presented to Plans when it is identified that a large number of Plans are identified to have data integrity issues related to

Submitter	Response
	reporting a specific measure.
Healthfirst	SNP Care Management (Part C) 1.We recommend that CMS distinguish between the deliberate submission of inaccurate data and the unintentional occurrence of minor errors and mistakes (this includes errors having a negligible impact to the overall calculation of the completion ratio). By assigning findings at the element/plan level (defined by CMS as the reporting section criteria level), this methodology disregards the impact of those findings on the assessment completion ratio at the contract level, which is the level at which the SNP Care Management measure is evaluated. If the finding on specific elements in the data validation is not substantial at the contract level, the penalty of achieving only a 1-Star Rating should not be assigned at the contract level. 2. RE: Proposed changes to SNP Care Management in the Medicare Part C Plan Reporting Requirements Technical Specifications Document Contract Year 2016. CMS is planning to add four new data elements to SNP Care Management reporting, including the number of initial HRA refusals, number of initial HRAs where SNP is unable to reach the enrollee, number of annual HRA refusals, and the number of annual HRAs where the SNP is unable to reach the enrollee. We fully support these additional reporting requirements and urge CMS to use this information to update the specification for the SNP Care Management Star measure by excluding members who refuse the HRA and/or are unreachable by the plan from the measure denominator. This update will align the SNP Care Management measure with the assessment measure in the Medicare-Medicaid Capitated Financial Alignment Model (MMP) program. It will also help to address some of the challenges that our health plan has experienced with our large dual-eligible population, namely: ? Low-income populations can be transient, leading to frequent address and phone number changes. Member transience leads to difficulties in contacting and completing assessments in a timely manner. ? Refusal rates are high, because members are hesitant to provide personal health information in fear that it will negatively affect their health insurance, or change the way they are treated by their health plan. ? Plans with a high proportion of low-income members face challenges in getting these members to complete their assessments, even if the assessment is short, due to the multiple social issues that these members may face. These may include issues with housing stability and financial stress. Again, we appreciate that CMS is requiring the documentation of members who were not able to be reached (after a reasonable number of attempts by the plan) and those who actively refuse to complete the survey, and request that CMS use this information to refine the SNP Care Management star measure. MTM Program Audit (Part D) Plans that fail the MTM program audit should be penalized by the same penalty standards as the routine Data Validation audit – automatic default to 1 star on measure. We request that CMS include the existing data validation

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	process as one component of the overall proposed MTM program audit and that the penalty structure be the same as what has been defined for data validation processes. This avoids different and/or duplicative penalty standards (beneficiary access measure impact vs. 1-star default).
HealthPartners	We agree with CMS that data used for star ratings must be accurate and reliable. However, we would request that CMS provide data integrity criteria that specifically explains when an issue is significant enough to reduce a contract's measure to 1 star. CMS should not apply MTM program audit findings to the MTM measure rating until the audit protocol is final. During the 2015 Medicare Advantage & Prescription Drug Plan Fall Conference & Webcast, CMS stated that the new MTM audit protocol would be piloted in 2016 and findings would not appear in final audit results or apply to the score. The purpose of the pilot is for CMS to obtain honest feedback from plans and refine/update the MTM audit protocol as needed. It would not be appropriate to use findings identified during the testing of the audit protocol to penalize plans. Furthermore, we are concerned that for certain measures that are in scope of both the program audit and Data Validation that plans could be penalized twice if there are data issues – once under the program audit which feeds into the Beneficiary Access measure and then again under Data Validation for the measure tied to Part C or Part D reporting.
Independent Health	Within section C on Data Integrity, the proposed changes state "CMS program audits will soon include review of Part D sponsors' MTM programs." To save duplication of efforts by auditing MTM two separate ways, we believe the additional auditing pieces could be done as part of the data validation audit where MTM is already audited. The MTM data validation audit is already quite extensive and the additional information described here seems like it could be incorporated into that audit. This would level the playing field as all plans go through the data validation audit each year.
Innovacare	We agree that data integrity is a crucial element ensuring the accuracy and reliability of Star Ratings. However, CMS's pilot audit will not be performed until 2016 and CMS has not yet published the protocols for the MTM program. Accordingly, CMS has stated that Plan Sponsors will not receive a score for this area. We believe that until the protocols are final and published the results of an MTM audit should not be considered to evaluate program integrity.
Martin's Point Health Care	Martin's Point believes that accurate and reliable data for all star ratings measures is important to the overall integrity of plan star ratings. We would request that CMS provide plans more specific descriptions on which data validation findings, under what circumstances, and for which measures would result in measure-level reductions in ratings.
Medica Health Plans	Medica supports ensuring that data used for CMS star ratings are accurate, reliable, and clear in order to implement improved processes and practices. Methodology should be consistent and

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	predictable, and plans given adequate time to assess impact as was done with removing the four star thresholds.
Molina Healthcare Inc.	Molina Healthcare supports the Agency's long-term vision to maintain a high degree of data integrity. To promote full transparency, we ask that CMS provide information about how the program audits will be conducted and specifically how "failure to adhere" to reporting or data requirements will be defined and applied by CMS auditors. Specifications, instructions and/or tools that can be provided prior to the implementation of any program audits will help plans better prepare and understand the focus of the data integrity activities.
OutcomesMTM	OutcomesMTM supports the enhanced monitoring of Part D plan sponsors' MTM programs through additional audits or reviews to ensure the validity of data, particularly as it pertains to the new 2016 Star Rating measure – Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR). Without a companion, outcomes-based measure to this new MTM Star Rating, we agree with CMS' assessment that new data integrity vulnerabilities exist. We encourage CMS to monitor for possible data integrity concerns for outliers on both ends of the spectrum – both low and high performing contracts.
PCMA	CMS states that program audits will soon include review of Part D sponsor's MTM programs, with particular focus on findings that demonstrate data were biased outside of the Data Validation results. PCMA supports CMS efforts to assure that data used for Star Ratings are accurate and reliable, but we urge CMS to take all necessary steps to assure that MTM program goals and objectives are in sync with the audit criteria applied to MTM programs. We are concerned about the potential for inconsistencies and disconnects between program objectives and the criteria applied by individuals conducting program audits in the field. We also have concerns about CMS relying primarily on audits to address possible gaps in the data validation process. Further, we would appreciate clarification for how CMS intends to track sponsor activities during the 60-day opt-out window. PCMA Recommendation: PCMA urges CMS to align MTM program oversight goals and objectives with the criteria used during MTM program audits, and build in safeguards to assure consistency and uniformity of application. We also seek clarification of how sponsor activities will be tracked during the 60-day MTM opt-out window.
PhRMA	CMS proposes to include in program audits a review of Part D sponsor's MTM programs. PhRMA supports the addition of Part D sponsors' MTM program reviews to CMS program audits to assure MTM data is not biased, that plan sponsors are not restricting eligibility from approved MTM programs or encouraging beneficiary opt-out within the first 60-days, and that CMRs meet CMS's definition per guidance.
PQA	This comment is for Socio-economic and disability status as a

Submitter	Response
	comment box was not available when choosing this section. As the measure steward, PQA is currently examining the impact of socio-economic factors on our measures used in the Star Ratings program. Based on our findings, PQA will determine if changes to the measure specifications are warranted. PQA supports CMS' efforts to examine the impact of Low Income Subsidy (LIS) status, Dual Eligibility (DE) status, and disability status on our measures used in the Star Ratings program. PQA encourages CMS to examine other sociodemographic factors, such as age, gender, clinical complexity, LIS status category (partial vs. full), and other environmental factors such as income and education level. We understand the availability of data will impact what factors can be used in a risk adjustment model. PQA encourages CMS to provide information on the impact of each of the proposed interim analytic methods, using historical data (2013 or 2014, if available). These real world examples would provide clarity for these complex methodologies, and would allow health plans to understand the impact on their populations.
SNP Alliance	C. Data Integrity SNP Alliance members, like CMS, are committed to data integrity in the administration of the Star Ratings program and support CMS' efforts to insure consistent and appropriate administration of plans' MTM programs. With respect to the criteria that CMS uses to identify situations in which biased or erroneous data have been submitted, we would appreciate CMS' clarification of what is meant by a contract's "failure to adhere" to reporting or data requirements. There needs to be a well understood definition of "failure to adhere" that is applied consistently by CMS' auditors. In addition, we believe a reasonableness standard should be used in assessing "failure to adhere," recognizing that a problem with a small number of PDE records, for example, should not be interpreted as "failure to adhere."
Triple S Advantage, Inc	TSA agrees with the Data Validation requirement for the measure.
VIVA Health, Inc.	The Plan is supportive of CMS efforts to ensure data is accurate, reliable and unbiased. The Plan requests that whenever possible CMS streamline administrative processes and consider ways to incorporate additional verification/ validation efforts into existing processes for data validation. The Plan notes that the MTM Program audit is described as a Pilot in the October 20, 2015 CMS memo titled "2015/2016 Program Audit Protocols and Process Updates." As CMS conducts these pilot audits, there may be changes in the auditing protocols or additional guidance issued to Plans on processes identified during the audits. For these reasons, CMS excludes Pilot audit program scores from the overall Program Audit score. The pilot period allows CMS time to stabilize the audit processes and protocols, and allows Plans to learn and adjust to guidance without experiencing potential negative impacts to Program Audit scores. The Plan requests that CMS delay application of any relevant MTM program audit findings as an eligible part of the Star measure rating until such time as CMS deems the MTM audit

Submitter	Response
	protocol finalized and no longer a pilot. This will provide consistency in administration of CMS Programs and avoid potentially detrimental consequences for Plans during what is considered a learning period.

D. Impact of Socio-economic and Disability Status

Submitter	Response
Academy of Managed Care Pharmacy (AMCP)	AMCP appreciates CMS' focus on understanding the extent to which socio-economic and disability status impact a plan's performance on the Star Ratings. AMCP, however, cannot endorse either of the options for interim analytical adjustments outlined in the memo at this time. AMCP recommends that CMS clarify how the Categorical Adjustment Index (CAI) or Indirect Standardization Approach (ISA) would differ from existent risk adjustments. In addition, AMCP recommends that CMS provide simulations for each of the proposed methodologies using historical data to increase understanding of each methodology and its benefits and consequences.
Aetna	As part of the RFC, CMS has put forward two different methods for administering an analytical adjustment that would serve as interim solutions to address the LIS/DE/disability effect in the Star Ratings program. While we recognize CMS' desire to put forward an interim solution as CMS and its contractors continue to develop a long-term solution, Aetna has concerns and does not support either adjustment proposed by CMS. We do not support any solution that penalizes high performing plans at the expense of trying to make adjustments to the Star Ratings Program for plans that are unable to achieve high quality when caring for dual eligibles and/or enrollees who receive LIS. By CMS' own account, the overall impact of either adjustment that was put forward is expected to have a relatively small impact in terms of resolving for the socio-economic discrepancies in the Star Ratings Program. Overall, we have serious concerns these proposals would make the Star Ratings Program even more complex than it is today, lessen the program's transparency, and more importantly not solve the socio-economic discrepancy in a meaningful way. Set forth below are more specific comments: • CMS does not provide adequate details to understand the specific calculations and how this would impact overall Star Ratings. Aetna respectfully requests that CMS release a simulation model that demonstrates the impact of these proposals utilizing plans' 2016 Star Ratings data. • The adjustments proposed by CMS create significant additional complexities around the Star Ratings calculations without clarity that the adjustments will fairly solve for the socio-economic discrepancies in the Star Ratings Program. Aetna believes the Stars Program should be simple and easy for consumers and external stakeholders (e.g., the provider community) to understand. • Aetna believes that any adjustment should include a "hold harmless" provision, as neither methodology takes into account the performance of health plans that are currently delivering

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	high quality to all Medicare beneficiaries. • We remain concerned that plans with high proportions of low-SES and disabled enrollees already have higher reimbursement rates paid through risk adjustment. Therefore, from a policy perspective, these plans are being provided additional resources to care for this population and invest in efforts that can help them provide high-quality care and services, even to a low-SES and disabled population. • Aetna has specific concerns that the Categorical Adjustment disproportionally affects high- performing plans. Further, lower enrollment contracts appear to have a disproportionate effect on the categorical adjustment which could inappropriately skew the calculations.
AHCCCS	Given that there are no 5 star plans among those that serve a high proportion of duals, AHCCCS urges CMS to continue reviewing all evidence linking low star ratings with those plans disproportionately serving duals. In past years, the SNP Alliance and other organizations have noted that Star Rating measures do not account for the effects of socio-economic status and related beneficiary characteristics that have been shown by long-standing research to influence an individual's ability to use health care services, and raise their health outcomes. As a result, we have elevated concerns that both process and outcomes measures in the Star Rating system can underestimate the performance of health plans that treat a disproportionate share of beneficiaries with low SES and related factors. CMS' attention to the issue represents a significant step in facilitating dialogue on the impacts of dual eligible and LIS status on MA Star Ratings. In addition, CMS' issuance of a Request for Information (RFI) for analyses demonstrating a link between dual status and lower quality ratings brought a welcome opening of dialogue on the issues. AHCCCS submitted comments to the RFI that included recent statistical analyses conducted by Inovalon as well as insights from our own experience leveraging the D-SNP platform to achieve alignment with a population comprised primarily of disadvantaged SES circumstances. Understanding the link between SES (and its many related factors) and quality of care is a complicated endeavor that will take time to fully explore. It will require sophisticated statistical analyses and a deep understanding of how lower income patients connect with the health system and vice versa. Additional Comment: The proposed adjustments are not expected to move the needle too much for these plans that serve a large number of beneficiaries with a disability, low SES, and dual eligibility. Even when all new measures are included, it still represents only a low percentage of the total. There is additional concern that health plans will have a greater degree of difficulty in calculating their own scores.
AIDS Healthcare Foundation	I do not think any plan should be "dinged" for any score. I know mathematically, the bell-shaped curve requires this but operational, if a plan is lucky enough to get their patients to respond positively to care, no adjustment should take this away.

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	I do think measures that rely on patient participation; i.e., attendance at appointments, taking medications, etc., should be adjusted somehow for LIS and disabled however, I suggest that the disability be based on number of co-morbidities including ADL's. Many of these patients should not even be in the denominator. For example, an HIV positive patient's most important focus is keeping the viral load suppressed. This already constitutes approximately 6 medications per day. If additional comorbidities exist such as hypertension and diabetes, the treatment fatigue alone to keep the HIV at bay prevents many patients from consistently adhering to therapies for hypertension and diabetes. It is a real fight. When one adds in the poverty level prevalent in this population, homelessness, substance abuse and mental illness, none of which are even considered in the current measures as exclusions, there is a definite disadvantage for plans with a high number of LIS and/or disabled members.
Alliance of Community Health Plans	Many organizations, including ACHP, have asked CMS to address the challenges of Special Needs Plans and plans with high enrollment of dual-eligibles. We appreciate and support CMS' efforts to develop a response that is grounded in research. We urge CMS to take action that addresses these concerns starting with the 2017 plan year. While ACHP has been concerned about proposals that we think would undermine the integrity of the star ratings system, we recommend that CMS consider options such as: - Review measures to make sure the denominator of each measure carefully reflects the recommended standard of care for the DSNP population. - Evaluate the appropriateness of measures for the SNP population and potentially develop a limited number of SNP-specific measures (as CMS has done with the HEDIS Care for Older Adults and SNP Care Management measures). We caution that the relevance of clinical measures should be determined by clinical science and not by the type of plan in which a beneficiary is enrolled. - Consider DSNPs with particularly challenging populations – for example, large numbers of enrollees who have complex health and social problems, perhaps involving behavioral health needs – as outliers so that they are excluded from reporting on certain measures that may not be applicable. - Consider temporary payment of the quality incentive bonus for DSNPs at the 3.5 star level for 2017 and possibly 2018, allowing CMS time to consider other options and plans to continue their quality improvement efforts. CMS has indicated their intent to work with measure stewards to update their technical specifications accordingly. We support this effort as the fairest, and most transparent, path to achieving appropriate measures across the Medicare Advantage population. Generally, we believe that CMS should consider policy options such as those we

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	have previously suggested to address the concerns of SNP sponsors. ACHP believes these proposals are a better long-term approach than risk-adjusting quality measures for socioeconomic or disability status. Measure risk adjustment is appropriate when there is a clear external factor that affects performance on a measure – for example, adjusting for age on mortality measures. But risk adjustment is not appropriate when it "risk adjusts away" problems of high quality care that the health plan and its delivery system partners are expected to deliver, regardless of the population. In that case, variations in outcomes by income, race or other factors included as adjustments to the measures are hidden, even though these variations may account for significant differences in the treatment of the patient across different plans or providers. CMS has attempted to address these concerns in this RFI by focusing on "within-contract" differences. While we agree that this is a preferable approach to looking at difference across contracts, it still falls short of the "causation" threshold CMS established when it submitted its first request for plan data on this issue a year ago. For example, are lower scores in some quality measures by those with low SES driven by population characteristics (like low medical literacy) or plan characteristics (like access to providers in low SES neighborhoods)? Both of these factors would drive within-contract differences, but only the former would represent a factor that we believe should be accounted for in a risk adjustment system. Because of issues such as these, we believe any quality measure risk adjustment proposal will be unable to fully create a fair performance evaluation system across MA plans. Nonetheless, as CMS considers two temporary proposals for risk-adjustment, we believe there are several issues that need to be considered if one of these proposals is implemented on a temporary basis. Based on the information provided in the Request for Comments, the issues raised below, and the absence of data from simulating the results of these options, ACHP finds it very difficult to provide a fully-developed evaluation of the "Categorical Adjustment Index" and "Indirect Standardization" approaches. We offer the following concerns and questions that we hope CMS will address as it continues to consider these or other options. Data Simulation: ACHP is concerned that neither proposal, as outlined in the Request for Comments, contains sufficient detail to fully evaluate its impact and sufficiency. We urge CMS to provide simulation results of both the "Categorical Adjustment Index" and "Indirect Standardization" approaches and create the opportunity for additional feedback from plans before a final decision on implementation is made. If CMS decides to include either of these options in the Call Letter in February, we believe that simulation data should be provided at that time so the plans can assess the impact of the adjustment. Data Collection: As ACHP understands these proposals, each measure would be adjusted based on the proportion of individuals with LIS or disability status

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	within its denominator (at least at the measure-level adjustments). This would require linking plans' HEDIS reporting systems with CMS data from plans on LIS and disability status. Because of the importance of capturing this information accurately for proper adjustment, we are concerned there will not be adequate time to properly review whether these assignments have been done accurately. We believe these concerns about the ability of plans to adequately review the proposed adjustments for 2017 are significant enough so that CMS should make participation optional for the 2017 star ratings until plans can review whether their data is being linked to HEDIS results accurately. ACHP is also concerned with the use of LIS status as a proxy for low-SES. While income is a component of LIS qualification, the qualification for the LIS benefit has different processes inside and outside of dual-eligible plans. Because LIS status is deemed for dual-eligible plans, but requires an administrative process outside of a dual-eligible plan to qualify, we believe SES is over-estimated in non-dual-eligible plans by using LIS as a proxy for income. Maintaining Transparency: ACHP has observed that when existing measures (such as the CAHPS results) undergo adjustment, detailed, unadjusted performance data is not made public. The public availability of detailed, unadjusted, performance data is essential to plan benchmarking and improvement activities. If CMS adopts either adjustment approach, we request that CMS continue to provide the detailed, unadjusted performance data by plan, the detailed equations used to make any adjustments to performance, and detailed adjusted performance scores. Additionally, we encourage CMS to adopt total performance transparency for all current risk-adjusted measures. Multiple Contract Organizations: One potential consequence of these proposals would be an unfair adjustment for organizations with multiple contracts in the same service area. For example, consider a plan that operates two contracts in a service area – one mostly consisting of non-LIS beneficiaries and one-tailored to a high-need, low-SES population in a DSNP plan. Furthermore, consider that this organization dedicates additional resources to its low-SES dominated contract, such that both contracts receive a final star rating of 3.80 stars (which rounds up to four stars). While the low-SES contract would likely receive a higher star rating under these proposals, the contract with fewer low income individuals would have its star rating reduced (possibly to the point of losing its quality incentive payments). Here, the organization has demonstrated that it provides superior quality to low-SES members, but happens to do so in a separate contract. However, because the adjustment models are based on national differences of within-contract performance, this organization's superior performance in treating low-SES members cannot be accounted for across contracts. ACHP recommends that CMS make allowances in its proposed approaches to provide relief for organizations that may be unfairly treated as a

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	result of national adjustment when within-organization performance demonstrates superior quality. Cut-Point Issues: Both proposals seem to suggest that CMS will maintain cut-points based on unadjusted scores rather than determine new cut-points. ACHP is concerned that if CMS believes that risk-adjustment provides a truer measure of plan performance, then CMS should consider recalculating new cut-points for the adjusted measure distributions for star assignment determination if either proposal is implemented. To this end, ACHP would like CMS, as part of its simulation, to run both proposals with and without re-determined star rating cut-points for the individual measures. Advanced Categorical Adjustment: CMS has requested feedback on whether plans would prefer an "advanced" Categorical Index Adjustment to star ratings to provide advance notice to plans. While this would provide some increased ability to review calculations, by the time this information is available to plans, it would be well after most care for the measures proposed to be adjusted is delivered; thus, the overall result is unlikely to be influenced. This approach could also create problems for contracts that start SNP plans, drop SNP plans, or have major changes in underlying demographics from one year to another. These shifts could have the potential to significantly decrease the accuracy of the Categorical Adjustment Index. Furthermore, the advanced option would also create issues for contracts that are in their first year of reporting HEDIS. These contracts could have a star rating, but would have no Categorical Adjustment because results were not available for the previous year. Measure Inclusion: If CMS pursues either of these options, ACHP would recommend including only measures for which the adjustments would result in several point changes in score performance; if adjustments would generally result in changes of a point or less, there is little value gained from the additional complexity. We would also be concerned about including measures for which the 5-star performance threshold is close to 100% (e.g., Adult BMI assessment, Kidney Disease Monitoring etc.). For these measures, a plan with 100% performance could be adjusted below a 5-star threshold, so that obtaining a 5-star rating on that measure becomes impossible. CMS also proposes adjustment for several measures that are included as part of the HOS survey. Because of differences in timing and the survey-based nature of HOS, we are concerned that adjustment of HOS measures could not be implemented in a comparable way to adjustment of the HEDIS measures. Comparison between Approaches: As noted above, ACHP does not believe there is sufficient information to provide a fully developed evaluation of the "Categorical Adjustment Index" and "Indirect Standardization" approaches. We believe that both options have strengths and weaknesses. Based on our conceptual evaluation, we have highlighted particular concerns with each approach that we hope will be addressed should either option be adopted. We are concerned about how determinative the

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	assignment of categories will be in the "Categorical Adjustment Index" approach. We believe that this will have a disproportionate and unfair impact on high-performing plans that will not only have downward adjustments that reflect measure score changes, but also the loss of r-factor and improvement measure points. Additionally, 4.5 and 5 star plans are likely to lose more r-factor points, on average, than 4 star plans, because higher mean plans are eligible to earn more r-factor points. If plans with near 4-star performance are categorized with 4.5 and 5 star plans, then they could lose r-factor points they were not eligible to obtain for their contract (because they would be averaged with plans who are losing r-factor points) – essentially getting over-penalized by being grouped inappropriately. Finally, categorical adjustment does not account for the fact that not all contracts report all measures. Plans that report a reduced number of measures could be given adjustments that are reflective of their category rather than the set of measures their contract reports. The "Indirect Standardization" proposal seems to avoid the unfairness that could result from contracts being categorized in unrepresentative groups. However, it does create the possibility of more variable results for plans that have similar overall performance and similar LIS and disability proportions. This would happen because sometimes the individual measure adjustments will result in a star rating change, while sometimes the adjustment will keep a contract's score at the same star rating level. Thus, some plans will, by chance, cross several star rating cut-points, while others will cross few or none. In some cases, these cumulative cut-point changes will result in the loss (or gain) of an overall star rating level. Because of our earlier concerns that risk-adjustment models are insufficient to capture true causality of LIS and disability status effects on performance (creating a larger than justified downward adjustment for contracts with fewer LIS and disability members), ACHP recommends that if CMS moves ahead with either of these adjustments, they be implemented in a hold-harmless framework.
AltaMed	AltaMed is appreciative of CMS' consideration of the impact of socio-economic and disability status on Star Ratings. As a federally qualified health center that focuses on serving the underserved and vulnerable communities, a large portion of our patients are low-income. Therefore, adjusting Star Ratings based on population risk adjustments and setting benchmarks by "peer groups" would allow a more precise rating.
Altegra Health	Altegra Health partners with MA plans in several unique ways to meet their HEDIS®, Star Ratings and other quality reporting needs in order to better manage beneficiaries' overall care. Altegra Health's HEDIS.com software and industry-leading expertise enable MA plans with full command over the management of their HEDIS and quality measure reporting and workflow processes. Altegra Health solutions feature a full, web-based, end-to-end approach for all quality and clinical outcomes reporting. Altegra Health's analytics

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	analyze a wide variety of data sources, identify gaps in care, and help improve quality through a large inventory of quality measures. To improve MA beneficiary gaps in care and other access issues, Altegra Health utilizes a number of outreach tools to the population: • SMART Connect™: Altegra Health's SMART Connect product helps improve health outcomes for MA beneficiaries by connecting them with care management support solutions. • Community Link™: Altegra Health's COMMUNITY Link product guides MA beneficiaries through an extensive database of more than 10,000 public and privately-sponsored community programs to which they may qualify. • Home health assessments: Altegra Health assists MA plans by arranging and conducting in-home health assessments. Altegra Health also provides care management support solutions to confirm these assessments through subsequent clinical encounters. In the current proposal, CMS will be calculating the category adjustments after the submission period. MA plans depend upon rating estimates to conduct more accurate beneficiary and provider outreach necessary to close rating gaps and more efficiently provide a higher level of care quality. To assist the industry in this process, Altegra Health recommends that CMS publish the category requirements with sufficient notice for MA plans to analyze their populations for outreach.
America's Health Insurance Plans	AHIP greatly appreciates the thought and detail CMS has put into the development of the Star Ratings system. We have strongly supported rewarding plans for the quality of care provided to their enrollees and support the agency's work to ensure the ratings fulfill this goal by most effectively measuring plan performance. We also commend CMS for undertaking a detailed examination into the concerns we and others have been raising that the Star Ratings system systematically disadvantages organizations focusing on vulnerable populations despite our members' considerable efforts to meet the needs of their enrollees. Recent research by the RAND Corporation for CMS and by the Medicare Payment Advisory Commission (MedPAC) demonstrates this is the case. We believe the agency's two proposals to address these findings are an important step forward. Studies demonstrate that by focusing on early intervention, person-centered care, and care coordination, MA plans are making a real difference in the lives of the low-income beneficiaries and individuals with disabilities they serve. A solution to the systematic disadvantages in the Star Ratings system is necessary to ensure these vulnerable populations continue to have access to the very services, such as care coordination and disease management, this population needs. We thank CMS for its willingness to provide an early preview of the proposals prior to the issuance of the Draft Call Letter, and for the call held on December 3rd, which significantly contributed to our members' understanding of these approaches. We recognize and greatly appreciate the agency's efforts to be more transparent on Star Ratings-related

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	issues. However, without receiving detailed analyses of the potential impact of each approach and having a chance to review the information to be provided under each approach, it is difficult for AHIP and its members to provide extensive comments at this time. The analyses and other information will be critical in assessing each proposal's complexity and ability to meaningfully address the systemic disadvantages in the Star Ratings system. CMS has noted it will be providing more granular information about the impacts of both approaches for each contract when the Draft Call Letter is released in February. We strongly urge the agency to release this information as far in advance of that time as possible based on the best data available, as well as CMS' estimates of the total impact of each approach on the program as a whole, so our members can fully understand these proposals and provide more informed comments. We continue to believe as much transparency as possible from the agency is fundamental to the future success of the MA program. We look forward to receiving the additional data. In the interim, we have developed the following principles that will be fundamental to our evaluation of the proposed approaches: 1. Solutions should be meaningful. Adjustments under a proposal should be significant so it addresses the full magnitude of the systematic disadvantages documented by the research that are faced by MA plans focusing on vulnerable populations. As noted in the RFC, CMS recently proposed changes to the MA risk adjustment model that are intended to more accurately reimburse organizations focusing on dual eligibles and individuals with disabilities. CMS states the proposed changes to risk adjustment and Star Ratings "are complementary; holding contracts to a same quality standard is most appropriate when contracts are adequately resourced to provide the support their beneficiaries need to achieve good health outcomes." While we agree, the agency's risk adjustment proposal does not directly address plan concerns, validated by the research, about the impact of beneficiary characteristics on performance. Changes are necessary to fully account for disadvantages faced by plans focusing on vulnerable populations in the Star Ratings system. Proposals to ensure the risk adjustment system more accurately predicts costs should not be viewed as directly addressing these Star Ratings challenges. 2. Solutions should be transparent. It is important to our members that a proposal provides information on Star Ratings adjustments at the earliest possible date. This is crucial to their ongoing activities with their providers to develop programs and influence behavior in ways that improve quality consistent with the agency's goals. In addition, it is important that a proposal provide enough information about an adjustment so that our members can understand how it is determined and can validate the result. According to the RFC, "Given the additional data processing steps, the analytical adjustments may result in a compressed timeframe for Part C and D contracts' review process of the ratings". During the

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	December 3rd call, CMS provided additional detail on how the information the agency will provide to plans during the plan preview period would differ under each approach. We will continue to consider these implications as we further evaluate the proposed approaches once CMS releases the detailed contract and industry impact analyses of the proposed approaches cited above. 3. Solutions should not penalize high performing plans and plans that have made significant investments in attaining high performance. The agency clearly stated in the RFC and during the December 3rd presentation that the proposed adjustments could reduce Star Ratings for some plans. We strongly disagree with this approach. No contract should be penalized if the adjusted Part C or D Summary Rating or Overall Rating calculated under the adopted approach would be lower than the unadjusted rating. It is our understanding the Social Security Act does not require changes to the Star Ratings system to be budget neutral, and CMS officials have publicly stated their goal that all plans eventually achieve high ratings under the system. Reducing the ratings of high performing plans and plans that have been working hard to achieve high ratings is inconsistent with that goal.
Anthem, Inc	Anthem strongly believes—and there is ample evidence to support this view—that the current MA and Part D Star Ratings system does not accurately reflect the significant impact that low-SES has on plan performance. Failure to account for SES in the Star Ratings negatively impacts the MA and Part D markets and especially the beneficiaries these plans serve. To that end, Anthem appreciates the research CMS undertook this last year to provide the scientific evidence as to whether MA and Part D sponsors who enroll a disproportionate number of vulnerable beneficiaries are systematically disadvantaged by the current Star Ratings. Furthermore, we commend the Agency for recognizing that a disparity does, indeed, exist and for working to identify solutions that appropriately address the issue at hand. In particular, Anthem thanks CMS for its diligence in developing potential interim policy responses that delineate the two aspects of the low-SES and/or disability issues: quality and payment. We agree with CMS that holding contracts to the same quality standards is most appropriate when contracts are adequately resourced to provide the support their beneficiaries need to achieve positive health outcomes. Anthem recognizes that resolving an issue of this magnitude is not an easy task and—as a committed partner in the MA and Part D programs—we continue to underscore our eagerness to engage with CMS and further discuss innovative solutions to enhance care integration efforts for beneficiaries. Anthem believes that increased transparency of data, additional insight into Star Ratings system changes, and a longer stakeholder process to review those changes are essential for sustainable and stable MA and Part D programs. As such, we thank CMS for the opportunity to provide comments on its

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	proposed interim analytical adjustments (the Categorical Adjustment Index [CAI] and the Indirect Standardization [IS]) prior to the release of the 2017 draft Call Letter. However, the complexity of the proposals combined with the lack of details provided to-date limits plans' abilities to truly understand the implications of both the CAI and the IS, as well as our ability to provide meaningful feedback to CMS. Anthem respectfully requests that CMS issue additional information on the CAI and the IS as soon as possible, and before the release of the 2017 draft Call Letter in February. Anthem requests that CMS release detailed examples of 1) how the CAI factor would be computed and subsequently added to or subtracted from a contract's Overall and/or Summary Star Rating, 2) how the expected measure score, the ratio of the observed-to-expected measure score, the adjusted measure score, and the ratio of the observed under the IS would be calculated, and 3) how each of the proposed adjustments would impact the industry. In 2014, when CMS proposed to remove the pre-determined 4-Star thresholds, the Agency provided contract-specific information on the impact of the proposals. Anthem asks CMS to conduct and provide plans with similar simulations of the CAI and IS using the most recent Star Ratings data available. In addition to this contract-specific information, we ask that CMS publish an industry-wide impact assessment of each proposal. It is imperative that we have clear insight into how our individual contracts and the industry as a whole will be affected by the CAI and the IS. If providing this level of information is not possible, CMS should be willing to vet initial analyses of its proposals with trade associations and other members of the plan community. The potential analytical adjustments laid out by CMS are incredibly complex and data-driven—given the limited details regarding how, exactly, these complicated adjustments would work in reality, plans cannot be certain that their assumptions regarding data inputs, processes, etc. are correct. This further constrains our ability to review these proposals and help CMS develop the most appropriate interim solution. While we also appreciate that CMS has encouraged the measure stewards to examine the Agency's findings and undertake an independent evaluation of the measures' specifications to determine if measure re-specification is warranted, Anthem notes that developing case-mix adjustments, as an example, would take a fair amount of time. This could lead to the proposed interim solution(s) being in place for several years. Given the long-range impact these proposals could have on plans' Star Ratings and payment amounts, we require complete information as soon as possible. Given the above, Anthem finds it difficult to provide specific or meaningful comments on either of CMS' proposed solutions at this time. We therefore ask CMS to delay implementation of any adjustment to account for low-SES and/or disability status within the Star Ratings system until more information is provided. Such a delay would allow plans to properly

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	assess the additional details and data we are requesting. In general, Anthem continues to believe that any solution must hold plans accountable for providing high quality coverage to vulnerable members, while recognizing the outsized challenges that are present and which grow as a plan's share of low-SES membership increases up the continuum. We are grateful that CMS is engaging stakeholders as it develops short- and long-term solutions to better account for the impact of low-SES and disability on performance, and we recognize that CMS took great effort to propose interim steps to address this deficit. Anthem appreciates the Agency's review of our comments and recommendations, and look forward to continuing to work with you to refine a short-term adjustment and to develop a long-term solution.
Association for Community Affiliated Plans	The Association for Community Affiliated Plans (ACAP) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) in response to the Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond. ACAP intends for this letter to provide feedback to CMS on the proposed Star Ratings methodology for 2017 and beyond to ensure that plans are being evaluated for their performance, rather than the underlying health needs of their enrollee populations. ACAP is an association of 61 not-for-profit, community-based Safety Net Health Plans located in 24 states. Our member plans provide coverage to over 15 million individuals enrolled in Medicaid, Children's Health Insurance Program (CHIP) and Medicare. Nineteen of our plans are Dual-Eligible Special Needs Plans (D-SNPs), fourteen of our plans are managed long-term care plans, and fifteen of our plans are Medicare-Medicaid Plans (MMPs) in the Financial Alignment Demonstration. Impact of Socio-economic and Disability Status on Star Ratings: ACAP shares in CMS' belief that to achieve greater value and quality for all beneficiaries, the Star Rating system must not distort quality signals in measures or mask true differences in quality of care. The current methodology fails to adequately account for socioeconomic and disability status and ACAP is pleased that CMS is looking into ways to adjust for SES in the Star Ratings. More information from CMS on both approaches is needed. ACAP is not able to determine how well the Categorical Adjustment Index or the Indirect Standardization adjust for SES with the information provided in the Request for Comments. We request that CMS provide more detail and numeric examples of how well each approach adjusts for SES, particularly for contracts with majority or 100 percent dual enrollment; estimates of how Star Ratings would change for contracts under each approach; and the strengths and weaknesses of each approach. We also ask for clarification on whether plans would have to have a minimum number of LIS/dual or disabled enrollees in order to receive an adjustment through either approach For the categorical adjustment index, for instance, we also ask for clarification on whether institutionalized individuals would be

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	one of the beneficiary subgroups included in the adjustment. ACAP also requests that CMS clarify whether the I-Factor will be applied before or after the Categorical Adjustment is applied. For indirect standardization, we ask CMS to clarify which specific measures would be adjusted. CMS should also clarify to what extent, if at all, the subset of adjusted measures would change year-to-year. ACAP also requests that CMS clarify whether issuers should expect both upside and downside- adjustment with this approach: In a select few measures, plans with high proportions of disabled dual eligible beneficiaries outperform other plans – should these issuers anticipate a negative adjustment for these measures? We further ask for clarification as to how the adjustment under indirect standardization would interact with case-mix adjustment in the CAHPs survey. ACAP urges CMS to provide more information on each of these models, including information on the accuracy with which each model adjusts for SES in contracts with large proportions of dual-eligible beneficiaries. Publishing specific examples and the strengths and weaknesses of each adjustment model will allow commenters to provide more useful feedback to CMS.
Blue Cross and Blue Shield of Minnesota	BCBSMN strongly supports CMS' goal to achieve greater value and quality in MA and Part D for all beneficiaries and its related work to fully understand and advance solutions addressing the impact of socioeconomic status and disability on Star Ratings. We also appreciate CMS' significant effort in providing two potential interim analytical adjustment options for stakeholder consideration well in advance of the 2017 Call Letter release. At least some immediate, meaningful relief to MA or Part D sponsors that enroll a disproportionate number of vulnerable beneficiaries is critical to incentivize serving these members and maintain the significant investment many SNPs and others have made in delivering high-quality, high-value care as defined by CMS Star Ratings. With limited modeling or simulation data available, of the two high-level options presented, BCBSMN believes the Categorical Adjustment Index (CAI) is superior to Indirect Standardization (IS). To fully understand the merits of each approach examples are needed of both models applied to hypothetical or, ideally, prior-year data. However, regardless of how these adjustments impact Star Ratings for any one plan, the CAI seems to comprise a stronger methodological approach both in terms of accuracy and flexibility. Accuracy The use of a fixed-effects regression approach allows for control of unobserved contract-level characteristics. Additionally, categorization of contracts allows for similar LIS/DE collation and appropriate adjustment without worry of attenuation of any signal due to the effect of plans without duals. For these reasons, the CAI should lead to a more accurate result so long as the categorization effectively groups like plans (especially in the second grouping when mean differences are taken). To that end, BCBSMN would like to know what degree of similarity across categories CMS envisions

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	leading to their combination and recommend that CMS ensure a stringent criteria that maintains as much of the original categorization as possible. Flexibility The CAI approach is also more flexible from year to year. It alleviates the burden on both plans and CMS to have to tailor specific measures for adjustment since it is done at the overall star level. It removes the potential difficulty of adding a set of data elements every time a new measure is created. BCBSMN recommends that CMS select an approach, such as the CAI, which will to the extent possible automatically adjust for unknown future variables such as the introduction of new measures. Additionally, the CAI allows for calculation based upon prior-year data, which could give plans greater lead time in evaluating how the adjustment will impact overall scores and in providing sufficient plan preview periods.
Blue Cross Blue Shield of Michigan	CMS confirmed there are within-contract differences in a specific subset of Star measures for plans that serve low-income subsidy (LIS) members, dual eligibles and disabled members. As a temporary solution, CMS proposes two options for adjusting for these within-contract differences: the Categorical Adjustment Index (CAI) and Indirect Standardization (IS). It is also encouraging the measure developers to evaluate measure specifications to determine if measure re-specification is warranted, and working with the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and other agencies to permanently address the issue and its impact on the Stars program. Though we strongly support efforts to address the unique challenges of serving traditionally underserved populations, such as dual eligibles, and applaud the work CMS is doing in this area, BCBSM is unable to provide meaningful feedback about the proposed CAI and IS approaches at this time. Instead, we would like to recommend the following: -We request CMS provide additional detail about each option—particularly the results of a full simulation—so we can better understand what the true impact on our individual plans will be. It is critical that this information be provided to plans in advance of implementing either methodology, and with meaningful time and opportunity for plans to provide feedback. -We support CMS's ongoing work on this issue, including its work with the measure developers and other government agencies, to identify a more permanent solution. Conversely, we caution against temporary adjustments as it may compromise the integrity of the Star Ratings program. There are a number of other factors impacting a plan's Star Rating, such as age, gender, location and risk score. Instead of implementing a complex, temporary adjustment, CMS should wait and adopt a more permanent solution after the work of ASPE and others concludes. As an alternative, CMS should consider applying the temporary adjustment only in the case it helps a plan, not hurts a plan, similar to the hold harmless approach for improvement measures for plans with at least 4 stars. -With the information CMS provided about each adjustment methodology, we currently believe

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	the IS option will minimize risk of categorical bias and may be a fairer way to adjust Star Ratings since it will be applied to specific measures that statistical analysis has shown are impacted by LIS/DE/disability. Conversely, we believe the CAI method is less meaningful because it is applied to a plan's overall Star Rating and may lessen the impact of granular level differences depending on how the categories are defined. -Any adjustment method, temporary or permanent, should be aimed at creating a level playing field for plans experiencing within-contract differences due to LIS/DE/disability and should not negatively impact plans that have been improving care and achieving at least 4 stars under current program rules and methodologies. -BCBSM strongly supports CMS's efforts to ensure the integrity of the Star Ratings program. We hope CMS will also investigate other factors which we think similarly impact member access to care and can result in within-contract differences. These additional factors include age, risk score, race, location (rural versus urban), and are not necessarily addressed by adjusting for LIS/DE/disability alone.
Blue Shield of California	There is insufficient data at this time regarding the two options. We would like to request that CMS provide an impact analysis on both options, so that plans can make an informed decision. When this is implemented, we would like to request that CMS roll this out gradually to make this work for all MAPD plans.
BlueCross and BlueShield Association	In an effort to ensure that the Star Ratings accurately adjust for the challenges incurred by enrolling a disproportionate number of dual eligibles (DEs), enrollees who receive a low income subsidy (LIS), and/or disabled enrollees, CMS proposes two potential adjustments to the Star Ratings. First, CMS proposes the Categorical Adjustment Index, which would modify a contract's overall and/or summary Star Rating to adjust for the average within-contract disparity in scores. Alternatively, CMS proposes the Indirect Standardization adjustment, which would be applied at the individual measure level to adjust certain measure scores. CMS also proposes making additional adjustments for Plan Sponsors offering plans in Puerto Rico where enrollees are not eligible for the Part D LIS program. BCBSA and Plans appreciate CMS's continued efforts to adjust the Star Ratings to account for the challenges incurred by enrolling a disproportionate number of DEs, LIS individuals, and/or disabled enrollees. We continue to believe that enrolling a disproportionate number of these individuals makes it more difficult for Plan Sponsors to achieve high Star Ratings, and we support CMS's commitment to appropriately measuring and compensating Plan Sponsors based on the beneficiary populations they serve.

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	BCBSA and Plans are committed to helping CMS evaluate its proposals, and request additional information and detail to allow stakeholders to provide meaningful comment. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.) Based on the incomplete information in the Request for Comments, Plans are unable to fully analyze the impact of CMS's proposals. In addition to providing more information, BCBSA and Plans request that CMS provide a global impact analysis so that stakeholders can better understand how CMS's proposals would affect all Plan Sponsors, including those that do not enroll a large number of DE, LIS, and/or disabled beneficiaries. For example, we request that CMS provide a "simulation" or test of the proposals to show how they would affect Plan Sponsors. We submit that CMS could use historical data with no such adjustments and compare the results to Plan Sponsors' performance under each of the proposed methodologies. Without such information and adequate time to respond (See also Key Recommendation: Use the Formal Notice and Comment Rulemaking Process to Announce and Implement Changes to the Star Ratings), BCBSA and Plans are unable to provide CMS with substantive and meaningful comment that the Agency can use to evaluate its proposals. We recommend that CMS delay the implementation of any changes until more information is provided. Recommendations: BCBSA and Plans request additional information – including a global impact analysis – as to the effect of the proposals to address the impact of enrolling a large number of DE, LIS, and/or disabled beneficiaries. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.) Comments Unique to Plan Sponsors Operating in Puerto Rico BCBSA and Plans appreciate CMS's attention to the fact that Plan Sponsors operating in Puerto Rico may require additional adjustments to account for the fact that their enrollees are not eligible to participate in the LIS program. Our Plan operating in Puerto Rico expressed strong support for the proposed intermediate changes to adjust for the impact of enrolling a disproportionate number of DE, LIS, and/or disabled individuals. The Plan emphasizes the critical need for such adjustments in Puerto Rico, where the per capita income is less than 50% of the national average in the United States.

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	Additionally, the Plan believes Plan Sponsors in Puerto Rico are further disadvantaged by the lack of the LIS program, the exclusion of the Supplemental Security Income program, and the deep cuts to Puerto Rico's already low benchmarks used in the bidding process. While the Plan also noted that the lack of information from CMS limits its ability to fully comment on the proposals, it did raise the following additional issues and recommendations: Given that the DE and (projected) LIS populations in Puerto Rico differ significantly from the DE and LIS populations in the mainland United States, the measures should be adjusted using separate proportions of LIS, DE, and disability populations. For example, DE individuals in Puerto Rico have access to coordination of care and other services due to the subsidies offered to plans; LIS individuals, however, have not had such access and may have lower scores. CMS should be cautious about using the DE population in Puerto Rico to predict the LIS population. As stated in the Request for Comments, the DE population in Puerto Rico and the proportion of beneficiaries there below 150% of the Federal Poverty Level would be used to calculate the LIS population, "using the percentage of DE using all MA contracts except those in Puerto Rico." Given the unique DE eligibility for beneficiaries in Puerto Rico, CMS should reevaluate this methodology. An alternative would be to use country census data for the 65 and older population. CMS should also adjust the Medication Adherence measures for contracts operating in Puerto Rico. Contracts in Puerto Rico have been improving their performance – at a rate much faster than the national averages – on the Medication Adherence measures over the past five years. Despite this improvement, these contracts remain far behind the national average, perhaps due in part to the lack of the LIS program for beneficiaries in Puerto Rico. In order to adjust for this disadvantage, CMS could, for example, either (1) adjust the performance of contracts in Puerto Rico by the average difference between the performance of LIS contracts versus non-LIS contracts around the nation; or (2) adjust the Star Ratings scale for contracts serving non-LIS beneficiaries such that they would receive a one-star "bump" in their performance.
BlueCross BlueShield of Tennessee	BCBST supports CMS' willingness to continue to review the effect of Socio-economic and disability status on Star Ratings, and agrees with CMS that continued research into this issue is warranted and will help to drive a more successful Medicare quality system. During the interim, however, BCBST suggests that CMS apply the Categorical Adjustment Index as the preferred method to adjust the overall and/or summary star rating. BCBST is concerned, however, that plans with SNP PBPs in an H contract with PPOs and/or HMOs

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	may have an advantage over plans with a SNP product as a standalone PBP within a contract due to the volume/percentage of enrollment available within contracts with combined PBPs due to volume of enrollment of LIS/DE beneficiaries. BCBST is also concerned that plans with low levels of LIS/DE members may not meet the proposed thresholds and would therefore be penalized by not being eligible to receive an adjustment. While both methods are described, at a high level, BCBST requests that more detail and examples, using data such as national data, be provided, and requests that CMS calculate simulated data using both examples. This simulated data should be published at least a year in advance of any application of the adjustments are made while simultaneously searching for a better long-term solution. BCBST urges CMS to consider covariates other than LIS/DE/Disabled status, such as chronic conditions in addition to the LIS/DE/Disabled which, may also impact the measure. Based on BCBST's socioeconomic study analysis using CMS' methodology, among the 13 measures mentioned, 9 of them showed that being LIS/DE or Disabled had a significant negative effect on the measures' compliance; 1 of them (BMI) showed that being LIS/DE or Disabled had a significant positive effect on the measure compliance, and 3 of them (OMW, ART and CBP) showed no significant impact of being LIS/DE or Disabled.
Cambia Health Solutions	We have many concerns about these models. We are concerned about the shortened plan preview period this will result in, as well as the additional data that will need to be validated during that shortened period. We are also concerned these models will likely cause plans with lower percentages of this population to experience drops in their Star Ratings, even if quality continues to improve. Based on the incomplete data found in the Request for Comments, we cannot fully understand the impact of the two methodologies to our plans. We would like to see a third approach where it's weighted by member. We request that simulations be made available to see how the SES methodologies would have impacted our 2016 star ratings, much like how CMS provided simulations to understand the move to fixed 4-star cutpoints. We appreciate the effort CMS has made to adjust for SES disparities and ask that more time be given before the methodologies are made effective. It is our preference to have a thoroughly vetted methodology implemented rather than adjusting the methodology from year to year. The SES methodology language in the Request for Comments makes it clear that plans will be compared to national averages. We would like to know if different geographical areas were used in analyzing disparities in SES populations. Many plans in our region of the country have been adversely impacted by past CMS initiatives when compared to national averages. Our recommendation is that CMS consider comparing SES disparities within geographical areas instead of national averages. Further information is needed to fully

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	address the impacts of the SES methodologies. At present, it is not clear whether plans with a low percentage of SES members will have their star ratings negatively impacted. We recommend that that high-quality plans not be negatively impacted making the SES methodologies an upside gain (for high percentage LIS plans) only.
CareSource Management Group	The current methodology fails to adequately account for socioeconomic and disability status. More information from CMS on both approaches is needed. We are not able to determine how well the Categorical Adjustment Index or the Indirect Standardization adjusts for SES with the information provided in the Request for Comments. We request that CMS provide more detail and numeric examples of how well each approach adjusts for SES, particularly for contracts with majority or 100 percent dual enrollment; estimates of how Star Ratings would change for contracts under each approach; and the strengths and weaknesses of each approach. We also seek clarification on whether we would have to have a minimum number of LIS/dual or disabled enrollees in order to receive an adjustment through either approach. For the categorical adjustment index, for instance, we also ask for clarification on whether institutionalized individuals would be one of the beneficiary subgroups included in the adjustment. We are also requesting clarification on if the I-Factor will be applied before or after the Categorical Adjustment is applied. For indirect standardization, we are seeking for CMS to clarify which specific measures would be adjusted and allow us time to determine impacts. Additional clarification from CMS is also needed to identify to what extent, if at all, the subset of adjusted measures would change year-to-year. Additional clarification on whether we as a plan should expect both upside and downside- adjustment with this approach: In a select few measures, plans with high proportions of disabled dual eligible beneficiaries outperform other plans – should we then anticipate a negative adjustment for these measures? We further ask for clarification as to how the adjustment under indirect standardization would interact with case-mix adjustment in the CAHPs survey. Publishing specific examples and the strengths and weaknesses of each adjustment model will allow us to provide more useful feedback to CMS.
Centene Corporation	Centene appreciates CMS' recognition of LIS/DE and disabled populations including the two proposed adjustment methodologies and looks forward to reviewing CMS' impact assessment and simulation results in the draft call letter. We request that the draft call letter also include all national data needed to assess the impact of each adjustment on our specific plans. We would like to voice concern at prematurely implementing any temporary adjustment that may cause increased administrative burden on both health plans and CMS before the supporting research has been completed and disseminated for review, and request that CMS provide information for any further methodologies under consideration such as an adjustment of cut points as opposed to measure rates. Centene

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	recommends that any adjustment plan include all 16 measures on CMS' list of potential adjustment measures. We also recommend that CMS adjust proposed future measures of medical reconciliation, medication adherence for statin use in persons with diabetes and cardiovascular disease, and hospitalizations for potentially preventable complications. Centene recommends that remaining HOS measures for Improving or Maintaining Mental/Physical Health be included in the LIS/DE and disability adjustments.
Centers Plan for Healthy Living, LLC	As this is a new measure, we recommend making this a display measure in year one so plans can assess the impact of this change. Additional Comment: Although unrelated to stars, we would also recommend CMS consider that beneficiaries in these categories may have higher social work and health care needs. As such, we would recommend CMS consider a revised compensation methodology that would apply to plans with a disproportionate share of members in these categories. Once a plan's membership exceeds a CMS defined threshold, the revised, risk-adjusted, methodology (which would take into account how sick these members are) would apply; and provide plans with the funding needed to care for this higher need population.
Cigna	We appreciate CMS' is consideration of alternative methodologies to address the Star Rating disparities among MAPD populations. Cigna-HealthSpring believes that an interim solution to address the disparity must be implemented as quickly as possible to protect low-income beneficiaries enrolled in these plans. We also believe that any interim solution must make a meaningful difference in correcting the ratings disparity. Unfortunately, we do not have enough information about the two alternatives proposed in the Request for Comments to make a recommendation about them. We ask that CMS provide more information about how each of the alternatives would be operationalized in advance of the draft call letter to allow plans more time to provide input. In addition, we ask that CMS provide simulation data utilizing 2016 Star rating information to show how each of the alternatives (Categorical Adjustment Index or Indirect Standardization) would affect industry ratings. Doing so will allow plans to determine the impact of this proposed change and allow plans to offer well-informed comments. Also, we believe CMS should consider regional disparities as a factor in their analytical adjustments.
Commonwealth Care Alliance	CCA wishes to acknowledge CMS's commitment to researching this issue and determining if/what adjustments are appropriate.
Constellation Health, LLC.	After evaluating the information provided by CMS in RFC, Constellation Health understand that Categorical Adjustment Index will mitigate the disadvantages of Puerto Rico LIS/DE/ disabled population in comparison with the states. In relation to the lack of LIS program in Puerto Rico, the proposed methodology needs to evaluate the 150% of FPL considering that Puerto poverty levels are higher than the states. The income of 65 and older population

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	available in the census data will be more precise for Puerto Rico than the FPL. In order to address the adherence differences of overall results in Puerto Rico compare to the states, lower the weight of the measures will improve the results and give opportunity to MA in PR improve the Stars rating.
CVS Health	SilverScript greatly appreciates CMS's continued focus on the important topic of risk adjustment for socioeconomic and disability factors to determine the extent these factors impact a plan's performance on the Medicare Star measures. Our overall comments are as follows: Similarly, SilverScript recommends that CMS provide simulations for each of the suggested approaches to increase understanding of CMS' proposed methodologies and how beneficiaries' and plans' data would be used throughout the risk adjustment process. Historical data, such as 2013 data, could be used for this purpose in order to compare plans' performance using the current Star ratings methodology versus the 2017 approaches proposed. Simulated data will allow plans the opportunity to make an informed recommendation to CMS on which interim risk adjustment is ideal. Below, we discuss each of CMS' suggested methodologies, the Categorical Adjustment Index and the Indirect Standardization approach, in more detail. The Categorical Adjustment Index (CAI) 1. Category groupings and definitions: SilverScript would like more clarity as to what quantitative threshold values will define categories and why these threshold values are appropriate. Further, it is difficult to comment on the usefulness and validity of the CAI without understanding which grouping approach CMS will use, e.g., deciles, 16 LIS * DE groupings, etc. 2. LIS and DE-based categorizations: We note an important limitation of the categorization approach is that it relies on grouping by disability status. PDPs do not have access to disability information, placing them at a disadvantage to MAPDs in efforts to improve care specifically for disabled beneficiaries and in understanding the performance of their plans by disability status. 3. The pitfalls of categorization: A broader concern is that categorization, by definition, removes the underlying heterogeneity in the data in favor of a homogenized category. This can obscure true differences between beneficiaries and plans. For example, 2 beneficiaries may have full LIS, but 1 beneficiary is deemed and institutionalized with 4 chronic conditions and a second is community-dwelling, non-dual eligible, and has 1 chronic condition. If the CAI were to define a "full LIS" category, the important differences between these two beneficiaries that may very well impact their individual-level Star measures are ignored. 4. Recommended improvements to risk adjustment methodology: SilverScript recommends that CMS capitalize on the heterogeneity of the data by avoiding categorization as the first step in constructing the index. To do this, SilverScript recommends that, at minimum, CMS adjust for several beneficiary-level variables available to both MAPD and PDP plans: 1) Age 2) Sex 3) RxHCC 4) Other measures

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	of clinical complexity 5) Community versus institutional residence Age and sex are well known predictors of morbidity and mortality and are associated with quality of care outcomes. These factors are readily available and easily included in models. The Clinical complexity is predictive of clinical outcomes and prescription drug utilization and adherence. RxHCC is a CMS-created, validated measure for adjusting for beneficiary-level risk associated with clinical co morbidity and complexity. Both PDP and MAPD have access to the RxHCC, making it a useful, practical, and appropriate variable for risk adjustment. Finally, additional measures of clinical complexity may also be considered. For example, the number of unique prescribers a beneficiary has, the number of unique prescription fills dates within a month, and the number of unique pharmacies utilized by the beneficiary may all serve as measures of clinical complexity. Finally, we recommend that CMS adjust for whether a beneficiary resides in the community versus an institutionalized setting, as each has a unique relationship with quality of care. After these variables are used in risk adjustment, categorization could then be considered as a way to group plans by their individual beneficiaries' risk profiles. 5. On page 12, the text describing specification #3 is unclear. We ask CMS to clarify the text here. The Indirect Standardization Approach 1. Concerns that beneficiary-level characteristics are not considered but rather aggregated into the proportion of LIS and/or DE within plan: SilverScript is concerned with CMS' proposed approach to use the proportion of LIS and/or DE within a plan for the purposes of indirect standardization. Similar to our comments above, this approach does not capitalize on the underlying heterogeneity of the LIS and DE populations and may indeed obscure or ignore important differences between them. As stated above, for example, 2 beneficiaries may have full LIS, but 1 beneficiary is deemed and institutionalized with 4 chronic conditions and a second is community-dwelling, non-dual eligible, and has 1 chronic condition. Extrapolated to the plan-level, 2 plans may have the same proportion of full LIS beneficiaries, yet their age, sex, and co morbidity profiles may be very different. We do not believe that the current approach can adequately address these concerns. 2. As above, we note an important limitation of the indirect standardization approach as described is that it relies on grouping by disability status. Unlike MAPD plans, PDPs do not have access to disability information. 3. On page 15, in describing the indirect standardization approach, the correct equation should read "F/G = H" 4. Recommended improvements to risk adjustment methodology: SilverScript recommends that CMS capitalize on the heterogeneity of the data by avoiding simplified grouping of plans by the percentage of LIS and/or DE beneficiaries. Instead, SilverScript recommends that, at minimum, CMS adjust for several beneficiary-level variables available to both MAPD and PDP plans: 1) Age 2) Sex 3) RxHCC 4) Other measures of clinical complexity 5)

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	Community versus institutional residence Age and sex are well known predictors of morbidity and mortality and are associated with quality of care outcomes. These factors are readily available and easily included in models. The Clinical complexity is predictive of clinical outcomes and prescription drug utilization and adherence. RxHCC is a CMS-created, validated measure for adjusting for beneficiary-level risk associated with clinical co morbidity and complexity. Both PDP and MAPD have access to the RxHCC, making it a useful, practical, and appropriate variable for risk adjustment. Finally, additional measures of clinical complexity may also be considered. For example, the number of unique prescribers a beneficiary has, the number of unique prescription fills dates within a month, and the number of unique pharmacies utilized by the beneficiary may all serve as measures of clinical complexity. Finally, we recommend that CMS adjust for whether a beneficiary resides in the community versus an institutionalized setting, as each has a unique relationship with quality of care. After these variables are used in risk adjustment, categorization could then be considered as a way to group plans by their individual beneficiaries' risk profiles. Finally, SilverScript recommends that CMS consider the use of community-level measures of socioeconomic status (such as the proportion of the community below the poverty level, proportion of the community that is unemployed and others) in risk adjustment methodology. ASPE, NQF, PQA, and others are studying this and related questions in detail. As additional evidence is generated, CMS could consider the additional predictive ability of these community-level factors by running 2 models, one without these community-level factors and one with them. In summary, SilverScript supports CMS's efforts to develop a risk adjustment methodology. Prior to endorsing either of the approaches outlined, we would need clarification of the considerations noted above. However, we believe that some risk adjustment done prudently is better than no risk adjustment at all. We recommend that CMS continue to move forward with interim methods that can be refined over time. SilverScript looks forward to further clarification in the Draft Call Letter to further assess approaches that could be used interim.
Elderplan	CMS needs to provide more information for each of the proposed models (Categorical Adjustment Index and Indirect Standardization) including information on the accuracy that each model adjusts for SES in contracts with large percentage of dual-eligible beneficiaries. For the Indirect Standardization, CMS intends to target specific measures which negatively impact a Plans overall rating. In addition, this methodology would require additional validation during Plan Preview period which is not part of the Plan's current workflow and may require additional resources.
EmblemHealth	Methodology - We agree there may be performance differences based on SES and the methodology changes needed based on

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	LIS/DE/Disabled status. It would be helpful if CMS could provide simulated results as an example by using last year's Star rates similar to those provided around the deletion of the pre-determined 4 star threshold. Categorical Adjustment Index - If a plan has a superior rate on a measure compared to its peers, what is the effect on the adjusted star rate? Does a different adjustment apply to the plan or is the same adjustment index value used across all plans within the same category. For plans that use only hybrid methods to calculate the measure in which a sampling of members is used instead of the entire plan's population, how will the dual-eligible low-income subsidy adjustments account for this? Without oversampling of the Dual-Eligible (DE), Low Income Subsidy (LIS) population any estimation may yield biased results using the Indirect Standardization (IS) method, as well as, the Categorical Adjustment Index (CAI) method. For smaller plans, a random sample of members might only pick up a handful of members that fit each of the four groups under consideration (DE-LIS, non-DE-LIS, DE-nonLIS and non-DE-non-LIS). Both of these methods assume a sufficient sample exists on which to base the calculate of a plan's coefficients for these factors. Will STARS ratings be adjusted on only those measures for which a plan submits full population data or will oversampling of this population need to occur to use hybrid measures? For example, blood pressure control is a measure that lacks good administrative data and our plan typically submits a sample of data for calculation of this measure. Will we need to oversample DE-LIS members in order to have a non-biased estimate for our adjusted DE-LIS STARS blood pressure control measure? Secondly, the impact of DE-LIS status on STARS quality metrics can largely be attributed to access to health care issues. Are there more direct measures of access to care that might be confounders of the DE-LIS quality measure relationship? For example, DE-LIS members who lack transportation might do worse than those who have a means into the doctor's office (health plans with transportation programs, institutionalized members). Are other confounders affecting a DE-LIS member's access to care being accounted for in these adjustments?
Essence Healthcare	The Indirect Standardization (IS) method appears to be a more valid approach compared to the Categorical Adjustment Index (CAI) approach for the following reasons: 1. IS applies an industry standard observed to expected ratio by metric. Given that the performance calculation is more specific to each plan's unique characteristics and measured performance, this approach allows for more real-time performance measurement, and adjustment and enhancement of quality improvement efforts to drive the highest possible performance in each of the identified 16 quality metrics. 2. IS avoids banding plans that are largely dissimilar except for one variable - the presence of LIS/DE and disabled membership. 3. IS allows greater opportunity to avoid the common criticisms of risk

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	adjustment methodologies, which is that they are non-transparent and non-replicable, and promotes further plan-level understanding of the risk adjustment methodology. We recommend that CMS use Indirect Standardization rather than the Categorical Adjustment Index to determine socioeconomic status risk adjustment.
Fresenius Health Plans	Thank you for the opportunity to comment on the impact of LIS and disability and specifically ESRD on Star Ratings. As a MA organization offering exclusively ESRD C-SNP plans we believe an adjustment to star rating based on ESRD and LIS status is essential and urgently needed. 100% of our patient have ESRD and over 90% are LIS. We believe that both adjustment methodologies will have a significant impact on star ratings for our plans and would welcome the opportunity to review data around the impact of such adjustments. We are concerned about the lack of applicability of some measures to our population (as explained in detail in other sections) and how that will impact the calculations. Please consider the possibility of excluding ESRD beneficiaries from star measures while the interim analytical adjustment measures are being studied.
Group Health Cooperative	Additional Comment: Group Health agrees that a key goal of the Medicare Advantage and Part D programs is to achieve greater value and quality for all beneficiaries; therefore it is important that we do not distort quality signals in our measures, or mask true differences in quality of care. Clinical quality and patient satisfaction should be at the core of the rating system. Measures should be evidence-based and meaningful for consumers, health plans, and providers. However, given the absence of data from simulating the results of these options, Group Health does not believe there is sufficient information to provide a fully-developed evaluation of the "Categorical Adjustment Index" and "Indirect Standardization". Group Health encourages CMS to provide additional details including a simulation using last year's performance and how it would look for health plans using the new methods. Further, we ask CMS to consider the benefits of doing both adjustment – including the increased burden, complexity, reduced transparency, and barriers to performance improvement that this new adjustment will have on health plans. Prior to moving forward, Group Health encourages CMS to consider temporary payment of the quality incentive bonus for DSNPs at the 3.5 star level for 2017 and possibly 2018, allowing CMS time to consider other options and plans to continue their quality improvement efforts.
Health Alliance	•During the user phone call, it was mentioned that CMS may be able to provide simulated data in the Spring of 2016 to show plans how adopting one of the interim calculations might affect their Star Ratings. We suggest the adoption of any calculation method be postponed until simulated data is available for plans to thoroughly evaluate. •It is our concern that contracts with a lower percentage of LIS and disabled membership could negatively be impacted by these changes which would not accurately reflect the Star Ratings for

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	these contracts. •CMS has said that implementing either of the calculations would decrease the Plan Preview period. It is our concern that the preview period will be shortened at the same time these solutions could create additional burden to plans in validating the data. -Regarding categorical adjustment, could CMS provide estimates of category thresholds and estimates of adjustment values for each category based on perhaps last year's data? It would be nice to have some idea of how those values might pan out. -Regarding indirect standardization, does CMS have a list of proposed measures to perform indirect standardization on?
Health Choice Arizona, Inc.	We are happy that CMS is proposing analytical adjustments to address socio-economic and disability status for the Medicare part C and D Star ratings. We look forward to the long term solution options put forth. Regarding the currently proposed interim solutions, we feel what information has been released lacks key components necessary to make a fully informed decision. Namely, which measures will be chosen for adjustment, what the national averages are that are described in each of the two proposals, the grouping categories and cut points for such described in the Categorical Adjustment Index (CAI) method, and how the adjusted measure score is converted to Star ratings based on current year measure thresholds in the Indirect Standardization (IS) method. So, our recommendation is being made on different criteria. Out of the current interim options, we prefer that Categorical Adjustment Index using the prior year's data be implemented as that appears to be the only one that can provide future modeling. Knowing in advance what our STARs level, and resulting financial implications, are is very important to understanding our financial health. It is also extremely important in our annual bid processes.
Health Net, Inc.	HN commends CMS' ongoing efforts to ensure the integrity of the Star Rating Program while acknowledging the challenges for Plans who are serving traditionally underserved subsets of the Medicare population. However, it was difficult to comment on the proposed interim solutions presented due to lack of technical information. It would also be valuable if CMS would simulate the two options using the 2016 Star rating, and include detailed information on the methodology used to calculate both results. HN requests CMS provide additional technical transparency and simulate/model the proposed options prior to implementation. CMS should provide plan level results rather than aggregate level impact for each of the approaches under consideration. Additionally HN has the following concerns: Are differences driven by unobserved factors which are not being accounted for in CMS current approach or is possible that DSNP/LIS/Disability are only correlated with the factors that are actually causing the differences in outcomes? Also, legitimate between contract differences may exist which are not attributable to differences in quality, but rather based on these unobserved factors. HN would also request that CMS revisit the CAHPS case mix

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	adjustment model in light of these findings to verify that the adjustments are equitable. Comments from HN based on information made available on two options are as follows: HN would like to know additional information on how long the proposed interim solution is planned before a permanent option is selected. Additionally, since this is an interim adjustment and there may be unobserved factors which can't be adjusted for, HN would suggest that CMS consider a "hold harmless" provision regardless of the approach selected. As a result of this provision no plans would see reductions but only increases in their overall ratings. Plans would be made aware of what any potential adjustment would have been, whether positive or negative. Categorical Adjustment Index: HN is not able to comment on this proposed solution as CMS has not fully released how case-mix adjustment (similar to the CAHPS patient experience measures) is calculated. HN requests that CMS provide Plans with the methodology used to calculate case-mix adjustment. HN requests additional information on the categories/levels used to establish Plan quartiles, (e.g., are different levels of LES status going to be factored)? HN has concerns that collapsing categories where the magnitude of the mean difference is similar may result in misclassification of those plans which are near thresholds between categories; as a result CMS should seek to make categories as distinct as is possible. Indirect Standardization: HN has concerns whether plans that use a hybrid methodology to calculate HEDIS rates will be representative of Plans level of LES/SNP/Disabled membership. HN also has concerns over the ability to validate the results during the plan preview period, due to lack of transparency.
Healthfirst	We appreciate CMS's continued work to understand the relationship between the Star Ratings and socioeconomic / disability status, and we are pleased to see CMS move forward by offering two options for interim analytical adjustment to address the LIS / Dual Eligible / Disability effect in the Star Ratings. We strongly support CMS in adjusting the 2017 Star Ratings program to recognize the effect of socioeconomic factors and disability status and continuing the adjustment until a permanent solution can be implemented. We offer the following thoughts and comments about the interim adjustment in general and the two proposed options specifically: Additional Detail and Simulated Data – We appreciate the technical detail of the analytical methods that was included in the Enhancements memo and in the follow-up technical call held by CMS. However, we are still left with many unanswered questions about the proposed methodologies. For example: When CMS tested the CAI methodology, what did the initial and final categories look like? What was the magnitude of the final adjustments? For each category, what was the range of contract-level differences between the adjusted and unadjusted overall star ratings and what was the mean difference in the category? Most important is the need for simulated plan-level data so that we can better understand how the

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	methodologies would work and their impact. We request that CMS release simulated contract-level data as soon as possible, and before the 45-day notice to the 2017 Call Letter, so that plans have enough time to assess the information. Measures Included in the Adjustment – CMS requested comment on which of the 16 measures from the RAND study earlier this year should be included in the interim analytical adjustment. We urge CMS to include any measure that is sensitive to socioeconomic factors and/or disability in the interim adjustment, including measures beyond the 16 that were studied by RAND earlier this year. Within-Contract Differences – Both of the interim analytical adjustments proposed by CMS focus on adjusting for the average within-contract differences in performance for LIS/DE/Disability compared to non-LIS/DE/Disability members. We have concerns about the way that within-contract differences are determined and the validity of using them to adjust the Star Ratings for socioeconomic factors in a meaningful and accurate way. More specifically: we are concerned that average within-contract differences as calculated in the RAND study are smaller than they should be because they do not account for the effect of LIS-lookalikes (i.e., non-LIS members who look very similar to LIS members with the exception of qualifying for the LIS) on Star Rating performance. The RAND study considers only binary variables (e.g., LIS/non-LIS), and is therefore unable to include the effect of LIS-lookalikes. Because of this, the average within-contract performance differences determined in the RAND Study do not fully and accurately reflect the impact of socioeconomic status (SES) on Star Rating performance. We ask that CMS adds other variables, including community-level variables of SES (e.g., residence in high poverty area, proportion of community that is unemployed, etc.), into the adjustment methodology to more accurately account for all members in a plan with low socioeconomic status. The following example from our plan illustrates the effect of LIS-lookalikes: More than half of Healthfirst's Medicare members are dual-eligible, and nearly 80% have a low income subsidy. Of the 20% of our members without any low income subsidy, many are still very low income, earning just above the qualification threshold ($23,895 for married Medicare members). Our non-LIS members (i.e., "LIS-lookalikes") live in the same neighborhoods as our LIS members and face similar challenges (e.g., residence in high poverty and high crime areas, low health literacy, multiple comorbidities, etc.). On some Star measures, our non-LIS members actually perform worse than our LIS members because they do not have the extra financial help that LIS members have. Because of this, the within-contract difference in performance for Healthfirst's LIS and non-LIS members is understandably small and may even be negligible or contrary to expectations in some cases. Both of the interim methodological approaches proposed by CMS aim to adjust for the average within-contract differences, and we are concerned that this average value is dampened by contracts

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	like ours, where the plan's non-LIS members are more similar to LIS members than to the average non-LIS member (i.e., middle class Medicare beneficiaries). By adding other SES variables into the adjustment, including community-level variables of SES, CMS can more fully and accurately account for the effect of SES on Star Rating performance. Hold Harmless Provision – The quality bonus is critically important to the viability of Medicare plans, especially plans like ours that serve counties that are below the fee-for-service benchmark. While we firmly support the need to adjust the Star Ratings for socioeconomic and disability factors, we are concerned that the interim adjustment may have unintended consequences, especially in the initial year of implementation. Given the lack of detail in the proposals, and the resulting difficulty in our ability to comment with the desired degree of understanding or precision, it is imperative that CMS "first do no harm" in experimenting with new approaches in a welcomed effort to address SES in the Star Ratings. We request that CMS holds plans harmless by awarding the higher of their adjusted or unadjusted overall star rating. Categorical Adjustment Index (CAI) – We are concerned about the use of categories of contracts to determine the Categorical Adjustment Index values. Because the CAI value is an average for all contracts within a category, there will be some contracts within a category that will receive a larger than expected adjustment and others that will receive a smaller than expected adjustment. We recommend that the initial category groupings be as fine as possible (e.g., deciles instead of quartiles) to increase the precision of the adjustment and decrease the likelihood that a meaningfully distinct category of contracts is lost amidst a larger grouping. Indirect Standardization – We appreciate the greater precision that Indirect Standardization offers in providing contract-specific adjustments. We share the concerns raised by MedPAC about the data challenges posed by this method on sample-based measures, and request that CMS provide information on how it would address these data concerns.
HealthPartners	We appreciate CMS' research and efforts to address the effects of SES and disability status on the Star Ratings. However, since additional research will be conducted by ASPE and CMS' work is not complete, we believe it is disadvantageous for CMS to rush to include such a complex "interim adustment" for 2017 Stars that may change the following year. Instead, we suggest CMS wait until research is completed and include a more comprehensive solution for future Star Ratings. If CMS determines to move forward with the interim solution, then CMS needs to quickly share more detailed information. CMS has not provided sufficient information for plans to provide a thorough and detailed evaluation of the proposed Categorical Adjustment or Indirect Standardization approaches. With the information that has been provided, we have concerns about plans' abilities to adequately validate the adjusted data. In addition, we have concerns that risk adjusting quality measures is

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	not appropriate and doesn't address plans with quality care issues. Risk adjustment on quality measures would penalize plans who diligently work to deliver high quality of care, regardless of the population served. If CMS moves forward with the interim adjustment, then we strongly recommend CMS pilot the interim solution.
Humana	Humana appreciates the analytic and transparent approach that CMS has taken on this issue. Consistent with this analytic and transparent approach, we believe it would be premature to implement any adjustment until the work of the HHS Assistant Secretary for Planning and Evaluation (ASPE) is complete and publicly released. Furthermore, we understand that CMS intends to share program-wide impacts in the draft Call Letter. We support this transparency and also encourage CMS to privately share plan level impacts with sponsors. We believe that sharing impacts will allow for a better understanding of the mechanics of these proposals and therefore more substantive comments. Finally, it would not serve program goals if certain plans were to receive positive adjustments to their Stars if there is little evidence of actual efforts by those plans to improve performance. To that end, we suggest that CMS examine the level of effort that plans are making. For example, CMS could reexamine Stars differences related to duals and disability adjusting for quality spend as reported through the medical loss ratio (MLR) requirements.
Independence Blue Cross	At this time, we believe that until CMS designs a more permanent solution, CMS should hold off on making any Star Rating adjustments based on Dual/LIS/Disability status.
Independent Care Health Plan	We have heard the observation from CMS officials that "D-SNP members tend to enroll in low performing plans." This observation would seem to label D-SNP members as "really bad consumers" and D-SNP plans that are dedicated to serving the needs of individuals who are disabled and who qualify for low-income subsidy as having "poorly focused missions." It is the generally held belief among the provider community (hospitals, clinics) that the way toward improvement in reimbursement and quality performance is to move out of the inner city and into the suburbs. In the plan community, the way to higher quality performance is to enroll well-elderly and to avoid D-SNP eligibles. CMS program designers need to understand that neither health plans nor providers can fully correct for the effects of poverty and disability any more than the public school system can correct for poverty or broken families. Consistent with this observation one might also hear that "inner-city students tend to go to bad schools" with low graduation rates, low transition-to-college rates, high court-involvement rates, high school pregnancy rates, etc. … where there is no appreciation of the connection between the effects of poverty on performance. The fact is that the educational system corrects somewhat for poverty and disability; school aids for special education students are higher than school aids for non-SE

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	students. The current Medicare/Medicaid reimbursement and performance evaluation programs (e.g.., lesser-of-logic reimbursement, 5-star performance rating) contribute to the disparity in health outcomes between the well-elderly and the poor/disabled; these systems remove needed resources for LIS-eligibles. These programs encourage provider and plan flight from inner cities. These programs are working with an "imaginary patient" who does not exist among the ranks of the poor and disabled. Instead, as with special education students, additional healthcare resources are need to level the playing field between the rich and poor. Our well-elderly will always outperform our poor and disabled beneficiaries without these adjustments. Recommendation: Pursue the current course of restoring resources to LIS and disabled beneficiaries who need them most. Additional Comment: The concern relates to the interface between the application of this adjustment to the subset occurs before or after the cut-points are established. If the "clustering methodology" for setting the cut-points occurs after the adjustment, the cut-points for these measures will rise for all MA members, again making it relatively more difficult for D-SNP members, especially D-SNP members with a disability, to compete. The impact of this adjustment on setting the cut-points needs to be studied and explained before this alternative method can be endorsed (or not). Recommendation: Make sure that the bias against D-SNP members with disability is not preserved within the method for setting cut-points. Additional Comment: It is difficult to evaluate the Categorical Index method or the Indirect Standardization method without understanding the effect it would have on our plan (H2237) and which "subgrouping" of measures would be selected to which the adjustment would be applied. It would be helpful if CMS released the Rand study for public review. It would be helpful if CMS prepared full-scale models show how these two methods would work with an actual set of raw score data. Surely there must be reasons for withholding the Rand study and for not showing the models at work with a set of raw score data … and perhaps for multiple raw data sets. What might those reasons be? Whatever the reasons might be for cloistering this information, there is a serious need to make sure that adjustments to the scoring of measures as they impact D-SNP members for plans as well as providers are well-considered and effective. Serious analysis beforehand will lead to a "meeting of minds" and avoid later confusion. Recommendation: Release the Rand study and provide full-scale models of the two adjustment methodologies for the same raw data set. Additional Comment: We are concerned about the adherence measures. Our concern is based on a number of factors: i) a review of our data indicates that members who are adherent are NOT less costly than those members who are non-adherent, failing one component of the Triple Aim; ii) the measure is based on delivery of medications and not on the ingestion of medications. On the first point ("i)"), we note that

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	much of the published research linking medication adherence with total cost containment is provided by the pharmaceutical industry (Pfizer, CVS, etc.); iCare is not observing this same connection across its 6000 D-SNP members between adherence and cost containment. On the second point ("ii)"), we have observed several members who consent to refills, but who do not actually take their medications. During one home visit, we asked a member why she was not taking her medications after observing a large cache of unopened bottles in her cabinets; she said that she "did not believe in medications." We asked why she was consenting to refills; she said that "it keeps my doctor happy." Recommendation: Reduce the weight of this measure for all DSNP participants regardless of geography.
Independent Health	Ideally, we believe it would be better to hold-off on implementing an interim socio-economic and disability status adjustment option versus rushing into one of the options provided. This would allow for further research and evaluation as to what is the wisest path forward. If one of the two socio-economic and disability status adjustment options must be used, the Indirect Standardization methodology is more preferable and would have less impact compared to the Categorical Adjustment Index. Further information and/or a simulation would be helpful to better and more fully evaluate the approaches. For this reason, CMS should not implement for the 2017 star ratings, but rather consider implementing beyond 2017 star ratings, once there has been sufficient time to fully evaluate. CAHPS measures (which play an important part in the overall star rating) are already case mix adjusted, so any further adjustment should not be made for these measures. If CMS moves ahead in the interim with either Indirect Standardization or the Categorical Adjustment Index, then the adjustment option should be implemented in a hold harmless framework. In other words, only use an adjustment if it is positive.
Innovacare	We appreciate CMS's efforts to properly measure and evaluate the quality of care provided to beneficiaries. However, the proposed adjustments include many variables, making it impossible for us to evaluate the potential impact to us, and accordingly express a view about them. We suggest that, as previously done with the proposal to eliminate pre-determined 4 star thresholds, CMS should generate simulations for each contract to enable Plan Sponsors to evaluate and understand the potential impact. We also have the following specific questions which we would like clarified: (1) What is the grouping approach? (2) How would disabled members over age 65 be accounted for? (3) How would members that are both dual-eligibles and disabled be categorized? (4) In the conference call of last December 3, it was said that plans were not expected to incur any additional administrative effort for HEDIS, but be very cautious about the use of HIC numbers at the patient level data. How is this information planned to be used? Will CMS be executing alternate

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	measure level calculation processes to determine national means per population segment?Additional Comment: The suggested methodologies use values limited to combinations of LIS/DE, or Disabled population proportions, but do not account for other factors such as age, sex, or health complexities (potentially derived from HCC) and others. The failure to consider such factors may have an unintended negative impact on some plans. Presently, the reward factor can go from .1 to .4, depending on the plan execution. However, per the illustration of the Categorical Adjustment Index, the maximum conceded adjustment at the overall and summary rating levels would be .049, and in fact some plans could receive a negative adjustment. Such a low maximum adjustment would likely have no impact and as a result provide no benefit to Plan Sposors who have incurred significant investment and effort to manage their population. Other than ensuring that adjustments are significant, it is recommended that such adjustment be discretionary, similar to the way Improvement measures are handled, so that at the end the rating assigned to the plan is the highest between the adjusted and the unadjusted. Another option to not adversely impact contracts that likely face the same membership profile (SES, Disabled, health complexities, age, sex distribution), would be to determine cut points for each group and then calculate ratings, rather than leaving cut points as is and incurring all the effort that the suggested alternatives represent. A national mean correlation can be included in this analysis not to promote for quality of care being diminished or otherwise masking lack of quality.Additional Comment: The percentage of Federal Poverty Level used in Puerto Rico to identify Dual Eligibles (DE) is 87%. This percent is far below the rate used in the states. Therefore, the difference between DE and LIS income eligibility would be greater in Puerto Rico potentially resulting in a higher amount of population being LIS eligible. From this baseline, using a regression model based upon states data to predict the volume of LIS in Puerto Rico would not be appropriate. There are however other options that pertain to actual Puerto Rico data, captured by a Federal entity such as the Census Bureau that can provide income information at the county level. In our response to RFI during 2014, part of our recommendations and analysis were based upon this data.Additional Comment: We believe the ratio of the observed rate for the Indirect Standardization should be equal to " F/G" rather than "F/H" and suggest that this be re-examined.
Kaiser Permanente	Kaiser Permanente is concerned that CMS is considering interim solutions that would require significant, complex changes in the calculation methodology for a number of measures —and corresponding increases in CMS' and plan sponsors' administrative burden—while likely having a small impact (and for some plans potentially a negative impact) on overall Star Ratings. Given that CMS has engaged with measure developers to discuss the potential

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	need for adjustments at the measure level, and given that CMS' research in collaboration with the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is ongoing and will be completed in 2016, Kaiser Permanente does not believe it is appropriate to apply an interim solution in for the 2017 Star Ratings. We recommend that CMS, ASPE and measure stewards develop fair solutions for measure-level adjustments that can be implemented and applied over the long term, based on the results of the research and evaluation currently underway. - Industry studies have shown that there are Star Ratings measures on which dual-eligible (DE)/low income subsidy (LIS)/disabled subgroups actually perform favorably compared to subgroups that are not DE/LIS/disabled. This prompts questions as to which subgroups should be adjusted for, and for which measures within the 16 listed by CMS. Adjusting measures based on inadequate or confounding covariates would weaken the accuracy of any adjustments. Measure stewards or other entities may be able to develop evidence as to the influence of low-income and/or disability status that can be used for adjustments. The responsibility of adjusting measures to account for disparities should remain in the hands of measure stewards. - We understand that simulated impacts of CMS' two options will not be available until the release of the 2017 Call letter, though we urge CMS to make such simulation data available as soon as possible. In the meantime, RAND has concluded that the effects of DE/LIS/disabled subgroups on overall star ratings are small and that the proposed adjustment effects are also small. Therefore, we question whether the implementation of a temporary adjustment is worth the substantial administrative burden that would be placed on CMS and plan sponsors. Further, the release of scores, cut points and ratings would be delayed and plan sponsors would incur a shortened (second) plan preview. It would be difficult to validate the adjustments, given both the shorter review period and the complexity and lack of comprehensive data to be made available to plan sponsors. This additional burden, which is more likely to be heavier using Indirect Standardization, threatens to dilute the effectiveness and reliability of the Star Ratings program. - Regarding the Indirect Standardization method, it is possible that the expected performance value may not include sufficient data based on measures that include sampling, as opposed to measures that capture full populations. Plans that report similar proportions of subgroups but greater volumes of beneficiaries would influence the calculations more heavily. Plans that use sampling would also not include similar proportions of beneficiaries from the subgroups of interest, based on plans that already have a small proportion of DE/LIS/disabled beneficiaries; many samples would exclude a significant number of beneficiaries in the subgroups to be adjusted. - If CMS implements an interim solution, plan sponsors should be held harmless in the case that the adjustment reduces their Star Rating. As we have

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	commented previously, creating fluctuations in Star Ratings due only to calculation methodology changes causes consumer confusion by creating the impression that a plan's actual performance has changed, which diminishes the credibility of the Star Ratings program.
Magellan Health	Magellan advocates that mental health diagnoses be among those considered to determine disability, which would be philosophically consistent with determination of disability for Social Security benefits. As CMS has suggested, there is limited research to date on the connection between our quality measures of focus and the LIS/DE/disabled population, but the burden of managing a mental illness has similarities, and perhaps increased challenge to managing a physical disability. Some of the categories addressed by the Social Security Administration include anxiety disorders; mental retardation; personality disorders; schizophrenia, paranoia, and psychotic disorders; and substance addiction. (http://www.disability-benefits-help.org/disabling-conditions/mental-disorders)
Martin's Point Health Care	Overall Concept: Martin's Point has concern with the proposed analytical adjustments of star ratings to account for the vulnerable beneficiaries who have low-income subsidy and/or disability status. The MedPAC report in March states "contracts whose majority of enrollment is beneficiaries who are Medicare-Medicaid dually eligible beneficiaries have low star ratings". Additionally we understand "there is also an association between low star ratings and the proportion of enrollment in a plan that consists of beneficiaries under age 65". But the Commission also notes that "not all D–SNP plans perform poorly in the star rating system". We feel that there are other factors that account for the differences that the vulnerable beneficiaries display. We would suggest that CMS consider factors such as income, education, or regional factors. We would support CMS making adjustments at the individual measure level after measurement, rather than a global adjustment to the overall rating. Adjusting the measures themselves is the most clear and transparent path to accounting for any differences due to LIS and/or disability status. Indirect Standardization: If CMS decides to move forward with an adjustment, we suggest use of "Indirect Standardization" as opposed to the "Categorical Adjustment Index" method. With Indirect Standardization (IS) contracts would not be held accountable for adjustments affected by measures they are not responsible to report, unlike Categorical Adjustment Index (CAI). The IS adjustment would be more accurate, as the adjustment factor would be the present year's data – using the current population – in real time. CAI would use data from two years prior, depending on the measurement for each measure. Additionally IS better connects individual contract performance with individual adjustment. Lastly, the greatest flaw we see in CAI is that certain contracts could be penalized (or rewarded) more than they deserve due to the use of deciles averages. Measures to Include: Measures that use

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	sampling methodology (CAHPS, HEDIS, HOS) may lead to reliability issues due to the small 'n'. It would be difficult to calculate the observed to expected ratio. This would likely be the case for contracts that have either small population of LIS and/or disabled members or small population of non-LIS and/or disabled members. Scores calculated from these segments with small "n" would not be reliable and could significantly impact the adjustment, regardless if IS or CAI was used. More importantly, plans with a wide geographic distribution, coupled with a small "n" would have a less accurate representation of the LIS population for their plan as a whole. Measures where 5-star performance is already very high would unintentionally hurt high performing health plans that have small population of LIS and/or disabled members. Depending on certain by measure adjustments, it could make it impossible for high performing plans to achieve 5-stars, for example BMI. We would recommend a "hold harmless" provision for high performing plans. Cut-Point Issues: It's unclear why CMS would base cut-points on unadjusted scores, if the adjusted score is a more accurate representation of plan performance. It seems that this would doubly-penalize high performing plans who happen to have a low percentage of vulnerable beneficiaries. Definitions and Simulation Data: We appreciated the call on December 3rd that added some clarity to the definitions of "LIS" and "disability" for these adjustments. However, we feel that additional clarification on these two methods is still needed. We are still unclear as to the segmentation of the vulnerable populations. In the slides that accompanied the call it appears that the segmentation would be based on the combinations of LIS quartiles and disability quartiles. But in the discussion, it was represented that there would be four segments – members who have LIS, members with both LIS and disability, members with disability only, and members who have neither. Either path would increase the datapoints significantly, with the quartile combinations being most data intense. We request greater clarity around the definitions of these populations, and, if CMS moves forward with IS or CAI, we request simulation data based on 2016 star ratings to help us fully understand the segmentation and the overall impact of the adjustment. Plan Previews: Additionally if CMS moves forward with either plan, we request adding an additional plan preview period or lengthening the current previews to allow for a member-level reconciliation period. Transparency to beneficiaries: We were confused by the presentation on December 3rd that states under this proposed system Medicare Plan Finder would display "both the unadjusted measure and domain scores and the adjusted Summary and Overall Star Ratings". The Star Rating Program was created to help Medicare beneficiaries assess MA plans on Medicare Plan Finder – to make an apples-to-apples comparison. By mixing adjusted and unadjusted scores and ratings the comparison becomes apples-to-oranges. High performing plans that are adjusted

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	down due to low enrollment of vulnerable populations would need to explain their confusing performance (high score, yet not high ratings) to potential beneficiaries and current membership.
Medica Health Plans	Medica appreciates the opportunity to comment on the proposed strategies and tactics CMS is considering to address disparities in populations, and the relative rewards and incentives for continuous improvement on star rating measures for all segments of SNP beneficiaries. Medica provided more general comments and data in the RFI in November 2014 and on the current complementary risk adjustment proposal as well. We applaud the steps taken by CMS to address disparity concerns raised by plans and supported in several studies. We support CMS in their endeavor to keep any methodology changes transparent and in support of actionable quality improvement steps. CMS has stated that these proposals would be used on an interim basis. We do have concerns about implementing any changes on an interim basis and with the complexity these two options would introduce, we are concerned about our ability to evaluate and predict our ratings throughout the year. It would help to see a simulation of each of the two proposals outlined in this Enhancement letter with our 2016 star ratings data. We will want to better understand the options and impact to the beneficiaries we serve, before fully supporting any interim solutions. Adjusting certain measure will create both winners and losers depending on the current performance of a plan on a given measure. It may be best to allow the measure stewards to evaluate their respective measure specifications, and keep the current, more predictable methodology. Medica offers a third option for CMS's consideration which would be simple to administer and more accurately measure and compare SNP plans' performance while CMS formulates a long term solution. The Categorical Adjustment Index: In order to give meaningful feedback to CMS, it would be helpful if CMS could provide a contract level simulation using 2016 star results and a defined set of categories to allow plans to determine the impact this new methodology will have on beneficiaries of their plans. It would also be helpful to provide additional clarity regarding how the process would be carried out. There are no clear indications regarding how the various groups will be identified. Also, in step 3 it is not clear how or why groups with similar adjusted means would be combined. Are the adjusted differences weighted based on sample size? Will regression standard errors be used when the adjustments are combined? The reliability of regression models depend on sample size and unexplained variability in data. If this is not accounted for, then any index that is computed based on combining regression results is suspect. The advantage of this option is that it specifically tailors adjustments to the patterns inherent in their plan's population. This would ensure fairness from plan to plan rather than using the Indirect Standardization method since plans will be in varying stages of

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	improving results by their specific measures. However, without further detail it is not apparent that it will result in valid adjustments. Indirect Standardization: The current methodology for calculating star ratings is very complex, and at times difficult to articulate to those without subject matter expertise. The Indirect Standardization approach would introduce additional complexity, and Medica has concerns that it would not address the needs of the segments of a given member population. By selecting individual measures the method could reward some plans and penalize others for reasons beyond the disparities in the population. Some plans will get an unfair advantage because the disparity between their subgroups will be smaller than the national average not because of anything they have done, but because that is the natural tendency within the pool of potential members just naturally larger. Also, since the measures have many changes year over year this model would introduce a large volume of required changes to any predictive models in use each year as measures go to display and return, or are redefined due to clinical best practices. This would make it harder to monitor and predict overall performance and adjust the allocation of resources to measures to ensure continuous improvement overall and product viability. This may or may not improve the quality of care for beneficiaries in specific segments of the SNP population. 3rd Option- SNP compared with other SNPs, not non-SNPs Since the methods proposed in the Enhancements letter are both defined as interim adjustments and are both very complicated Medica believes that a third alternative would support SNP beneficiary plans with a predictable methodology. Using the current star ratings methodology and specifications, we recommend CMS simply analyze the data from SNPs separately from non SNP plans when comparing and rating individual plans. To support continuous quality improvement the only variation would be from plans selected for the comparison group rather than pitting one measure against others for adjustments and impact. CMS may then choose to use the proposed changes to the Risk Adjustment methodology to determine financial impact of the ratings and incentives by segmented populations to reduce disparity. Summary Medica supports rating SNPs in a comparison cohort with other SNPs for star ratings. If this third option is not agreeable to CMS, then Medica would need more plan specific and method specific information on the two options proposed by CMS, and more information supporting the rationale to use any interim complex solutions. The methodology in place currently does not address disparity based on the population variants of Disability and LIS, but it is predictable, when looking at performance on all measures year over year for continuous improvement for our beneficiaries. Medica will plan to comment further on any additional responses from CMS in the Advance Care Letter.
Medicare Payment Advisory Commission	The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare and

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	Medicaid Services (CMS) memorandum entitled “Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond” issued by the Medicare Drug Benefit and C & D Data Group on November 12, 2015. The memorandum proposes a number of possible changes to the Medicare Advantage (MA) star rating system, which may be included as proposals in the advance notice to be released in February of 2016. We appreciate your staff’s ongoing efforts to administer and improve the quality measurement and payment systems for MA, particularly considering the competing demands on the agency. The specific issue on which we wish to comment is how to take into account within-contract differences in MA plan performance when there is evidence that a difference in performance is due to the low-income status or disability status of plan enrollees. The research your agency has undertaken provides evidence of such differences, findings consistent with our own research. Both CMS and the Commission found that, for a limited subset of quality measures, there are systematic differences by population, though the differences are relatively small. And, for some measures, performance was actually better among low-income or disabled populations. The memorandum notes that CMS is continuing to examine this issue. In the meantime the memorandum offers two possible interim approaches to address it. One approach is to use a Categorical Adjustment Index. As noted in the memorandum, this approach is similar to the casemix adjustment methodology used to adjust MA patient experience measures, where there is an adjustment based on a contract’s distribution of enrollment by age, education, income status, and other factors affecting beneficiaries’ survey responses. The Categorical Adjustment Index approach would group MA contracts together, by deciles (for example), based on their share of the relevant populations (low-income, disabled). For each of these initial contract groupings, there would be a comparison between the overall or summary star rating determined under the current methodology, and an overall or summary star rating determined if there are adjustments made to measure results. The adjustment to the measure results would be based on a beneficiary-level regression model that determines the average within-contract difference in measure results for the relevant populations. The initial grouping of contracts would then be combined (if appropriate) into final groups for adjustment purposes so as to group together contracts that had similar mean differences between adjusted and unadjusted summary or overall results. Once that final grouping is determined, each contract within the group would receive the same adjustment to its summary or overall star rating, and the adjusted star rating determines the contract’s status for purposes of

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	determining bonus payments. The alternative proposal included in the memorandum is to use indirect standardization to derive adjusted results. Under indirect standardization, an all-contract average measure result for a subpopulation is computed, which becomes the expected result for the given subpopulation, and plans are rated based on the relationship between observed and expected results for their enrolled population. We have two concerns regarding the indirect standardization approach. First, several of the measures for which CMS and the Commission found population-based differences are measures that are reported based on medical record sampling (generally 411 records per contract) or measures for which some contracts report results based on sampling while other contracts report based on the universe of enrollees to whom the measure applies (for example, results for all diabetics in a plan versus results for a sample of 411 diabetics). Two concerns arise. One is whether a sample of 411 records yields a sufficient number of records for a subpopulation within a contract to be able to determine a valid measure result for the subpopulation. For example, many contracts are likely to have only a very small number of beneficiaries under the age of 65 (disabled) who are low-income in a sample of 411. For some contracts, the subpopulation may be entirely missing from the 411 sample because the subpopulation is such a small share of the overall population. Our second concern in indirect standardization is that, if all enrollees within a subpopulation are used to determine an all-contract expected rate, then undue weight would be given to contracts that report based on the universe of enrollees to whom the measure applied. For example, assume that there were only two MA contractors, each with 50,000 enrollees and a similar distribution of subpopulations. One contract reported results by subpopulation for its 10,000 diabetic enrollees while the other reported results for its subpopulation among a sample of 411 diabetics. Even though the contracts have the same number of enrollees and similar subpopulation shares, the former contract reports results for many more enrollees, and therefore represents a disproportionate amount of the results in the total universe that is used to calculate an all-contract expected rate. In summary, given the agency's desire to implement an appropriate

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	interim measure as it develops a more analytically rigorous long-term solution, we believe that of the two approaches discussed in the memorandum, the Categorical Index Adjustment is administratively less complicated but still addresses the concerns plans have raised. In addition, although in our recent October meeting the Commission did not formulate a recommendation on this issue, there was conceptual support for an approach similar to the proposed Categorical Index Adjustment. We would thus urge CMS to implement this approach as an interim measure rather than the indirect standardization approach. MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the CMS and its contractors. The Commission also values the ongoing cooperation and collaboration between MedPAC and CMS staff on technical policy issues. We look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact Mark E. Miller, the Commission's Executive Director.
MetroPlus health Plan	MetroPlus believes that the discussion regarding LIS/DE is a step in the right direction however we believe that what is currently proposed is inadequate to address the issues and other factors should be considered in the discussion about risk adjustments for the LIS/DE population. We believe that LIS/DE is inadequate as proxies for socioeconomic status and that other factors such as health literacy, race and household income should also be considered. We know that members with low health care literacy are less likely to be adherent to prescription guidelines so it may be important to include this factor in the discussion. On the Medication Adherence measures, MetroPlus Non LIS members continue to perform worse than our LIS population. As a Plan, we can identify these members and try to support them as much as we can but ultimately we believe that our Non LIS members are just above the poverty level and have even less resources than our LIS members which impacts their adherence and compliance to engage in other aspects of care. We believe that the adjustments that do not take income, literacy and race into account may further hurt our ability to attain four plus star levels. MetroPlus is also concerned about the timing and resources that will be needed to validate the additional data elements that will be needed during a shortened plan preview. It is anticipated that there would be a need to validate up to 240 new data points during this time and resourcing will be challenging. Lastly, MetroPlus has questions regarding the measures that are under review for the proposed adjustment methodologies referenced on page 18 of the PowerPoint presentation presented by the agency on December 3, 2015. We thought the presenter stated that measures would not be eligible for the LIS/DE adjustment factor if they were already adjusted (CAHPS and HOS measures), were plan issues, and were applicable to SNPs only. We would need to better understand how the measures that appear on page 18 that have already been

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	adjusted (Flu, Monitoring Physical Activity, Plan All Cause Readmission) would further be adjusted. We provided medication adherence data above that indicates that our LIS members perform better in the Adherence measures than the non-LIS members and we therefore would not be supportive of adjusting the LIS membership as we will in all likelihood be negatively impacted.
Molina Healthcare Inc.	Molina Healthcare is encouraged by the work by CMS to redesign and refine the Star Rating quality measures to more equitably compare performance across all MA plans that serve dual and non-dual populations. Molina requests that CMS make adjustments to the model to address the inequity as quickly as possible. The current Star Rating system does not recognize the inherent population differences between SNPs and MA and MA-PD plans. By failing to differentiate SNPs from MA and MA-PD plans, CMS is penalizing SNPs; and D-SNPs in particular are hit hardest by this inequity. Low-income beneficiaries are a very difficult population to identify and manage as they tend to be more difficult to find and track because of their lack of consistent housing, accurate phone numbers, and general resources to adhere to the care regimens prescribed to them. Consequently, it is well known that SNPs, and D-SNPs specifically, have lower average Star ratings than standard MA and MA-PD plans. As a result, D-SNPs, which typically have the need for additional resources to manage this population, end up with lower Star incentive payments than standard MA and MA-PD plans. We believe the Agency's two proposals are an important step forward. Molina recommends that CMS adopt the Categorical Adjustment Index model. We believe that this approach will provide greater transparency focused on the application of the Star Rating model. However, without receiving detailed analyses of the potential impact of each approach and having a chance to review the information to be provided under each approach, it is difficult for Molina to provide extensive comments at this time. As CMS finalizes its analyses on this critical issue, we ask that the following principles guide the Agency's work: 1) adjustments should be significant and meaningful in order to address the extensive magnitude of the disadvantages documented by the research; 2) the final adjustment model should be released as early as possible to ensure there is adequate transparency through an extensive period of further review and discussion; and 3) plans should not be penalized through the application of this model. We look forward to receiving the Agency's detailed analyses in early 2016 that assess the complexity and reasonableness of each approach to address the systemic disadvantages in the Star Ratings System.
PCMA	CMS research on whether sponsors with high enrollments of Low Income Subsidy (LIS) and Dual Eligibility (DE) members are disadvantaged found evidence of a within-contract LIS/DE/disability effect for a subset of star ratings measures, which varies in size across measures. CMS is exploring two options for interim analytical

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	adjustments to address the LIS/DE/disability effect—a Categorical Adjustment Index or Indirect Standardization. Previously, PCMA asked CMS to develop a methodology to address the LIS/DE disparity in the Star Ratings and suggested CMS should enumerate the methodology for comment. PCMA commends CMS for undertaking this important task. But, we have concerns about the complexity of the options proposed and the extremely short turnaround afforded stakeholders to comment. We appreciate that CMS organized the December 3 phone briefing to provide stakeholders with more detail about the proposals and respond to questions. However, we believe that five business days from the briefing to the comment due date is not an adequate timeframe for stakeholders to review and assess the options, and to prepare detailed comments. It appears that CMS has presented evidence of disparities across LIS/DE categories for MA-PD plans but has not presented similar evidence for PDPs. PCMA believes PDP-specific research should be conducted and the results made public. We also believe CMS should provide simulations for each of the proposed analytic approaches to increase stakeholder understanding of how beneficiary and plan data would be used and affected. Our initial thoughts and comments on the two approaches appear below: • Categorical Adjustment Index (CAI) o Need to clarify what quantitative threshold values will define categories and why these values are appropriate; o The categorization approach relies on grouping by disability status and PDPs do not have access to disability information; o Categorization can obscure true differences between beneficiaries and plans; and o CMS should avoid categorization at the first step in constructing this index and adjust for several beneficiary-level variables available to both MA-PD and PDP plans: ? Age ? Sex ? RxHCC ? Other measures of clinical complexity ? Community versus institutional residence • Indirect Standardization (IS) o Beneficiary-level characteristics are not considered but are aggregated into the proportion of LIS and/or DE beneficiaries within the plan; o Like the CAI approach, does not take advantage of the heterogeneity of the LIS and DE populations and may obscure or ignore important differences; o Relies on grouping by disability status, which is not available to PDPs; o Should adjust for beneficiary-level variables as suggested above for CAI; and o CMS staff noted this approach could yield up to 240 values for plans to review but probably won't be available until the second preview: this raises many concerns such as the utility of producing so many values when the time allowed for plan review and assessment is extremely limited. ? PCMA suggests that CMS consider using community-level measures of socioeconomic status, such as living below the poverty level or unemployment. ASPE, NQF, PQA and others are studying these measures and related questions in detail. As evidence is developed, CMS should consider the predictive value of community-level factors through modeling and comparative

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	analyses. PCMA believes CMS should provide more information and modeling pertaining to how the two analytic approaches would work, as well as the potential impact on stakeholders. We urge CMS to share additional information as soon as it becomes available and not wait for the draft Call Letter to release it. Even an interim attempt to address the LIS/DE/disability effect should make a meaningful difference in correcting current disparities. The proposed interim analytical adjustments would affect Star Ratings for 2017, which would not affect bonuses or rebates until the 2018 payment year. In the meantime, beneficiaries are losing access to greater benefits, as well as lower premiums and cost sharing, because of the ratings disparity. We request that CMS consider more immediate actions to protect affected beneficiaries and compensate affected plans until interim adjustments and/or long-term solutions are fully implemented. PCMA Recommendation: PCMA is unable to endorse either of the proposed approaches for the reasons stated above. We urge CMS to provide additional information, including detailed modeling, about how the proposed analytic approaches would affect stakeholders. We request additional time for stakeholder review of the approaches and submission of comments. We request that CMS consider more immediate actions to protect affected beneficiaries from the LIS/DE/disabled effect and compensate affected plans until interim and/or long-term solutions are fully implemented.
Peoples Health Network	We respectfully recommend CMS to consider adjusting the star cut points individually or to provide a "curve" scoring system for plans with significant SNP populations due to the negative impact SNP plans have on the overall star rating. Ex: Plan's SNP population=20% add XX "SNP factor" points (Like the "I" factor points we get.) =25% add xx.....etc
Pfizer	Description of the Issue or Question: CMS is committed to ensuring that Star Ratings methodology is appropriately sensitive to the socio-economic and disability status of enrollees. CMS is requesting feedback on possible adjustments and permutations of options and approaches. Suggested Revisions/Comments: Pfizer appreciates CMS' sensitivities to the impact of socio-economic and disability status on the Star Ratings. Pfizer stresses the importance of appropriate risk adjustment to ensure proper comparison when examining outcome performance in real-world settings. Any risk adjustment should be rooted in evidence and should not disincentivize plans from enrolling dual/low income subsidy eligible (DE/LIS) or disabled populations. Pfizer encourages CMS to continue to work with organizations like the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF) to determine what methodology must be put in place to better risk adjust for SES in measures that require such attention.
PhRMA	CMS seeks input on two potential interim adjustments to the Star Ratings to account for differences in plan enrollment of dual eligible/low income subsidy (DE/LIS) and disabled beneficiaries: the

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	categorical adjustment index and indirect standardization. PhRMA appreciates CMS' attention to the potential impact of DE/LIS and disabled beneficiary enrollment and Star Rating performance and openness as it evaluates this issue. While we agree that it is critical to address any unintended results of the Star Ratings methodology, including the potential risk of disincentivizing plans form enrolling DE/LIS or disabled populations, it is essential that CMS retain high standards for quality in the Star Ratings program and continue to incent plans to provide high quality care to vulnerable populations. Throughout this process, CMS has articulated several policy goals for any potential changes to risk adjust the Star Ratings measures for socioeconomic status, including: (1) recognize the challenges of serving vulnerable populations and providing incentive for a continued focus for improving health care for these important groups, (2) proposing adjustments that reflect the actual magnitude of the differences, (3) provide valid quality ratings to facilitate consumer choice, (4) provide incentives for quality improvement, and (5) recognize the need for options that are both transparent and feasible for the plans and CMS to implement. PhRMA strongly supports these principles. We recommend that CMS continue to evaluate any adjustments to the Star Rating Measures against these goals. As CMS notes, it has encouraged the measure stewards to examine its findings with respect to DE/LIS and disabled beneficiary enrollment and undertake an independent evaluation of the measures' specifications to determine if respecification is warranted. PhRMA believes that is important for measures to go through a rigorous development and testing process to ensure their evidence base and validity prior to implementation. In keeping with the intent of the Star Ratings to serve as a strong incentive and accurate indicator for plan quality, CMS should allow time for measure stewards to complete their assessment of their measures and to develop any appropriate adjustments in lieu of implementing an interim adjustment. We encourage CMS to work closely with measure stewards and to defer implementing adjustments to the measures until measure stewards have completed their review of the issue and developed, with public input, any specification changes. We also note that there may be alternate approaches to addressing disparities in the Star Ratings. For example, CMS is considering changes in the risk adjustment model for payment in order to ensure that plans are appropriately resourced to care for DE/LIS and disabled beneficiaries. CMS is also testing changes to the Part D Medication Therapy Management requirements that may allow plans to better target interventions and improve performance on related measures. As an additional interim approach, CMS could consider including structural measures in the Star Ratings program to evaluate if plans have appropriate supports in place for DE/LIS and/or disabled beneficiaries to achieve optimal outcomes. Should CMS move forward with an interim adjustment such as those outlined in the RFC, PhRMA agrees that within

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	contract differences should be the area of focus. Adjusting for any between contract differences could have the unintended effect of masking real differences in plan quality. Further, such adjustments should only be applied to measures where there is evidence of a meaningful within-contract disparity. Finally, we urge CMS to continue to share evidence about the potential unintended consequences of the rating system and potential solutions. It is critical that CMS proceed with caution to avoid either creating a double standard of care or inappropriately lowering standards for chronic disease management.
Puerto Rico Healthcare Crisis Coalition, Medicaid and Medicare Advantage Products Association, Puerto Rico Hospital Association, Entrepreneurs for Puerto Rico	November 25, 2015 Andy Slavitt Acting Administrator, CMS Sean Cavanaugh Deputy Administrator and Director of the Center for Medicare Amy K. Larrick, Acting Director Medicare Drug Benefit and C & D Data Group Submitted via Link provided by CMS https://cmsgov.wufoo.com/forms/enhancements-to-the-star-ratings-for-2017/ Puerto Rico Community Comments to the Proposed Updates to Request for Comments (RFC): Enhancements to the STAR Ratings for 2017 and Beyond CMS Memo dated November 12, 2015 Dear Acting Administrator Slavitt and CMS Leaders: We are writing in response to the “Request for Comments: Enhancements to the STAR Ratings for 2017 and Beyond” issued by CMS on November 12, 2015. We acknowledge CMS’ effort to address critical national level issues related to socio-economic status, STAR ratings, and current payment methodologies. Moreover, we are appreciative of the additional and particular effort that the CMS leadership has been devoting to the case of over 740,000 Medicare beneficiaries in Puerto Rico, including over 570,000 in MA and Part D, and over 270,000 dual eligible beneficiaries in MA. We send our comments looking forward to the execution of legitimate changes in the STARs rating methodology as proposed by CMS, but we need to note that it is still our urgent concern that, while there are steps in the right direction, we are still far from providing meaningful relief for the citizens enrolled in MA that reside on the island. A detailed review of the unique statutory, programmatic, and socio-economic situation of Puerto Rico, as it related to the STARs program, was submitted to CMS in November 2014 in response to the CMS STARs RFI. In the following sections, we briefly review the perspective of the proposed changes within the special context of Puerto Rico, while making suggestions and including an additional proposal to address the lack of Part D LIS benefits as it relates to medication adherence measures. 1. We strongly support CMS’ initiative to implement an adjustment to

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	the STAR rating based on socio-economic status, without further delay In line with comments from the Puerto Rico stakeholders from the past couple of years, and with multiple meetings and conversations with CMS leaders, we fully support the CMS initiative to implement the interim analytical adjustments to address the LIS/DE/disability effect. It is noteworthy that the information provided in the RFC does not allow us to clearly understand the magnitude of the proposed adjustments, and how it may mitigate the unique disadvantages for the MA and Part D programs in Puerto Rico. However, we support the immediate implementation of a CMS proposal that creates an adjustment to provide more balance in the case of plans that have to serve a higher proportion of LIS/DE/disabled beneficiaries. The general feedback from our stakeholders is in line with supporting the Categorical Adjustment Index described in the CMS RFC. 2. Addressing the Lack of LIS for Enrollees in Puerto Rico - CMS' proposal to estimate LIS beneficiary proportion is necessary to avoid the underrepresentation of similarly situated low income beneficiaries in the socio-economic status adjustment methodology. We appreciate that CMS recognizes that the lack of an LIS program in Puerto Rico affects the application of the enhancements described in this document based on mainland US experience to the Star Ratings in Puerto Rico. We have the following concerns with the proposed approach, as well as alternative suggestions. General dual eligibility (DE) in Puerto Rico is limited to a much lower percentage of the Federal Poverty Level (FPL) than in the states, with an 85% FPL eligibility threshold for full duals and no Medicare Savings Programs (MSPs), which would extend dual eligibility up to 135% FPL. The difference between Medicaid and LIS income eligibility (150% FPL), as a result is much greater than it is in the states, and the size of the LIS population in PR is likely to be quite large relative to its proportion in the states. Also, in the states, LIS eligibility is available without reliance on actual income level and so can be used to confirm assumptions used in the regression to predict LIS from DE. Therefore, it is not appropriate to assume that a regression that accurately predicts LIS from DE in the states, will produce an accurate prediction in Puerto Rico. In line with the same objectives, CMS could use more precise income information available by county using census data for the 65 and older population to estimate the LIS proportion for each contract. 3. The "NON-dual, LIS Like" population in Puerto Rico reflects unique challenges of a low income population that has significant gaps in benefits, and lower STAR ratings compared to beneficiaries everywhere else. We would argue that it is not appropriate to collapse DE/LIS as is done in the mainland model, as the LIS population is likely to be quite large in PR, given the actual

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	distribution of income, and characteristics of care for LIS and DE populations are likely to be quite different. For some measures, performance for LIS and DE populations may be so different that their collapse washes out important differences. Given this context, the categorical adjustment for Puerto Rico should be implemented based on establishing a larger number of original categories that do not combine LIS and DE until the average ratings have been calculated at the most granular level. At that point, the categories may be able to be collapsed into a smaller number of categories empirically. The comments submitted by the community in Puerto Rico for the November 2014 RFI, and specific data analysis submitted by at least a couple of plans, demonstrate the distinct situation. Different from the situation in the rest of the jurisdictions, the Non-Dual enrollees in the island include a significant proportion of low income beneficiaries (<150% FPL) that do not have the same benefits as similarly situated individuals elsewhere. Table: MA Enrollment in Puerto Rico as of November 1st, 2015 (CMS Enrollment Reports) In our response to the November 2014 RFI, there is a more detailed explanation and description of this population. The table included below is part of said report, and describes an estimate of 52% for the proportion of low income beneficiaries in Non-Dual/Non-EGWP MA plans in the island. Therefore, using any of these approximations, roughly half (~100,000) of the Non-dual/Non-LIS population should in fact qualify for LIS. From Response to the CMS RFI November 2014, Puerto Rico Medicare Coalition for Fairness Page 6 In addition, the company specific reports from plans in Puerto Rico also explained how this population tends to exhibit lower STAR ratings that the dual population. This unique situation for Puerto Rico, requires an additional adjustment in the CMS proposal to avoid excluding a recognized disadvantage with regards to the existence of a significant group of “low income + non-dual + non-LIS” population. Low income beneficiaries in the LIS eligibility income range, have not had access to the same types of benefits and services. Proposal, An option to address the Low-Income/NON-Dual/Non-LIS socio-economic status adjustment CMS could address this particular situation of Puerto Rico by: 1. Defining the categorical adjustment as proposed, based on intra-contract differences across the nation. 2. Estimating the proportion of LIS beneficiaries in Puerto Rico, considering our recommendations to use census data. 3. Defining an adjustment for Puerto Rico that accounts for the distinct disadvantage of the NON- Dual/Non-LIS population a. Step 1 - Calculate factor based on the average difference between the Non-Dual / Non-EGWP plans in Puerto Rico and the D-SNP plans in Puerto Rico. b. Step 2 – Apply to Puerto Rico plans an adjustment that is based on the same categorical adjustment index calculated nationally combined with the additional factor for the Non-Dual/Non-

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	LIS population. The factor would be applied based on the proportion of the group of DE + LIS Estimated + disabled beneficiaries. The size of the DE and LIS populations in Puerto Rico plans are likely much larger than the residual beneficiary population, and so separate treatment in the ratings should better represent the socio economic differences in Puerto Rico in these ratings. 4. Addressing the Unique challenges that Puerto Rican contracts face in improving medication adherence We are appreciative of CMS' recognition of the unique circumstances in Puerto Rico and the related challenges for medication adherence performance. We also understand, and have more clarity, about the assessment CMS performed with the option of lowering the weighting of medication adherence measures. In order to define other proposals, we reviewed the context and relative performance of the contracts in Puerto Rico. The Charts below (1, 2, and 3) illustrate the average performance for the medication adherence measures in Puerto Rico compared to the rest of the contracts. Some observations are very clear: • Contracts in Puerto Rico have a distinct lower performance compared to national averages, but have reflected higher average year to year improvements in the past 5 years. • National average performance has been significantly above the 3 STAR threshold, while in Puerto Rico the average has consistently been 1 STAR, even when performance has improved at a faster pace. • The gap for the NON-LIS plans and beneficiaries in Puerto Rico is too large in order for plans to get reasonable STAR rating results under a disparate Part D coverage platform. (3 Charts here. Submitted by email.) On Table 1 below, we calculated the percentage change in the average medication adherence performance as reported by CMS (% of compliance with adherence). A very significant observation is that the improvement for plans in Puerto Rico between 2012 and 2016 has been approximately from 2 (diabetes, hypertension) to 3 times (cholesterol) higher than the change at the national average. Notwithstanding, as explained in our response to the CMS RFI of November 2014, performance remains an outlier at the bottom and maintains STAR ratings at the lowest levels. Table 1: CMS Stars Rating Percentage Change of the Average Score for Medication Adherence Measures 2012-2016 As a vicious cycle, this result pulls down overall ratings and has created additional barriers for plans in Puerto Rico to reach bonus-level ratings that can help to mitigate year to year cuts. With a more limited capacity to reach bonus-level ratings, plans have had to make additional copay increases and benefit cuts that impact performance for the following year. Unless action is taken to stop this cycle, the STAR rating methodology for medication adherence in a NON-LIS jurisdiction may be contributing to an increasing disparity in benefits and access to care. We present some interim proposals below. Proposals to Account for the barriers in Puerto Rico contracts to Improve Medication Adherence In

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	regards to plans serving Medicare beneficiaries in NON-LIS jurisdictions, CMS can establish an interim adjustment to the medication adherence STAR rating as follows: A. Adjusting medication adherence performance for each MAPD contract in Puerto Rico by the average difference between the medication adherence performance of LIS contracts vs NON-LIS contracts around the nation. a. CMS could calculate the average difference of LIS vs NON-LIS for each of the three medication adherence measures. b. With regards to the determination of the STAR rating for each medication adherence measure in NON-LIS contracts, the STAR adjudicated will be based on the contract performance plus the average difference calculated at the national level. c. The specific medication adherence performance by measure would stay the same, and would apply in the same and usual manner for the calculation of the improvement measure. d. This adjustment would provide balance to the STAR rating in the medication adherence measures for plans with different (less) Part D benefits due to No-LIS. Meanwhile, it would also maintain performance differences among the plans serving within the same NON-LIS service area. B. Alternatively, CMS could adjust the STAR threshold scale by +1 STAR for plans serving NON-LIS areas. This would mean that a 2 STAR rating would be included as a 3 STAR rating for the purposes of calculating the Part D and the Overall STAR ratings in NON-LIS areas. 5. Aggravating Circumstances in Puerto Rico Unfortunately, in the case of Puerto Rico, no proposal or comments to a proposal for MA and Part D policy would be complete without reiterating the aggravating circumstances of the island. The need for legitimate enhancements to account for socio-economic status in the STAR rating system has been a concern and a request nationally. With an income per capita of less than 50% of the national average, the national concern finds an extreme situation in Puerto Rico just because of socio-economics. However, multiple statutory differences aggravate the situation for beneficiaries that reside in the island, unless administrative methodologies provide adjustments to restore balance. Some of the major ones impacting STARs are: • Exclusion of the Part D Low Income Subsidy Benefits. • Exclusion of the Supplemental Security Income program, which lowers disposable income for the poor. • Highest MA cuts in the nation for the already lowest MA benchmark, resulting in significant benefit cuts for low income populations. In 2011, PR MA benchmarks were 21% lower than the state with the lowest average (Hawaii), and in 2016 the PR benchmarks are much farther down, 34% lower than Hawaii. We are very appreciative and support the CMS proposals to finally create more balance in the STARs methodology with adjustments for socio-economic status and for the benefit disparities. However, we have to note that revenue implications of STARs increases would hopefully

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	impact plans by 5% approximately, while the reality is that rates for Puerto Rico have gone down over 20% since 2011, with the MA benchmarks alone going down 18%, and 23% compared to the Pre-ACA rate. Table 2 We look forward to the implementation of changes by CMS, and remain available to discuss and answer any questions about the proposals presented for the particular case of Puerto Rico. Respectfully, Healthcare Community Stakeholders of Puerto Rico
Rite Aid Corporation	We support the adjustment of certain measures to account for within-plan differences based on LIS/DE/Disabled enrollment. Both the Categorical Adjustment Index and the Indirect Standardization methods seem to be objectively sound. Since the methodology used to adjust the CAHPS scores has already been proven effective over time, the Categorical Adjustment Index may be preferred since it more closely matches the CAHPS adjustment methodology. If the Categorical Adjustment Index is used, we suggest that the adjustment factor be based on enrollment for the current measurement year, even though this would not allow contracts to know the adjustment factor in advance. Using enrollment for the current measurement year aligns the adjustment factor with the population that is actually impacting the measure. Using enrollment information from the prior year does not account for shifts in LIS/DE/Disabled enrollment that may occur year-over-year.
RxAnte	RxAnte supports adjusting Star Ratings for LIS/DE/Disability enrollment, as noted in our previous submission of comments in response to the Request for Information on this topic in February 2015. Specifically, we recommend the proposed models affect scores and not measure specification. Our main concern with the approach presented is the potential for plan sponsors to receive a negatively adjusted score, which could create a disincentive for payers that could cause them to limit/bias enrollment. We encourage CMS to consider positive adjustments only. This is particularly true in the categorical approach in which there is no clinical relevance amongst the deciles/categories that are only based on LIS percentages.
SCAN Health Plan	SCAN supports the research and analysis CMS has completed to better understand the impact of socio-economic status and disability on beneficiaries performance on star ratings. We applaud CMS for taking initial steps on an interim basis to solve for the disparity plans are facing in the current Stars structure. While we are pleased to know the long term goal for adjusting measures is to case-mix measures on an individual basis, we are concerned we do not have enough data to fully evaluate the two interim proposals included in the Request for Comment (RFC). If CMS were to provide more of the methodology and data, we believe we would be able to provide more detailed and robust comments. We agree that any adjustment method needs to be "transparent and feasible for the plans, as well as to maintain the integrity of the Star Ratings and the core of its

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	methodology." With this objective in mind, SCAN has the following comments and suggestions: Categorical Adjustment Index (CAI) • As described in the RFC, It is not clear how contracts will be grouped into "categories" based on LIS/DE and disability mix. SCAN believes it is critical for contracts within the each individual category to receive the same adjustments. • When contracts are grouped into categories and the adjustment only applies to the category level, we believe there is potential for larger variation and uncertainty. For example, if CMS uses a decile approach, the adjustments will be very different for plans at the 49th percentile vs. 51st percentile (0.063 using the example provided). • Using the example provided, the potential adjustments between the highest decile to lowest is just 0.1. This may not be sufficient. On the other hand, if CMS were to create more categories, there will not be enough contracts within each category and the estimated adjustment (category adjustment index) can be very unreliable. Indirect Standardization (IS) • Although we believe this method may be slightly more feasible compared to the Categorical Adjustment Index (CAI), we still have concerns that CMS will assume homogeneity within the standardization category. Recommendations: • CMS should study the stability of adjustment model(s) using data from multiple years and if adjustment models and factors are consistent across years, we encourage CMS to publish and use factors developed using prior year data such that plans have better visibility of performance and Star Rating. Health plans dedicate substantial resources to monitoring and evaluating performance on Stars measures and it is important to be able to predict how contracts are performing and make adjustments as needed. While we appreciate the work to date, we think it is critically important for CMS to work closely with the measure developers to develop case-mix adjustment models as quickly as possible in order to finalize a long term solution that can provide health plans and CMS stability, predictability, and accuracy within the 5-Star Rating System.
Security Health Plan	Our recommendation for an interim choice is the Indirect Standardization over the Categorical Adjustment Index. We request that CMS provide simulation results for both proposals using 2016 Star Ratings, including both with and without re-determined star rating cut-points for individual measures.
SNP Alliance	D. Impact of Socio-economic and Disability Status on Star Ratings We commend CMS for its commitment to addressing the fact that plans enrolling large percentages of dual eligible (DE) enrollees, enrollees who receive a low income subsidy (LIS), and/or enrollees with disabilities experience systematic disparities in Star performance ratings due to characteristics of their enrollees that are independent of plan performance. The SNP Alliance believes there is long-standing and robust evidence for adjusting quality measures used in a pay-for-performance system, such as the MA Star Ratings system. It is incumbent on measure developers and CMS as

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	stewards and consumers of their measures to reflect evidence in quality measurement. We appreciate and support CMS' recognition that effective care for persons dually eligible for Medicare and Medicaid requires both adequate payment and appropriate adjustment of performance ratings as Congress has now tied payment to quality. As a result, methodological approaches to measurement must be sound and fair or CMS risks doing more harm than good with its quality ratings. We appreciate CMS' effort to propose options for an interim solution while CMS continues to work with ASPE and measure developers in their efforts to examine the effect of individuals' SES on quality measures. We thank CMS for continuing to move forward and gather comments on the issue. On Masking Disparities We want to be clear that the SNP Alliance has no interest in masking true differences in quality of care or lowering expectations for those who most need improved quality. Our position is quite the contrary. The SNP Alliance is committed to advancing high quality for all Medicare beneficiaries, and for poor, high-risk/high-need beneficiaries in particular. Our primary concern is that the existing Star Ratings system masks the well-documented burden that people with poverty and low socioeconomic circumstances have in achieving levels of health and health care outcomes, especially when compared to people of average or greater resources. We view Medicare beneficiaries who are dually eligible as persons with special health needs given their challenging financial and social circumstances. Our issue is that these individuals and the providers and plans who specialize in their care should not be penalized in the Star Ratings system for the added challenges they face. Moreover, where superior care is provided, the Star rating should recognize the added resources and work that is required by beneficiaries and plans to achieve a higher rating, and that in some cases, the contributions of the health system are not going to fully account for differences in expected outcomes. We know plans serving dual eligibles are putting in a tremendous amount of effort to provide care and improve outcomes. We believe there is robust evidence that demonstrates the impact of social determinants of health on Star measures. If social determinants of health were properly accounted for in the Star Ratings system, some plans serving a high percentage of people with low socio-economic status may actually have, on average, a higher rate of performance than plans that do not. Our commitment to advancing change in the Star ratings system is related to the importance of establishing a level playing field in performance measurement for the poor and the non-poor, and between plans that specialize in care of the poor and plans that serve a relatively normal distribution of Medicare beneficiaries. Concerns about CMS' Proposed Options Based on our review and information available to us, the SNP Alliance has four principal concerns with CMS' proposed options for interim adjustments to address the effects of LIS/DE/disability on Star ratings: 1) Both options may only

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	minimally account for underlying disparities in Star performance for plans specializing in care of poor Medicare beneficiaries. A wide body of research suggests, and recent analysis by Inovalon shows, that adjusting for dual and/or low-income subsidy status alone does not capture the full amount of within-contract differences in Stars performance. As a result, the impact of either option will be constrained and negligible for most contracts serving a sizeable proportion of dual/LIS/disabled beneficiaries. In addition, the number of measures targeted for inclusion in both models represents a subset of measures that research suggests are impacted by SES. We strongly urge CMS to apply the interim adjustment to all measures in the Star Rating system related to patient care, e.g., exclude measures of customer service and appeals rates that are directly related to plan activity. Although a handful of Star measures are case-mix adjusted, they are adjusted for other purposes rather than to control for SES disparity. We believe many of those measures likely have SES disparity that should be accounted for in order to make the interim adjustment meaningful and fair. 2) Neither option incorporates many of the factors shown in the research to be of greatest importance in accounting for social determinants of health. The CMS proposals focus only on adjusting for dual/LIS/disabled status. This discounts the findings of previous research demonstrating that adjusting for dual/LIS/disabled status will not close the disparity gap found in Star Measures that are the result of socioeconomic status.(1) Research over the last 25 years has demonstrated the role of social determinants of health, such as income, education, occupation, and social supports as significant contributors to health outcomes.(2) The 2002 Institute of Medicine report titled "The Future of the Public's Health in the 21st Century" observed "research has increasingly demonstrated the important contributions to health of factors beyond the physical environment, medical care, and health behaviors, e.g., socioeconomic position, race and ethnicity, social networks and social support, and work conditions, as well as economic inequality and social capital."(3) A large meta-analysis seeking to assign weights to determinants of health found that, on average, access and quality of clinical care contribute about 20 percent to health outcomes, while social and economic factors such as education, income and family/social supports contribute 40 percent. Health behaviors such as alcohol and drug abuse contribute 30 percent to health outcomes.(4) Neither option proposed by CMS addresses any of these issues to any significant degree. Yet research underscores the need to include socioeconomic factors beyond dual and LIS status in the risk adjustment models, including factors such as living in a high poverty area, education level, home ownership and household size (indicator of social supports), and other factors prevalent in this population such as alcohol/drug/substance abuse, mental health conditions such as depression and bipolar mania, and other chronic conditions

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	that are significantly more prevalent in disadvantaged special needs populations. We understand CMS is collaborating with ASPE on research in this area and will have more to say over the long run. However, we strongly urge CMS to include more factors for which evidence and data are available now – such as indicators of neighborhood poverty and physician shortage. Coupled with dual/LIS/disabled status, we believe these factors would more fully capture SES disparity until ASPE research is complete. Dual eligible/LIS/disabled status is significant but not sufficient to account for the effects of SES on quality measures. 3) CMS' Request for Comments and the related webinar on December 3rd have not provided sufficient information needed by plans to understand and fully evaluate the feasibility and impact of the two options. As a result, our ability to provide comprehensive comments is limited. We thank CMS for the information contained in the RFC and the webinar. However, in seeking to evaluate the options it became apparent that additional conceptual details are needed to fully understand what CMS proposes. We look forward to additional information and detail from CMS in the coming months so we can continue to provide feedback on options. For example, in the Indirect Standardization approach, we would like to know how CMS will calculate "adjusted national dual means" and "adjusted national non-dual means." The CMS memorandum implies they will be generated based on stratified national averages rates for dual versus non-dual enrollees, but different and conflicting information was provided during the webinar indicating that a logistic regression model will be used. The exact specification of the model remains in question with CMS promising a response in writing. In addition, we would like more detail about the "Adjusted Pass Rate," which is not defined or mentioned in the text or CMS slide presentation, but is used in the table on page 14 of the memorandum. What is the adjusted pass rate? Is "pass rate" simply the national adjusted mean rate for dual and adjusted mean rate for non-dual enrollees? The CMS memorandum states that in the Indirect Standardization approach, "Measure Stars are not used because that would assume assignments of measure stars are linear in the underlying measure and lead to measurement error." We agree as Inovalon's prior research has demonstrated that the proportion of dual and/or LIS enrollees in a contract is not related to Star Ratings in a linear fashion, but has a quadratic distribution. We are uncertain as to why this limitation is also not noted for the CAI approach, as this would also hold true given the similarity in risk adjustment models proposed (fixed effect for contract with dual status indicator for beneficiary within contract). Plan impacts also vary, depending upon which measures are selected. More detail about the methodology used in completing the steps for each option will enable plans to fully assess the effects of these options on their Star ratings. 4) The SNP Alliance is concerned that the interim proposal could easily become

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	long-term policy without a more aggressive approach to address social determinants of health. While we recognize the importance of engaging measure developers, including NCQA and the PQA, to determine if measure re-specification to risk adjust for beneficiaries' socio-demographic factors is warranted, we are concerned about the long and laborious process that is involved before any modified measure could be implemented and contribute to plans' Star ratings. Without CMS being more proactive about advancing adjustment of performance measures, the proposed interim approach could easily become something more permanent. The SNP Alliance believes there is already ample evidence to begin the process of adjusting selected Star measures to more fully account for factors that influence the health and healthcare outcomes of poor and disabled Medicare beneficiaries. The SNP Alliance understands CMS' policy to use consensus-based measures for the MA Star Ratings system. However we also believe it is incumbent upon CMS to do more to lead the consensus-making organizations to re-specify measures in a more timely manner so that measures approved are appropriate for MA's pay-for-performance program which gives and takes resources away from Medicare beneficiaries who are entitled to a fair distribution of their benefits. Under MA statute, CMS has every authority to only use quality measures in the Star Rating system that either do not need risk adjustment or that have been appropriately vetted for risk adjustment to protect the integrity of the MA quality program. We urge CMS to use its authority so that re-specifications of measures are done in a timely way where warranted. More timely actions by measure developers will mitigate the need for interim solutions. Recommendations Given these concerns, the SNP Alliance recommends that CMS: 1) Provide more detail about the calculations and effects of the two options on Star ratings. We strongly urge CMS to release more information about the calculations that would be used to implement each option so we can better evaluate the relative pros and cons. More specifically, we would like to see the specifications for the regression analyses that go into each option. These equations are the basis for which CMS would measure SES disparity in the measures. In addition, we would like to see analyses of the impacts of the two options on Star ratings overall as well as plan-specific simulations. This information should be made available to plans in advance of the Draft Call Letter released in February in order to allow plans time to fully evaluate the option(s) being proposed. 2) Expand the socio-demographic factors included in the adjustment models beyond dual and low-income subsidy status. In advancing proposals to address performance measurement of plans serving poor and disabled Medicare beneficiaries it is important to recognize the full array of independent factors that influence health and health outcomes and that cannot be influenced by the health system. These include neighborhood characteristics, such as rates of poverty, crime, pollution, and access

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	to nutritious food; social factors, such as levels of education and types of employment; real income disparities that go beyond simple calculation of Medicaid eligibility; and the higher prevalence of certain chronic conditions among the poor to include conditions such as dementia, co-morbid illnesses, and later-stage illness that involve higher and more complex levels of self-care and professional support. 3) CMS should risk adjust quality measures in the Star Rating system for beneficiaries' socio-demographic characteristics beginning in 2018. It is our understanding that the science is already there to begin adjusting quality measures for these social determinants of health. We believe the starting point should be measures where there is solid evidence for significant disparities in Star ratings for DE/LIS/and/or disability. A leading candidate for risk adjustment, sooner rather than later, is the Plan All-Cause Readmission measure. Despite some risk adjustment, research finds there are statistically significant within-plan disparities between dual and non-duals on this measure, even though the measure is already adjusted for age, gender and conditions. This measure is also of broad concern to other industry segments specializing in care of poor beneficiaries. Other measures could and should be added to a targeted set of measures to receive priority for adjustment in 2018, based on existing evidence of within-plan performance disparities for DE/LIS/and/or disabled Medicare beneficiaries. 4) Implement a modified interim solution in 2017. We believe it is imperative that CMS implement a modified interim solution in 2017. While we have concerns about specifics of the options presented by CMS—particularly how they measure the influence of social determinants of health—we believe they represent a step in the right direction toward a long-term solution and a step is urgently needed in 2017. By 2017, benchmark rates will have been tied to quality ratings for 5 years without any consideration for SES of the beneficiaries served by MA plans. While the SNP Alliance is not able to convey a strong preference for one option over the other at this time, we believe it is possible to come to a reasonable interim solution with more information and time for stakeholder input before the final 2017 Rate Notice and Call Letter. We are particularly interested in having an interim solution that accounts for the full adverse effects of significant DE/LIS/and/or disability enrollment under the existing Star Ratings System. One factor that is critical to achieving this outcome is measure selection. Another is the specification of the regression to estimate the full impact of SES factors. As a result, regardless of which option is implemented, we strongly recommend that CMS err on the side of maximizing rather than minimizing the number of measures selected as well as expanding the range of socio-demographic factors used for adjustment. At a minimum, all of the 12 measures showing a negative performance gap for dual eligible members, as well as consideration of neighborhood poverty and physician shortage factors, should be included in the adjustment.

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	Otherwise, the effect of the adjustment on a plan's overall rating is not likely to be sufficient to meaningfully reflect the SES disparity in quality measures. (1) An Investigation of Medicare Advantage Dual Eligible Member Level Performance on CMS Five-Star Quality Measures, Inovalon White Paper, March 2015. (2) Booske,B., Athens, J., Kindig, D., Park, H., Remington, P., Different perspectives for assigning weights to determinants of health, County Health Rankings Working Paper, University of Wisconsin Population Health Institute, February 2010. (3) The Future of the Public's Health in the 21st Century, Institute of Medicine, 2002. (4) County Health Rankings & Roadmaps, University of Wisconsin Population Health Institute, Accessed at http://www.countyhealthrankings.org/our-approach on October 20, 2014.
SouthWest Catholic Health Network	Southwest Catholic Health Network (SCHN) dba Mercy Care Advantage (MCA) supports CMS efforts to assess and account for the impact of socio-economic status on the Star Rating Program. Along with efforts to quantify the barriers to care that our low income subsidy (LIS) members must overcome, MCA would like to mention other barriers that impact our Dual Special Needs Plans (D-SNPs) populations. These barriers include hunger; homelessness; low literacy rates; lack of transportation; complex mental health issues; severe physical disabilities; and drug and alcohol dependencies which are in higher proportions than non-LIS Medicare beneficiaries. It is our hope that any future refinements of the Star Rating Program acknowledge these barriers in an effort to support these plan types with negative member perception of plan performance ratings due to circumstances beyond our control. D-SNPs are an important safety net for millions of Americans. However, the current Star Ratings do not accurately reflect the efforts and improvement in health care delivery of these plan types because we must first focus our efforts to mitigate the lack of financial and social support characteristic of our members.
Tenet Healthcare	The plan appreciates CMS's continued focus on the important topic of risk adjustment for socioeconomic and disability factors to determine the impact on a plan's performance and associated Medicare Star measures. CMS has responded to the concern of those contracts with a higher proportion of vulnerable beneficiaries and has comprehensively gathered information to determine if the Star Ratings are sensitive to the socio-economic status of a contract's enrollees. We believe that smaller plans with a disproportionate number of dual eligible enrollees are systematically disadvantaged by the current Star Ratings. We applaud CMS for moving forward with an interim analytical adjustment understanding the disparity that is presented with the current process. A few larger sponsors might have benefited in years past under the current process but the changes being discussed will help make the process fair for all contracts.
Triple S Advantage, Inc	TSA proposes to have a Simulation for the 2017 ratings, or if time

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	allows for it; to have it with the SR2016 data by January in order for plans to submit comments prior to the Call Letter publication. If a simulation is not considered, then TSA suggests the use of the Categorical Adjustment Index versus the Indirect Standardization. There still are some gray areas in relation to the methodology, and where will Puerto Rico fall given our unique situation when compare with the MA plans across the nation. Sufficient information is not available to evaluate the expected impact of the alternate methodologies proposed would adjust each contract star rating due to population enrolled (Categorical Adjustment Index or Indirect Standardization). For the proposed change to the weight of the Medication Adherence Measures; TSA suggests not to proceed with the change. It does not represent an impact in the Part D and/or overall Star Rating.
Tufts Health Plan	D. Impact of Socio-economic and Disability Status on Star Ratings We oppose both of the methods intended to adjust for differences in socio-economic status and/or disability status between contracts. For years, the Medicare Advantage Plan community has argued that a plan's socioeconomic makeup has a large impact on its Star Ratings. CMS has confirmed the relationship exists, but that it is much smaller than what was anecdotally expected. With this in mind, we believe that neither of the two proposed methods to account for this change are needed, given their complexity. The Categorical Adjustment Index would apply an adjustment for all plans within a particular grouping. The method is blunt in a) how these groupings are formed and b) how the adjustment is applied. Furthermore, the method does not appear to account for plans whose measure set excludes or includes those measures which are most influenced by socio-economic, LIS, or disability status. For example, we interpret slide 24 of [Research on the Impact of Socioeconomic Status on Star Ratings(v1 09082015).pdf] as showing that the odds that a woman with a fracture who is Dual-Eligible or who receives a Low Income Subsidy will receive a BMD test or a prescription filled for an applicable drug is statistically significantly lower than the odds for a woman who breaks a bone if she is NOT Dual-eligible or receiving a Low Income Subsidy. We also know that, of the 369 contracts that received an Overall Star Rating for 2016 Star this past fall, only 273 (less than 75%) were given a score for Osteoporosis Management in Women who had a Fracture. The other 94 plans would have their Overall Star Rating adjusted due to the CAI even though they have too few eligible members to report a score on this measure. Though the Indirect Standardization method accounts for the problem we mentioned above, its complexity lessens transparency to an extent that far outweigh the benefits. The Indirect Standardization method makes it impossible for plans to know how they're performing throughout the year. In fact, this method leaves dozens of measure scores unknown until the first plan preview period. We are aware of this frustration when trying to predict what our Plan All-Cause

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	Readmission score will be. Like the Plan All-cause Readmission measure, the Indirect Standardization method will compare an observed rate to an expected rate to reach a final rate. The expected rate would not be available until much time has passed and the mean national performance for each subgroup could be calculated. Thus, the final rate would not be known until very late into the data cycle. Were plans aware of their performance earlier, changes could be made sooner, and beneficiaries would be healthier. Finally, CMS admitted that both methods would add complexity to the reporting process, and this complexity would lessen the amount of time available for plan preview periods. This is problematic, as these periods are one of the best ways to ensure that plans are not misclassified.
UCare	It is encouraging to see that CMS is acknowledging the LIS/ disability effect. We appreciate that CMS is committed to continually improve methodology in a way that more fully addresses the unique challenges of this population. That said, we find indirect standardization to be a more accurate adjustment method, but would be in agreement to move forward with either option as a starting point.
UnitedHealthcare	UnitedHealth appreciates CMS' efforts to address the impact of socio-economic and disability status on Star Ratings. However, UnitedHealth has the following comments and questions on the proposed interim analytical adjustments: 1. Given that the Categorical Adjustment Index and Indirect Standardization are intended only as interim solutions, UnitedHealth urges caution in the interest of maintaining rating system stability and avoiding retroactive application of the adjustments. UnitedHealth asks that CMS delay implementation of either proposed adjustment for a minimum of two years. This would allow plans time to analyze the potentially significant impacts and allow CMS to develop greater specificity around the proposals, which are difficult to accurately evaluate with the information currently available. Plans would then have an opportunity to make more informed comments regarding the proposed adjustments. 2. If CMS decides to proceed with the Categorical Adjustment Index, UnitedHealth would recommend an adjustment factor based on data reported the year prior, as described in the 12/3/2015 User Call, rather than the current Star year. This would allow plans to have the adjustment factor further in advance, consistent with UnitedHealth's interest in removing retroactivity from the Star rating system. 3. UnitedHealth also asks CMS to provide simulated scores in January of 2015 for all UnitedHealth contracts, including all detail to be provided in Plan Preview, so that errors and issues can be mitigated in advance. 4. Based on our preliminary evaluation, UnitedHealth finds that for both proposed adjustments, Star Ratings tend to converge in the center. This could have the unintended consequence of making more difficult for plans to attain a 4-Star or 5-Star Rating. 5. Finally,

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	UnitedHealth requests that future guidance on the proposed adjustments address the following methodology questions: • Will the LIS/DE or Disability factors still be considered in the measure regression models even if they are not determined to be statistically significant? • How will the reward factor get handled in both methods? Is it applied before or after the adjustments, and will the reward factor levels be calculated from the unadjusted scores? • When calculating the mean differences in Adjusted Overall Star Ratings and Unadjusted Star Ratings, will it be based on the summary rating raw scores or rounded scores? Also, will the average adjustment be calculated as a straight average or weighted average? If weighted, what will be used as the weight? • Will CMS be able to provide the regression coefficients for each measure used for the adjustments? • Why are deciles proposed for grouping the contracts and not percent of LIS/DE or disabled? For example, one decile group may contain contracts with percent of LIS/DE between 30% and 60% but there may be significant variation in scores between a contract with 30% LIS/DE versus 60% LIS/DE but both will have the same adjustment applied because they fall into the same decile. • For the HEDIS hybrid measures, will the case mix adjustment and proportion of LIS/Dual and Disabled be based off of the hybrid sample or eligible population? • Will the CAHPS and HOS measures case-mix adjustments remain the same or are there plans to calculate them according to this proposed methodology? Has it been determined that the current case-mix adjustment methods for the CAHPS and HOS measures appropriately adjusts for socioeconomic and disability status? • How will CMS determine if these methods are working as intended and applying adjustments appropriately? • What enrollment source and timeframe will CMS use to determine the LIS/Dual/Disabled status? • How are the adjusted national means calculated for the IS method?
UPMC Health Plan	UPMC, through UPMC for Life Dual, operates the 17th largest dual-eligible special needs plan (D-SNP) nationally and has long been committed to serving dual beneficiaries by offering high-quality, cost-effective SNP products that place a strong emphasis on care management and coordination. First and foremost, we applaud the Agency for its thorough analysis of the Star Ratings methodology and for the proposed changes designed to improve the process and appropriately incentivize plans for actions that will best serve beneficiaries. We also appreciate the Agency for taking into account the extensive data and analyses submitted by health plans and other stakeholders that demonstrated the difficulties attendant to achieving maximum MA or Part D Star Ratings in Plans with high concentrations of dual- eligibles. We believe the proposed changes to both the risk adjustment model and the Star Rating methodology will complement one another and allow high-quality Plans that serve a large percentage of dual-eligibles to remain viable. It is with that support in mind that we offer the following comments regarding the

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	two potential analytical adjustments – the Categorical Adjustment Index (CAI) and Indirect Standardization. First, we note that neither the CAI nor Indirect Standardization proposal include sufficient data, modeling, or examples to adequately evaluate their potential impact. To assist stakeholders in fully understanding the impact of the proposals, the Agency may consider simulating the potential adjustments for both CAI and Indirect Standardization utilizing 2016 Star Ratings and the corresponding contract-level dual-eligible and low-income subsidy (LIS) population characteristics. Also, we ask for further clarification as to whether the Agency intends to maintain cut-points based on unadjusted scores or identify new cut-points going forward. We believe that the concept of the CAI adjustment, which groups like contracts based on dual-eligible and/or LIS enrollment, and thereafter provides a potentially significant adjustment to the contract's Overall Star Rating, could result in a more appropriate balance and adjustment for those Plans that provide coverage to a large number of dual-eligible and LIS individuals. In order to fully evaluate the CAI approach, however, it would be helpful to understand the criteria for the groupings of contracts proposed in the sample table on page 13. We respectfully ask for further details on the CAI approach. As compared to the CAI, we believe that the concept of Indirect Standardization, which would likely provide a minimal adjustment to individual Star Rating measures pursuant to the Plan's level of dual-eligible and/or LIS enrollment, is less likely to result in an appropriate adjustment. In order to fully evaluate the Indirect Standardization approach, we respectfully ask that the Agency clearly delineate the set of measures that would be eligible for adjustment in 2017 and indicate whether this subset would be subject to change in future years. Finally, as it has throughout this process, we encourage the Agency to share any simulation analysis and estimated contract-level impact with the plans. We look forward to continuing to partner with the Agency to address this issue while maintaining the goal of providing all Medicare beneficiaries with the highest quality care possible.
VIVA Health, Inc.	The Plan appreciates CMS's acknowledgement and action toward addressing the impact of Socio-economic and Disability Status on Star Ratings. The Plan serves a significant population of LIS/Dual and Disabled members and has noted significant additional barriers this population encounters which directly impact their to ability access to care and achieve desired outcomes. While the Plan anticipates significant comments from Plans nationally, we urge CMS not to delay implementation of an adjustment factor any longer and to ensure it is implemented. As a general recommendation, The Plan requests that CMS implement the adjustment factor so as not to be punitive to plans during the initial effort by modeling the adjustment after Reward Factor methodology. That is, to apply only upward adjustments to plans whose population demonstrates a need for positive adjustment. This would allow disadvantaged plans some

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	relief while not destabilizing the industry as a whole during the initial year of implementation. CMS has requested general comments on the two proposed methodologies for analytical adjustments to address the LIS/DE/disability effect: a Categorical Adjustment Index or Indirect Standardization. The Plan has participated in the CMS educational presentations and attempted to independently understand each methodology put forth in so much as to give the general commentary requested by CMS. The Plan requests that due to the complex nature of the methodologies, CMS issue additional guidance and provide Plan data modeling using both methodologies as soon as possible (ahead of the February call for comments) to allow the Plan adequate time to evaluate each model and thoroughly understand the potential impact of each. Based on our current understanding of the models, The Plan favors the Categorical Adjustment Index. The reasoning behind our current determination is simply that the model is easier to understand and potentially validate during a limited Plan Stars preview period. Transparency in methodology and the ability to predict, measure and validate performance are extremely important to the Plan. The CAI methodology seems to better fit these needs CMS has specifically requested commentary on whether the adjustment factor should be computed based on the current year of Star Ratings data, or based on a prior year of data, such that contracts would know the adjustment factor in advance. The Plan recommends CMS utilize the prior year of data to provide more stability in implementation and the adjustment effort. The Plan recommends CMS conduct the Plan categorization using the prior year's data and release this categorization information as soon as possible in 2016. Plans can then get a baseline understanding of the national landscape with respect to the Plan categories and where they fit into the categories. CMS also requested feedback on the Star Ratings Measures to be adjusted. The Plan recommends adjustment to all the 16 measures currently identified, plus additional measures of MTM CMR and the HRM measure (which CMS has proposed removing and the Plan recommends leaving intact for Star year 2017.)
VNSNY CHOICE Healthplan	The current methodology fails to adequately account for socioeconomic and disability status and VNSNY CHOICE is pleased that CMS is looking into ways to adjust for SES in the Star Ratings. More information from CMS on both approaches is needed. VNSNY CHOICE is not able to determine how well the Categorical Adjustment Index or the Indirect Standardization adjust for SES with the information provided in the Request for Comments. We request that CMS provide more detail and numeric examples of how well each approach adjusts for SES, particularly for contracts with majority or 100 percent dual enrollment; estimates of how Star Ratings would change for contracts under each approach; and the strengths and weaknesses of each approach. We also ask for clarification on whether plans would have to have a minimum

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	number of LIS/dual or disabled enrollees in order to receive an adjustment through either approach. For the categorical adjustment index, for instance, we also ask for clarification on whether institutionalized individuals would be one of the beneficiary subgroups included in the adjustment. VNSNY CHOICE also requests that CMS clarify whether the I-Factor will be applied before or after the Categorical Adjustment is applied. For indirect standardization, we ask CMS to clarify which specific measures would be adjusted. CMS should also clarify to what extent, if at all, the subset of adjusted measures would change year-to-year. VNSNY CHOICE also requests that CMS clarify whether issuers should expect both upside and downside- adjustment with this approach: In a select few measures, plans with high proportions of disabled dual eligible beneficiaries outperform other plans – should these issuers anticipate a negative adjustment for these measures? We further ask for clarification as to how the adjustment under indirect standardization would interact with case-mix adjustment in the CAHPs survey. VNSNY CHOICE urges CMS to provide more information on each of these models, including information on the accuracy with which each model adjusts for SES in contracts with large proportions of dual-eligible beneficiaries. Publishing specific examples and the strengths and weaknesses of each adjustment model will allow commenters to provide more useful feedback to CMS.
WellCare	WellCare appreciates CMS' ongoing commitment to studying the dual eligible population and the effects serving the dual eligible population has on plan payment and performance under the Star Ratings system. We continue to believe that dual eligible status has an impact on Star Ratings and that plan performance should account for differences in populations. We support CMS' efforts to engage the measure developers, NCQA and PQA, to examine the measure specifications used in the Star Ratings program. Furthermore, WellCare supports the work of the National Quality Forum to highlight the performance differences of various populations. We hope that NCQA and PQA will participate in the National Quality Forum's work on the impact various population differences has on measure performance and to tailor their measures to appropriately account for population differences. CMS has proposed two interim options to adjust for low income status/ dual eligible/ disability status. While we deeply appreciate CMS's efforts in proposing interim solutions, WellCare finds it difficult to provide meaningful feedback on the two proposals due to the lack of specificity regarding the process and methodology. We ask CMS to provide additional detail, including a completed example of each of the proposed interim solutions, so plans and other stakeholders may accurately model the proposals and provide appropriate feedback. In addition, we encourage CMS to provide additional details and provide ample time for plans to model the proposals, determine impact, and provide

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	meaningful feedback to the Agency. Additionally, in its guidance CMS states that it does "not expect either approach to generate major adjustments in the overall Star Ratings, though any adjustment may be significant for individual contracts." WellCare, again, would like to reiterate the need for a meaningful solution to the Star Ratings methodology. Substantial adjustments are needed to appropriately account for the challenges plans undertake when serving dually eligible and LIS populations. CMS requested comments on the specific measures that should be adjusted. WellCare appreciates CMS' research to date on the impact of low income and disability status on 19 of the measures included in the stars methodology. WellCare encourages CMS to examine the impact of adjustment on all measures, process, intermediate outcome, outcome and administrative to determine where differences in performance based on low income and disability status exist. We ask CMS to seek stakeholder feedback on which measures should be adjusted once the Agency provides additional details on the impact of low income and disability on all measures and examples of the impact of the two proposed interim options.

E. 2017 CMS Display Measures

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Anthem, Inc	Anthem supports CMS' proposal to change the data timeframe for the 2017 display measures from the first six months of the current year to January 1–December 31 of the previous year. We believe that aligning the timeframe of these measures with the timeframe used for the Part D Appeal Star Ratings measures promotes additional consistency across the program.
BlueCross and BlueShield Association	CMS proposes to change the data time frame for two Part D measures: Timely Receipt of Case Files for Appeals and Timely Effectuation of Appeals. Specifically, CMS proposes to shift the data period from the first six months of the current year to the full twelve months of the previous year. For example, the 2017 display measures would be based on IRE data from January 1, 2015 through December 31, 2015. BCBSA and Plans support this change in data period and appreciate CMS's efforts to align the timeframe of the display measures with the timeframe used for the Part D appeal Star Ratings measures. Recommendations: BCBSA and Plans recommend that CMS finalize the data time frame changes as proposed.
BlueCross BlueShield of Tennessee	This is actually a response to the General Policy section - Form would not allow me select it unfortunately. BCBST supports CMS

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	having a Display Page that contains measures that have been transitioned from the Star Ratings, new measures that are being tested before inclusion into the Star Ratings, or measures displayed as informational. Since this page is designed to allow plans to track their performance on the given measures, BCBST recommends that CMS develop reasonable standards and that national data, similar to the Star Ratings cut-points, be provided to assist plans with knowing whether performance is at or near the national averages or CMS performance standard. Without such information, plans cannot define what would be considered a poor score by CMS.
Kaiser Permanente	APPLICABLE TO ALL SECTION E: Kaiser Permanente strongly recommends that CMS not report new (first year) HEDIS measures on the Display Page. First-year measures are designated by NCQA as inappropriate for public reporting. They are collected and submitted to NCQA to ensure that plan sponsors do not experience unanticipated data collection challenges, and to identify and accommodate technical specification refinements that may be necessary prior to public reporting in the second year. Only after a measure has been reported in the second year should it be eligible for inclusion on the Display Page. Additional Comment: Kaiser Permanente supports the proposed modification to the timeframe for these appeals display measures. In addition, we request that CMS provide some clarifications regarding measure DMD02, Timely Effectuation of Appeals. First, In the Display Page technical notes, the “Exclusions” section states, “These data are based on the report generation date.” We request that CMS clarify the following: - Which report is being referenced; and - Whether the report generation date affects only which data are displayed, or also the timeliness of effectuation for this measure. Second, the “Exclusions” section further notes, "If the IRE does not receive a notice of effectuation before the timeframe has elapsed, the IRE will count the appeal as non-timely. Discrepancies may occur if the IRE receives the effectuation notice late, despite the actual effectuation occurring timely." We request that CMS clarify, in the case where the notice of effectuation is received late but the effectuation occurred timely, and the discrepancy is corrected and addressed, whether CMS will automatically count the appeal as untimely for purposes of the Display Page. Kaiser Permanente recommends that any discrepancies identified in the effectuation timeliness data, which the plan sponsor addresses and corrects with the IRE prior to the date that CMS pulls the data for Display Page reporting, be counted as timely for the Display Page, regardless of the timeliness of the effectuation notice.
Medica Health Plans	Medica supports this change to align timeframes.
PCMA	1. Timely Receipt of Case Files for Appeals (Part D) and Timely Effectuation of Appeals (Part D) – CMS proposes to change the timeframe from the first six months of the current year to January 1 through December 31 of the previous year, matching the timeframe

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	for the Part D Appeal Star Ratings measures. PCMA Recommendation: PCMA supports this change.
SCAN Health Plan	E.1 2017 CMS Display Measures - Timely Receipt of Case Files for Appeals (Part D) and Timely Effectuation of Appeals (Part D). Data time frame changed from 6 months to current year (Jan 1- Dec 31) to align with Part D Appeal Star Rating measures. SCAN Comment: Agree with Change
Security Health Plan	The following comment applies to all display measures as there wasn't an option to include all in the above drop-down box: NCQA does not publically report First Year measures in Quality Compass. NCQA analyzes the results from First Year measures and does not report the measures publicly until the results are deemed satisfactory. While most measures are publically reported the second year, there have been instances when NCQA has not publically reported certain measures due to measure concerns. In the November 12, 20015 Request for Comments memo, CMS indicates the intention to add several First Year measures to the 2017 Display page and potentially add the measures to 2018 Star Ratings. We request that CMS wait to display and use these measures in Star Ratings until NCQA has determined the results are satisfactory for public reporting. Displaying the results prior to NCQA validations could mislead consumers about Health Plan quality results.
UnitedHealthcare	UnitedHealth supports the timeframe change.

2. Medication Reconciliation Post Discharge (Part C)

Submitter	Response
Academy of Managed Care Pharmacy (AMCP)	AMCP appreciates CMS' intent to expand the Medication Reconciliation Post-Discharge (MRP) measure. AMCP, however, requests CMS clarify the following questions prior to finalizing expansion of the measure: • The National Quality Forum (NQF) database of quality measures currently includes three NQF endorsed medication reconciliation measures. Although these three measures were all updated within the same year (2014), the measures are very different in the make-up of their numerators and denominators (i.e. age, time to complete a MRP). Additional clarity of the measures and their impact on improved patient care, as well as the financial resources required to deliver on the measurement, is imperative. • Research demonstrates the positive impact that pharmacists have on MRP and the ability of pharmacists to capture errors and issues that may have been missed by other health care providers. AMCP supports that pharmacists are vital to performing complete, accurate, and quality MRPs and therefore CMS should consider pharmacists as the preferred health care provider to perform MRPs. • Will the proposed data integrity audits for CMR, discussed in section C, also include MRP? • How does the proposed expansion of the MRP measure differ from the existent MRP measure that is required of physicians? In addition, AMCP asks CMS to reconsider whether MRPs should require that a standard patient take-away be mailed to

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	patients post-discharge. AMCP members report significant issues with this allowance because the delay in mailing a document often means that the patient has had a follow-up visit and medication changes prior to receipt of the letter. This situation results in confusion by the patient, and health care professionals with whom a patient may share it, in determining whether the medication regimen is appropriate and may result in adverse drug events, and even re-hospitalization. Should the mailing requirement continue, AMCP urges CMS to consider requiring that a MRP be sent to the physician via mail who can then discuss with the patient at a follow-up visit whether additional medications were added or changed. References: A. National Quality Forum Database. Available at: http://bit.ly/1ijI5Ar. (Accessed December 9, 2015). B. Schnipper JL, Kirwin JL, Cotugno MC, et al. Role of Pharmacist Counseling in Preventing Adverse Drug Events After Hospitalization.Arch Intern Med. 2006;166(5):565-571. doi:10.1001/archinte.166.5.565.
Aetna	Currently there is already a Star measure to hold plan sponsors accountable for hospital readmission prevention. As a result, we have developed programs to reduce readmission rates that have successfully demonstrated year-over-year decrease on this measure. Introducing a measure specific to medication reconciliation post discharge presents a number of concerns. Therefore, we recommend this measure not be included as a display measure in 2017 or a star ratings measure in 2018. More specific comments are set forth below. • Medication reconciliation is a key component of the overall readmission reduction program, introducing a specific measure seems to be duplicative of the existing measure. • Medication reconciliation post discharge measure is a process-based measure; the current measure is a better measure since it is a true outcome-based measure. • Current readmission prevention measure allows plan sponsors the flexibility to design programs better tailored to the specific population needs. Introducing a cookie-cutter standard measure might limit plan sponsor's ability to innovate and design programs that are specific to the patient population they are managing. This might result in less optimal ways to utilize health plan resources and negatively impact the true outcome we need to focus on, which is overall reduction of readmission rate post hospital discharge. • The inclusion of this measure is also problematic for MA only plans that have no role in administering MA enrollees drug benefit.
Alliance of Community Health Plans	ACHP recognizes the benefits of this measure in promoting high quality care. However, we recommend it remain on the display page for an additional year beyond 2017 due to concerns regarding the validity of the measurement methodology. ACHP member plans have encountered difficulty in collecting accurate information that medications were reconciled post-discharge for their D-SNP population. Given this difficulty and the lack of experience in applying the measure for a larger population, an additional year on the display

Submitter	Response
	page would allow more time to address questions of methodology and appropriateness of the population for the measure.
Anthem, Inc	Anthem applauds the expansion of the MRP measure to include all MA plans and all members 18 years and older. These changes promote the use of best practices that aim to prevent readmissions for beneficiaries of any age.
Blue Cross and Blue Shield of Minnesota	BCBSMN urges CMS to delay inclusion of these measures in the 2017 display page and subsequent Star Ratings. Changes to the technical specifications (e.g., eligible population for the MRP measure) are substantial and are first year changes. For display data to be meaningful, even as benchmarks, plans must be given adequate notice to establish effective programs.
BlueCross and BlueShield Association	CMS proposes to include the Medication Reconciliation Post Discharge measure on the 2017 Display Page and in the 2018 Star Ratings. BCBSA and Plans appreciate CMS's proposal to move the measure on the Display Page, as the metric has recently undergone changes made by the NCQA to include all Medicare Advantage enrollees and to increase the age range to members 18 years and older. We encourage CMS to consider whether the changes to the metric were significant enough so as to warrant removing the metric altogether in 2017 and bringing the metric back to the Display Page in 2018. Plans also continue to have concerns as to the ability of Plans to influence provider behavior in reconciling medications post-discharge, and request that CMS use the metric's Display Page-status to further evaluate the appropriateness of the measure. Recommendations: Provided that the Agency does not consider the changes significant enough to remove the metric altogether for one year, BCBSA and Plans recommend that CMS include the Medication Reconciliation Post Discharge measure on the Display Page, as proposed.
BlueCross BlueShield of Tennessee	BCBST recommends that this measure remain on the Display Page through at least 2019 and allow plans to have an opportunity to comment again before this measure becomes a Star Rating. Given that NCQA finalized the measure in July 2015, expanding its applicability to all Medicare-eligible members, the additional display year would allow plan sponsors to respond to a full year of valuable display data while ensuring their Medication Reconciliation efforts meet all requirements. BCBST also requests that CMS provide additional definition of the metric to be used for this measure,

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	including who is most appropriate to lead medication reconciliation activities with members and whether expansion to the all members is appropriate versus a tighter criteria for targeting members at most need for these services.
Centene Corporation	Centene does not oppose the addition of this measure on the 2017 display page. However, we request a benchmarking and cut point proposal including case mix adjustments in the 2017 request for comment prior to considering this measure for the 2018 Star Rating.
Cigna	More information about this measure is requested, such as who would be required to complete the medication reconciliation (i.e. plan pharmacist vs nurse) and in what setting (i.e..telephonic or face to face).
Clover Health	Clover Health supports the inclusion of this measure which represents a key component of the patient safety and reduction of readmissions.
Commonwealth Care Alliance	CCA supports inclusion on 2017 display page and in 2018 Star Ratings.
GlaxoSmithKline	CMS proposes to implement two changes to this measure made by NCQA, expanding the coverage of the measure to all MA plans, and expanding the age range for the measure to 18 years and older. GSK supports medication reconciliation during post discharge, as this transition of care time period is when patients are most vulnerable and a lack of care coordination may result in adverse consequences to the patient including preventable readmission to the hospital. GSK believes a special emphasis on medication reconciliation during a recent time of transitions of care offers providers the potential to avert preventable medical misadventures; and therefore supports the measures changes proposed by CMS.
Health Net, Inc.	Request that any proposed Star measure be included on display page for a minimum of two rating periods, particularly after specifications to the measure has been changed to monitor impact. Feel measure is duplicative of Readmission measures.
Healthfirst	We do not support the inclusion of first year NCQA HEDIS measures in the 2018 Star Ratings. Plans will not have had sufficient time to assess measure validity, evaluate performance, and begin targeted improvement efforts as the 2018 Star Rating measurement begins on January 1, 2016. We advocate for first year NCQA HEDIS measures to be placed on the display page for at least two years prior to being included in the Star Ratings. Additionally, this measure is primary collected via chart review. For plans such as ours, with multiple Medicare product lines, this would have a significant impact to our HEDIS processes. The proposed new Star measure would significantly increase administrative burden and cost on the health plan, and would divert plan resources from other potentially more impactful activities.
HealthPartners	This measure is too new for inclusion on the 2017 display page. CMS has not added a brand-new HEDIS measure to the display page in the past and we encourage CMS to wait until the measure is

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	refined by NCQA prior to including on the display page.
Independence Blue Cross	We are concerned because members do not have to comply with outreach and plans cannot offer any incentives for Part D. Members may be difficult to reach. Would an incentive program be allowed for Part D?
Medica Health Plans	Medica does not support this measure as it is nearly impossible to determine when community based members are discharged from skilled nursing facilities to ensure ambulatory encounters with the members' providers. Medica would like clarification on the exact roles that are able to complete the Medication Reconciliation such as Care Coordinators or Home Care Nurses. Does this measure require reconciliation via the MTM program?
Molina Healthcare Inc.	Molina Healthcare requests that CMS reconsider publicly displaying first-year or newly revised measures. We believe it would be beneficial for the Agency to first review the impact of rates for the new or revised measures prior to public reporting. We recommend that CMS wait to publicly display measure rates until after the second year of reporting and Star Rating measures not be incorporated until after the first year of public display. This comment applies to all new or revised Star Rating measures.
OutcomesMTM	OutcomesMTM supports the changes made to this measure by NCQA and the addition of this measure to the 2017 display page and 2018 Star Ratings. Medication reconciliation represents another opportunity for plan sponsors to engage local pharmacy networks through MTM to reconcile medication discrepancies post-discharge.
PCMA	2. Medication Reconciliation Post Discharge (Part C) – This measure assesses the percentage of discharges from acute or non-acute inpatient facilities for members 66 years of age and older for whom medications were reconciled within 30 days of discharge. NCQA expanded: 1) coverage from SNPs only to all of MA; and 2) the age range to members 18 and older. CMS plans to include this measure on the 2017 display page and in the 2018 Star Ratings. PCMA questions the clinical and medical values underlying this measure due to its extended timeframe. Research findings show improvement in medical and quality outcomes when medication review and reconciliation occur directly after discharge, but a 30-day timeframe may have limited benefit if a patient continues to take inappropriate medications for 30 days after discharge. PCMA Recommendation: PCMA recommends that CMS not add this measure to the 2017 display page or to the Star Ratings in 2018.
PhRMA	CMS proposes to implement two changes to this measure made by NCQA, expanding the coverage of the measure to all MA plans, and expanding the age range for the measure to 18 years and older. PhRMA is supportive of the measure changes and efforts to reconcile medication upon discharge from an inpatient facility which can help reduce medication errors and prevent readmissions.
PrescribeWellness	We support this critical enhancement.
Senior Whole Health	While we support including this measure in the display page, we

Submitter	Response
	would discourage CMS from moving it too quickly to being a Star measure. Plans need to understand their performance relative to other plans and develop strategies to improve performance on the measure. Moving the measure too quickly to the Star program would disadvantage plans that had not been historically focused on this topic.
SNP Alliance	2. Medication Reconciliation Post Discharge (Part C) We support CMS' plans to include this measure on the 2017 display page and to include it in the 2018 Star Ratings.
Tufts Health Plan	E.2. Medication Reconciliation Post Discharge (Part C) We agree this is a good aspect of care to encourage as it truly affects quality of care. Our concern with this measure is the validity of the measurement methodology. Our experience with this measure for the D-SNP population revealed significant difficulty in collecting proof that medications were indeed reconciled post discharge. First, few physicians code accurately for a medical reconciliation, requiring medical record review. Second, the strict requirements for how the medication reconciliations must be documented in the medical record make it very easy for successful medication reconciliations to not count toward the numerator. With these problems and little experience within a larger population, we propose that CMS hold the measure on the display page for two (2) years as the measure's feasibility and appropriateness are adequately assessed.
UnitedHealthcare	UnitedHealth recommends that the denominator be limited to members who have the Part D benefit; we do not have full visibility to all of a beneficiary's drugs using only Part B claims data.
VIVA Health, Inc.	The Plan requests that this measure be postponed for use as a 2018 Star Ratings to at least Star year 2019. There are multiple reasons for this request. Plans need time to determine and adjust to the administrative impact of the expansion of the eligible population. The data collection for this measure is largely hybrid, and Plans currently do not have adequate data from the expanded population from which to measure current performance. The HEDIS timeframe for this measure is a complete calendar year therefore the measure year for Star year 2018 is CY 2016. Plans need to use CY 2016 to adapt to the HEDIS changes prior to implementation as a Star measure. The Plan also questions the validity of the construction of the HEDIS measure. The intent of the measure is to promote medication reconciliation upon discharge, and the Plan heartily supports this effort in members with chronic conditions and multiple medications. However, the Plan notes that the current construction of the HEDIS measure is very narrow with respect to the most recent medication list and who can perform medication reconciliation, and overly broad with respect to membership requiring medication reconciliation. The construction of measure does not adequately address situations where members are utilizing multiple providers of care concurrently. The measure also assumes that the member had a relationship with an outpatient provider of care prior to

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	hospitalization. This simply may not be the case and the current measure does not allow for situations where a current medication list does not exist or cannot be obtained. Health Plans may be well positioned to have timely knowledge of a member's discharge and/or the member's last provider seen or most prevalent treating provider. However, due to the construction of the HEDIS measure, Plans' facilitation of this measure may be limited due to needing access to both inpatient discharge instructions as well as the last seen outpatient provider's medical records. Members must also voluntarily participate in this effort, and the measure construction contains no exclusions for Members who refuse to do so. The Plan recommends CMS reconsider the addition of this measure until the measure construction can be refined. The Plan also notes additional challenges with timely measure obtainment with the LIS/Dual and Disabled populations. The Plan requests that the measure be included in the adjustment factor for socio-economic disparity and consider weighting this measure by enrollment prior to benchmarking plans against one another.
WellCare	WellCare supports this measure, but we have concerns about the timing. Specifically, CMS plans to post results of this measure in 2017 on the display page. However, this is a new HEDIS measure, and the data will not be publicly reported on NCQA's Quality Compass until after 2017. We ask CMS to delay publication of the data on the display page until 2018, so as to align with NCQA's publication schedule.

3. Hospitalizations for Potentially Preventable Complications (Part C)

Submitter	Response
America's Health Insurance Plans	CMS is proposing to include a new HEDIS 2016 measure, Hospitalizations for Potentially Preventable Complications, on the 2017 display page and consider this measure for 2018 Star Ratings. This measure would assess the rate of hospitalization for complications of chronic and acute ambulatory care sensitive conditions. However, during the initial years of implementation of a new measure, MA plans need to gain experience with the technical elements of the measure's specifications and work in partnership with providers to ensure proper implementation. Further, during this initial time period, NCQA may make modifications to a new measure based on feedback from plans, providers or other stakeholders. It is also important for CMS to ensure that the measure developer's validation of new measures has been completed and that technical specifications are provided prior to the posting of new measures on the display page. For these reasons, we recommend that CMS provide at least two years for plans to gain experience with reporting new measures, including the Hospitalizations for Potentially Preventable Complications, prior to considering them for inclusion on the display page.
Anthem, Inc	CMS notes that it plans to add to the 2017 display page and the

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	2018 Star Ratings a risk-adjusted measure of hospitalization for ambulatory care-sensitive conditions that was first used in HEDIS 2016. While Anthem believes that this measure is important in preventing complications that result in hospitalization, we do not believe that it is appropriate to include it as a Star Rating in 2018. Given that the Hospitalizations for Potentially Preventable Complications measure is only a first year measure for HEDIS 2016, plans will not have a line of sight into their performance until 2016, when data vendors are able to program and certify the measure in their software. To that end, Anthem requests that CMS keep the measure on the display page through 2018, and not add this measure to the Star Ratings until at least 2019. This will ensure that plans and data vendors have sufficient time to prepare for its inclusion. More broadly, as CMS adjusts its Prevention Quality Indicators (PQI), Anthem recommends that the Agency first focus on measures that stand to impact the greatest number of members. We encourage CMS to focus its measures on conditions highly prevalent in the Medicare population, and believe that this approach will incentivize plans to target improvement efforts in the areas of greatest need.
Association for Community Affiliated Plans	ACAP encourages CMS to leave certain measures that are new as display-only for several years, as their effectiveness and accuracy is tested and refined. In particular, ACAP suggests that the Part C measures, Hospitalization for Potentially Preventable Complications and Statin Therapy for Patients with Cardiovascular Disease be included only as a display measure for at least two years.
Blue Cross and Blue Shield of Minnesota	BCBSMN urges CMS to delay inclusion of these measures in the 2017 display page and subsequent Star Ratings. Changes to the technical specifications (e.g., eligible population for the MRP measure) are substantial and are first year changes. For display data to be meaningful, even as benchmarks, plans must be given adequate notice to establish effective programs.
Blue Cross Blue Shield of Michigan	BCBSM does not support including this measure on the 2017 display page. Although BCBSM understands the importance of evaluating the effectiveness of care coordination, we believe the measure, which lacks prior experience or trends, is too new to include on the 2017 display page or in the 2018 Star Ratings. CMS should wait until NCQA has had more time to validate the measure and its technical specifications before including it on the display page or in the Star Ratings.
BlueCross and BlueShield Association	CMS proposes a new measure, Hospitalizations for Potentially Preventable Complications, for the 2017 Display Page and the 2018 Star Ratings. BCBSA and Plans understand that the measure is intended to assess the quality of ambulatory care – including coordination of that care – to prevent the complications of chronic and acute conditions that result in hospitalization. Although BCBSA and Plans appreciate

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	CMS's efforts to bring attention to the quality of ambulatory care, we believe this measure needs further testing and refinement before it can serve as an accurate indication of Plan performance. In particular, we note that the concept of care coordination, just one aspect of the proposed measure, is complex and not easily defined, much less quantified. We are also concerned that a measure of the rate of hospitalization may not accurately reflect the overall quality of ambulatory care. Accordingly, BCBSA and Plans encourage CMS to delay the measure's inclusion on the Display Page until the measure is further tested and refined. Recommendations: BCBSA and Plans recommend against inclusion of the Hospitalizations for Potentially Preventable Conditions measure on the Display Page in 2017 or in future Star Ratings until the measure is further tested and refined. We submit that the measure should not be included until 2019, at the earliest.
BlueCross BlueShield of Tennessee	BCSBT suggests that CMS push out the display date to 2018 and the star metric to the 2019 ratings. This would allow plans ample time to assess the display measure results and fine tune activity and strategies for the metric. BCBST also requests that CMS define coordination of care and explain what the expectation is for plans.
Cambia Health Solutions	As this is a brand new HEDIS measure, we would like this to remain on the display page longer
Centene Corporation	Centene recommends that this measure remain in display for 2018 while it undergoes further testing and review before its incorporation into the star ratings.
Cigna	We understand CMS rationale for including this as a Display measure and potential Star Rating from a quality perspective, but it could put newer MA plans at a slight disadvantage. To ensure good quality care, we recommend CMS add a longer runway period to allow for the establishment of coordination teams, processes, and provider education to ensure accurate reporting. We encourage CMS to incentivize hospital health systems regarding the increased need to interact with the MAPD plans. Newer plan performance may suffer some in this measure initially, as seen with the current All-Cause Readmission measure which also depends largely on Care Coordination.
Commonwealth Care Alliance	CCA would like to see more information regarding the research evidence regarding the validity of this measure as an independent measure of quality. Comorbid conditions - especially additive - need to be factored in any "preventable hospitalization" and the current risk adjustment is not well enough refined, especially around Behavioral Health, to accurately define Ambulatory Sensitive Condition. CCA does not support the inclusion of this measure on

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	the display page or in Star Ratings on the timeline proposed.
Fresenius Health Plans	We agree and support the measurement of hospital admissions for the NQF ambulatory sensitive conditions. However, as an ESRD C-SNP we would want to be compared with other ESRD C-SNPs or specific ESRD populations in this measure. It would not be meaningful or appropriate to compare the ESRD population with a general Medicare Advantage population.
Health Alliance	•Medication Reconciliation Post Discharge and Hospitalizations for Potentially Preventable Complications-- We suggest CMS consider reporting these measures as Display Measures for two years. This would allow plans time to study data from HEDIS 2016 reporting period (calendar year 2015).
Health Care Service Corporation	CMS states, "CMS is planning to include this measure on the 2017 display page and is planning to include it in the 2018 Star Ratings." CMS makes the same proposal for "2. Medication Reconciliation Post Discharge (Part C)." MAOs have experience reporting on the HEDIS medication reconciliation measure; so it is appropriate to move it to the Display Page and then include it in the 2018 Star Ratings. In contrast, this proposed hospitalization measure is a new measure that MAOs have not been reporting on to date, so MAOs and CMS do not have experience with the measure. HCSC recommends that CMS add this new measure to the Display Page for two years to evaluate it and provide MAOs with time to gain experience before counting it as a Star Rating measure. If the experience indicates the measure is valid and reliable, then CMS should consider adding it to the Star Ratings no sooner than 2019.
Health Net, Inc.	Request that any proposed Star measures be included on display page for a minimum of two rating periods. This measure will negatively impact Plans who serve lower SES members.
Healthfirst	We do not support the inclusion of first year NCQA HEDIS measures in the 2018 Star Ratings. Plans will not have had sufficient time to assess measure validity, evaluate performance, and begin targeted improvement efforts as the 2018 Star Rating measurement begins on January 1, 2016. We advocate for first year NCQA HEDIS measures to be placed on the display page for at least two years prior to being included in the Star Ratings.
HealthPartners	This measure is complicated with multiple inclusion and exclusion criteria. In addition, there is a risk adjustment measure layered on top of the complex measurement criteria. Given that this is a new measure that plans have no experience with, we recommend several years to pilot the measure prior to CMS adding to the display page. We believe that even subtle changes to the measurement specifications could produce variable results. Furthermore, CMS has not added a brand-new HEDIS measure to the display page in the past and we encourage CMS to wait until the measure is refined by NCQA prior to including on the display page.
HealthPlus	Healthplans have little experience with the technical specifications of this measure due to the introduction by NCQA beginning in HEDIS

Submitter	Response
	2016. It is recommended the measure remain on the display page for CY2017 and CY2018 Star Ratings.
Independent Care Health Plan	Our plan (H2237) would tend to encourage this and similar approaches, presuming that this measure also becomes a valued-based-purchasing withhold measure or quality star measure for hospital providers, nursing home providers, home health agency providers, etc. The performance measurement program (5-star and display measures) in its present form tends to produce a silo effect, with each provider community pursing its own set of measures, indifferent to other providers. At present, only one measure is shared across providers and plans – all-cause hospital readmission – where coordination of resources is encouraged as in the IMPACT Act of 2014. The silo effect deteriorates the potential for collective impact where all components of the provider community are integrated and focused on the same end. Recommendation: Introduce more measures that fit a collective impact model of population healthcare management.
Medica Health Plans	Medica would like more information on specifically what the "ambulatory sensitive conditions" are for this measure before commenting further.
Molina Healthcare Inc.	Molina Healthcare requests that CMS review this measure for validity and reliability. This type of risk-adjusted measure is a newer category of measure for NCQA and CMS should systematically evaluate the final rates prior to release. We also ask for CMS to review whether this measure is clearly linked to quality of care and allow for additional evaluation time before the rate for this measure is publicly displayed.
Senior Whole Health	This is a brand new HEDIS measure. There is a benefit to producing the measure for 2-3 cycles to work out the "bugs." While we support including this measure in the display page, we would discourage CMS from moving it too quickly to being a Star measure. Plans need to understand their performance relative to other plans and develop strategies to improve performance on the measure. Moving the measure too quickly to the Star program would disadvantage plans that had not been historically focused on this topic.
SNP Alliance	3. Hospitalizations for Potentially Preventable Complications (Part C) Our primary concern in regard to this measure is that it is new, and we believe that CMS is moving too quickly in considering it for inclusion in the 2018 Star Ratings. We believe this measure should remain on the display page for a longer period of time, at a minimum through 2018, in order for both CMS and plans to gain experience with the measure. At this point in time, plans do not know how they are performing on this measure, nor have they had adequate time to assess the efficacy of care coordination interventions to avoid potentially preventable complications arising from chronic or acute health care conditions. In advance of the measure moving to Stars, plans need time to understand both their current performance and, with that information, to consider opportunities for performance

Submitter	Response
	improvement. This is a significant new measure which will likely require additional physician-, hospital- and other provider-led interventions and coordination efforts driven by health plans. We are particularly concerned that health plans will only have access to relevant HEDIS data by the end of May 2016, leaving plans with inadequate time to assess the efficacy of these interventions. Therefore, to allow health plans to further analyze data, address opportunities for improvement, and interface with physicians and other care providers, we respectfully encourage CMS to consider keeping this measure on the display page for 2018 rather than including it as a 2018 Star Rating measure.
Triple S Advantage, Inc	TSA suggests is too early to include this measure in the Star Ratings. We propose to include it as a Display measure for 2017 & 2018; move it to Star Ratings by 2019.
Tufts Health Plan	E.3. Hospitalizations for Potentially Preventable Complications (Part C) We are concerned by the expeditious manner in which CMS intends to use this measure. Placing this first year's results on the display page and then planning to include it on the 2018 Star Rating assumes there are no issues with the measure. As we have seen with Plan All-cause Readmissions, NCQA has modified this measure since its initial introduction. At a minimum, we recommend that CMS exercise more caution in this measure's use and put it on the display page for two (2) years, waiting at least until 2019 to place this on the display page.
UCare	UCare requests that this measure remain on the display page for an additional year before moving to a ratings measure. This will allow adequate time to learn how the measure works and how to best operationalize it.
UnitedHealthcare	UnitedHealth believes that this measure is too broad in the scope of ambulatory conditions included. UnitedHealth recommends that CMS narrow the list of ambulatory-sensitive conditions to the top conditions as defined by the Agency for Healthcare Research and Quality (http://www.qualitymeasures.ahrq.gov/content.aspx?id=47604).
UPMC Health Plan	Recently, the National Committee on Quality Assurance (NCQA) developed a new risk-adjusted HEDIS 2016 measure of hospitalization for ambulatory care sensitive conditions based on the National Quality Forum-endorsed Prevention Quality Indicators (PQI). Its intent is to better measure the efficacy of ambulatory care in preventing the complications of chronic and acute conditions and reducing avoidable hospitalizations. The Agency intends to include this newly-developed measure on the 2017 display page and treat it as a Star Rating measure in 2018. At UPMC, we view effective care coordination as essential in the battle to reduce preventable complications arising from chronic or acute health care conditions. With that said, this is a significant new measure, which will likely require additional physician-, hospital- and other provider-led interventions and coordination efforts driven by health plans. We are

Submitter	Response
	particularly concerned that health plans will only have access to relevant HEDIS data by the end of May 2016, potentially leaving plans with inadequate time to assess the efficacy of these interventions. Therefore, to allow health plans to further analyze data, address opportunities for improvement, and interface with physicians and other care providers, we respectfully encourage the Agency to consider keeping this measure on the display page in 2018 as well.
VIVA Health, Inc.	The Plan recommends that this measure be delayed at least one year and instead be considered for inclusion in the 2018 display page and 2019 Star Ratings. As a newly introduced NCQA 2016 HEDIS measure, additional lead time before implementation into the display page and Star Ratings would allow for a more reasonable time period to collect and analyze measure data and adjust to any recommended measure specification changes.
VNSNY CHOICE Healthplan	VNSNY CHOICE encourages CMS to leave certain measures that are new as display-only for several years, as their effectiveness and accuracy is tested and refined. In particular, VNSNY CHOICE suggests that the Part C measures, Hospitalization for Potentially Preventable Complications and Statin Therapy for Patients with Cardiovascular Disease be included only as a display measure for at least two years.

4. Statin Therapy for Patients with Cardiovascular Disease (Part C)

Submitter	Response
Aetna	Having two measures related to Statin use, one in Part C and one in Part D, creates concerns in terms of data integrity given diabetes and cardiovascular diseases are highly comorbid in the Medicare population. There is also additional concern related to the Part C measure in terms of plan sponsor's ability to timely identify patients with atherosclerotic cardiovascular disease in order to intervene on those who do not take statins. Therefore, we recommend this measure not be included as a display measure in 2017 or a Star Ratings measure in 2018.
Alliance of Community Health Plans	ACHP is concerned that this measure does not account for statin intolerance among certain patients, which is an issue that has been examined in clinical studies. ACHP member plans have seen instances of patients with atherosclerotic cardiovascular disease who are deemed statin-intolerant after numerous trials with different statins and dosages. Given the occurrence of members who cannot tolerate statin therapy, ACHP urges CMS to examine ways to exclude members with a statin intolerance from the measure. If this measure is added to the 2018 star ratings, ACHP is also concerned plans will have inadequate time to understand and implement effective clinical interventions through coordination with providers, since plans will only have access to relevant HEDIS data by the end of May 2016. Given this concern, ACHP recommends CMS consider keeping this measure on the display page for an additional year.

Submitter	Response
America's Health Insurance Plans	CMS is proposing to include a new HEDIS 2016 measure, Statin Therapy for Patients with Cardiovascular Disease, on the 2017 display page and consider this measure for 2018 Star Ratings. This measure focuses on the percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity statin medication during the measurement year. For the reasons stated above for the new HEDIS measure on Hospitalizations for Potentially Preventable Complications, we recommend that CMS provide at least two years for plans to gain experience with reporting new measures prior to considering them for inclusion on the display page. Also, we understand that there are concerns with the measure's current specifications that have been raised with and are being considered by the NCQA. For these reasons, we recommend that CMS delay inclusion of this measure on the display page for 2017.
Anthem, Inc	CMS plans to include the statin therapy for patients with cardiovascular disease measure that NCQA added to HEDIS on the 2017 display page and in the 2018 Star Ratings. Since this is a first year measure for HEDIS 2016, plans will not have a line of sight into their performance on it until 2016. As a result, we recommend that CMS not add this measure until the 2019 Star Ratings, when plans and their data vendors will have sufficient time to prepare for its inclusion.
Association for Community Affiliated Plans	ACAP encourages CMS to leave certain measures that are new as display-only for several years, as their effectiveness and accuracy is tested and refined. In particular, ACAP suggests that the Part C measures, Hospitalization for Potentially Preventable Complications and Statin Therapy for Patients with Cardiovascular Disease be included only as a display measure for at least two years.
Blue Cross and Blue Shield of Minnesota	BCBSMN urges CMS to delay inclusion of these measures in the 2017 display page and subsequent Star Ratings. Changes to the technical specifications (e.g., eligible population for the MRP measure) are substantial and are first year changes. For display data to be meaningful, even as benchmarks, plans must be given adequate notice to establish effective programs.
Blue Shield of California	There are other ways to treat CV disease besides statins, which are not taken into consideration. Also, we are requesting for CMS to take into consideration patients with contraindications to statins.
BlueCross and BlueShield Association	CMS proposes to adopt a measure of Statin Therapy for Patients with Cardiovascular Disease for the 2017 Display Page and the 2018 Star Ratings. As proposed by CMS and as developed by the NCQA, the measure assesses the percentage of males, ages 21-75, and females, ages 40-75, who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate intensity statin medication during the measurement period.

Submitter	Response
	BCBSA and Plans appreciate CMS's attention to cardiovascular disease, but suggest that the Agency consider that there are other appropriate ways to treat the condition apart from a statin. Additionally, Plans note that some patients cannot take statins because of contraindications with other medications. As such, we are concerned that the measure is not an accurate reflection of appropriate member care, and therefore should not be included in the Star Ratings. If CMS decides to include the measure, we submit that, given its recent development, it should not be included until 2019, at the earliest. Recommendations: BCBSA and Plans recommend that CMS refrain from including the Statin Therapy for Patients with Cardiovascular Disease measure on the Display Page or in the Star Ratings. If CMS does include the measure in future Star Ratings, BCBSA and Plans request that it not be included until at least 2019.
BlueCross BlueShield of Tennessee	BCBST supports CMS' efforts in alignment of this metric with the guidelines and for choosing to not make it duplicative with the Statin Use in Diabetics measure.
Cambia Health Solutions	Of the two statin measures, the ASCVD measure relies on medical claims data to qualify members into the denominator. This matches more closely with the ACC/AHA cholesterol guideline for eligible population who will benefit from a statin. The Diabetes measure relies on PDE data to identify eligible members, which will simplify the reporting and targeting needs for plan sponsors. We would be supportive of either measure but we would favor the diabetes measure to begin with. Both measures incentivize higher patient care and we are supportive of the one that is claims based. We also support the age cap of 75.
Centene Corporation	For continuity with the Statin Use in Persons with Diabetes (SUPD), Centene recommends that hospice exclusion be added to this measure. Centene also requests a data definition for what constitutes a "High or Moderate Statin medication" to review in order to provide an informed response and recommends that CMS supply a list of NDCs as part of this definition. Similar to the comment above, we are concerned that CMS is moving too quickly in considering this measure for the 2018 Star Ratings. More experience with this measure is needed, in large part because there is not full consensus regarding the validity of the 2013 ACC/AHA blood cholesterol guidelines. As a result, we are concerned that there is not

Submitter	Response
	agreement on whether this is a valid measure of quality of care.
Cigna	We agree with CMS' proposal of establishing an age limit for the Statin Therapy for Patients with Cardiovascular Disease because the proposed age limits support health care quality, and we look forward to receiving data from CMS. We do have several recommendations for implementation: 1. CMS should provide plans with monthly data 2.CMS delay the proposed Star rating (2017 data) to 2019, which would allow plans to review initial reports received from CMS and the time needed to develop the type of programs CMS expects to improve member health outcomes. To achieve improved member health outcomes, plans musts be afforded the opportunity to develop quality programs. 3. CMS establish the same age criteria for Drug Adherence - Statin.
Commonwealth Care Alliance	Despite various guidelines to this effect, CCA does not feel that the evidence is clear enough to support the inclusion of this measure on display page or as a Star measure. Evidence and treatment recommendations continue to rapidly evolve and often in contradictory directions. CCA does not support measures using Statin therapy as a quality indicator at this time. If one is used, it should account for the presence of contraindications and possibility of alternative effective treatments, including new K9 agents.
Fresenius Health Plans	Current ESRD clinical practice guidelines recommend against starting lipid lowering agents in beneficiaries with ESRD. We request that CMS consider the fact that ESRD patients are a different population from the rest of Medicare beneficiaries and be excluded from this measurement's calculations.
Health Care Service Corporation	CMS states that the agency is planning to include a HEDIS measure that focuses on statin therapy for patients with cardiovascular disease on the 2017 display page and is planning to include this measure in the 2018 Star Ratings. HCSC agrees that this is an important area to monitor in members; however we have several concerns about the measure, which we have described below. Limiting the numerator to include those members dispensed at least one high- or moderate-intensity statin medication may not be inclusive of guidelines that allow for people to be on maximally tolerated doses. The 2013 AHA/ACC Guidelines state, "The maximum tolerated intensity of statin should be used in individuals for whom a high- or moderate-intensity statin is recommended, but not tolerated." Therefore members may have titrated to a maximally tolerated statin medication (such as pravastatin) that is not a high- or moderate-intensity statin medication (i.e. atorvastatin or rosuvastatin). Additional exclusions for members in the denominator should include (1) those taking gemfibrozil, which also is used to impact the lipid profile, but is contraindicated (i.e. not recommended) with statin use; and (2) those taking the new PCSK9 agents, which while recommended to be used with statin, also can be used without a statin to lower the lipid profile in persons intolerant to statin therapy. HCSC recommends that CMS work with NCQA to revise

Submitter	Response
	this measure to address these concerns before including it on the Display Page. We are concerned that public display without these revisions could be confusing and misleading.
Health Net, Inc.	Measure should be moved to Part D vs. Part C. Request that any proposed Star measures be included on display page for a minimum of two rating periods.
Healthfirst	We do not support the inclusion of first year NCQA HEDIS measures in the 2018 Star Ratings. Plans will not have had sufficient time to assess measure validity, evaluate performance, and begin targeted improvement efforts as the 2018 Star Rating measurement begins on January 1, 2016. We advocate for first year NCQA HEDIS measures to be placed on the display page for at least two years prior to being included in the Star Ratings. Additionally, we are concerned that this measure does not take into consideration members who may not want to start therapy or may not be able to tolerate the therapy.
Kaiser Permanente	For Statin Therapy for patients with atherosclerotic cardiovascular disease (ASCVD), Kaiser Permanente recommends a narrower list of diagnostic codes. Clinical ASCVD should not include atherosclerosis of aorta, generalized atherosclerosis, unspecified atherosclerosis, or atherosclerosis of other arteries. Research has shown that atherosclerosis in the aorta is highly prevalent (e.g. 39% of a cohort with a mean age of 44 in the Dallas Heart Study, a majority of those age 50 and over in the Rotterdam Study, see Footnotes 1 and 2), and is not predictive of myocardial infarction (MI) risk. We also submitted this comment in a letter to NCQA, endorsed by three prominent American College of Cardiology/American Heart Association cholesterol and risk assessment leaders, to recommend removing these codes from the inclusion criteria. Additionally, we recommend the ages of inclusion be 50-75 for females, as there are many potentially fertile women aged 40-50, and removing them from the denominator would help reduce their risk of inappropriate statin treatment during pregnancy. Footnotes: 1. Van der Meer IM, Bots MI, Hofman A, Del Sol, AI, Van der Kuip, DAM, Witteman, JCM et al. Predictive Value of Noninvasive Measures of Atherosclerosis for Incident Myocardial Infarction: The Rotterdam Study. Circulation 2004; 109: 1089-1094. 2. Maroules CD, Rosero E, Ayers C, Peshock RM, Khera A. Abdominal aortic atherosclerosis at MR imaging is associated with cardiovascular events: the Dallas heart study.Radiology 2013 Oct 269(1):84-91.
Medica Health Plans	Medica supports inclusion of this measure in the display measure set, but would encourage CMS to provide further definition of "Clinical Atherosclerotic Cardiovascular Disease," and we recommend the designation of "high to moderate intensity statin."
Molina Healthcare Inc.	Molina Healthcare requests that CMS take additional time to fully evaluate the scientific evidence supporting this measure and evaluate the final reported rates for this measure before results are publicly displayed or included in the 2018 Star Ratings. We

Submitter	Response
	specifically ask that CMS review the literature surrounding this measure since there is not consensus regarding the validity of the 2013 ACC/AHA blood cholesterol guidelines.
OutcomesMTM	OutcomesMTM supports the addition of this measure to the 2017 display page and 2018 Star Ratings. Beneficiaries with cardiovascular disease are often targeted for enrollment into MTM programs, so local pharmacies have already been responding to targeted medication reviews related to this measure and can be a valuable partner for plan sponsors looking for innovative ways to manage beneficiaries with cardiovascular disease.
Pfizer	Description of the Issue or Question: NCQA has developed 2 new measures for cholesterol management that reflect recent changes to the guidelines. CMS has selected one of these measures (Statin Therapy for Patients with Cardiovascular Disease [Part C]) for inclusion in the display for 2017 and within Star Ratings for 2018. Suggested Revisions/Comments: Pfizer supports NCQA's efforts to develop measures that reflect the updated guidelines and CMS's efforts to reincorporate cholesterol management measures into the Star Ratings. However, statins are indicated for and recommended in the guidelines for patients over the age of 75. As such, we recommend CMS not cap the age range for these measures at 75, but include all age ranges incorporated within the guidelines. Additionally, we encourage the development of distinct measures for different risk levels as the currently proposed measures may result in under treatment of patients for which high-intensity statins are guideline recommended. Finally, we also recommend reinstating measures related to LDL-C measurement as part of appropriate care. While guidelines do not currently focus on treatment targets, the full set of guidelines does incorporate LDL-C levels into recommendations for statin intensity.
PhRMA	PhRMA supports the addition of a statin therapy measure that aligns with the 2013 ACC/AHA blood cholesterol guidelines as a complement to the existing statin adherence measure. However, we remain concerned that the new measure is not sufficient to fill the gap created by retirement of the previous cholesterol screening measure or provide a complete reflection of current treatment recommendations. Cholesterol screening and ongoing monitoring of LDL levels for patients receiving treatment continue to be important aspects of the 2013 ACC/AHA guidelines, but these aspects of care are not reflected in the new measure. In addition, the proposed measure is a process measure and does not address the outcome of treatment. We encourage CMS to work with the measure developer to enhance the measure in order to evaluate screening, monitoring, and the outcomes of treatment in accordance with both the new guidelines as well as evidence demonstrating the benefit of LDL-C lowering and managing LDL-C to a target goal.
Senior Whole Health	This is a brand new HEDIS measure. There is a benefit to producing the measure for 2-3 cycles to work out the "bugs." While we support

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	including this measure in the display page, we would discourage CMS from moving it too quickly to being a Star measure. Plans need to understand their performance relative to other plans and develop strategies to improve performance on the measure. Moving the measure too quickly to the Star program would disadvantage plans that had not been historically focused on this topic.
SMT, Inc	As the CDC has pointed out, cardiovascular disease accounts for more than one third of all US deaths, and in 2010, the total costs of cardiovascular diseases were estimated to be $444 billion. We applaud CMS for making ASCVD a priority and establishing measures to promote appropriate focus on patients who have ASCVD event and diabetic patients who have not had a cardiovascular event. The statin measures will increase the number of patients having cardiovascular care, and this is an important objective for the patient, society, and overall healthcare. The measure as drafted, however, may have some unintended consequences that should be addressed before inclusion in the CMS STARS measure set. The measure does not support patient centric prescribing based upon response to medication, side-effects or available options outside the traditional statins. The intensity of statin dosing is not required to satisfy the measure which would be required for the measure to have the highest impact on reducing ASCVD risk and events. This is also true of the existing Statin Medication Adherence measure (D14). This means the measures can be 'passed' even when the dose prescribed is not consistent with the level of patient risk, giving the impression that appropriate care has been provided without achieving the desired reduction in ASCVD events. Schoen et al reported that 32% of their high-risk patients would need to have an increased dose to meet the new guidelines and achieve the desired 50% reduction in LDL-C. In this measure, they could pass and not be identified as receiving less than optimal management. (Schoen 2014. Am J Med) There would be no incentive for physicians to match the patient's dose with their level of risk. The measure specifications also do not recognize use of non-statins alone as an element in the denominator. Intolerance to statins has been recognized as an important element in cardiovascular care. There is an additional unintended consequence of not recognizing nonstatins therapy. There is significant misunderstanding about the importance of nonstatins as a result of the 2013 ACC/AHA guidelines. Although statins are recognized as first line of therapy for the majority of patients, nonstatins are recognized in the 2013 ACC/AHA guidelines the NLA recommendations and others, as important for subpopulations of patients in order to achieve control and reduce their risk for ASCVD events. Failure to recognize them in a performance measure aimed at patient adherence to treatment for elevated cholesterol gives the impression that they are not recognized by CMS and by other payers. This translates into restricting access in the pharmacy

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	benefit. The ACC/AHA 2013 Guideline Full Report acknowledges that the report of the side effects, e.g. muscle related effects, are underreported in RCTs because they systematically exclude all patients who have risk factors, serious comorbidities or concomitant drug therapy that might predispose them to these adverse events. (Stone, Full Report, 2013) The prevalence in trial conditions is 1.5-3%, but community based studies report a higher prevalence of 10%, up to 20%. (Fernandez Cleve Clin J M ed 2011, 393-403) In community practice, there may be milder forms of myopathy that do not rise to the level of reporting as in an RCT but do impact the patient's willingness to continue taking the drug. As written, they currently would exclude some of the muscle-related side effects. Up to 25% of the patients on statins have muscle related side effects which impact continued use of statins alone. (Cohen 2012; 208-215) In those who discontinued statins, 60% reported muscle-related symptoms as the reason. These patients would not be included in the measure. The measure would not address the quality of care of high risk patients as defined by ACC/AHA guidelines. This measure does not include use of combination statin/nonstatins. Maddox et al reported that ~50% of patients were on a statin alone and ~ 30% of patients in all subpopulations are on combination therapy. (Maddox 2014 JACC; 2183-2192). There are 2 populations this would affect: those with statin intolerance and those with statin resistance. Patients who are at high ASCVD risk and are statin resistant require treatment with statins and nonstatins to achieve the desired 50% reduction in LDLs are not addressed in the measure. Inclusion of use of statin/nonstatin combinations would address those at high risk of an unintended consequence of less than optimal care. The Star ASCVD statin measures should achieve optimal care for patients treated with statins, and combination of statins and non-statins. This would insure access to optimal care and outcomes. It would insure the rapid integration and patient access as new interventions emerge by avoiding an encumbered process that FDA approved agents would undergo created by the measures as currently written before they can address the clinically unmet need of, and improved outcomes for, these patients and providers. In 2016, ACC will be convening a panel to update the 2013 guidelines. We expect the update will include new evidence as well as address the myths and gaps related to the guideline recommendations and their application in daily clinical practice. It is anticipated that they will address two major controversies, the need for and use of LDL-C levels in treatment management and the importance and acceptance of nonstatin therapy in achieving therapeutic goals.
SNP Alliance	4. Statin Therapy for Patients with Cardiovascular Disease (Part C) Similar to the comment above, we are concerned that CMS is moving too quickly in considering this measure for the 2018 Star Ratings and recommend that this measure not be come a Star rating measure until 2019 at the earliest. More experience with this

Submitter	Response
	measure is needed, in large part because there is not full consensus regarding the 2013 ACC/AHA blood cholesterol guidelines. As a result, we are concerned that there is not agreement on whether this measure is a "quality" measure. In the process of gaining more experience with this measure, we believe it is important that CMS consider the following: ? Is the quality of diagnosis coding sufficient to identify the disease state for this measure? ? By limiting the numerator to individuals who were dispensed "at least one high or moderate-intensity statin medication during the measurement year," is the measure consistent with the 2013 AHA/ACC guidelines which state: The maximum tolerated intensity of statin should be used in individuals for whom a high- or moderate-intensity statin is recommended, but not tolerated? For certain individuals, the maximally tolerated statin medication, e.g. pravastatin, may not be a high- or moderate-intensity statin medication, i.e. atorvastatin or rosuvastatin. ? New PCSK9 agents also can be used without statin to lower the lipid profile in persons intolerant to statin therapy. ? Individuals taking gemifibrozil, also used to impact the lipid profile but which is contraindicated with statin use, should be excluded from the measure denominator. Lastly, we request clarification as to why this measure does not exclude beneficiaries in hospice consistent with the Statin Use in Persons with Diabetes measure below.
UCare	UCare requests that these remain display measures until more is learned about the potential risks of Statin use. Recent studies suggest Statins may significantly increase a person's risk of developing Type 2 Diabetes, after adjusting for other factors. Also, the measure specs do not exclude members that cannot tolerate Statin medications.
UnitedHealthcare	We are concerned about the large number of patients who may fall into the denominator for this measure from single outpatient diagnosis of atherosclerosis of the extremities, or unspecified atherosclerosis. We would recommend that the measure require two different diagnoses from the same value set, where only one of the diagnoses can be an atherosclerotic condition. Additionally, studies suggest any statin has the potential for control or lower cardiovascular risk, not just those classified as "high or moderate intensity statins." UnitedHealth recommends that CMS combine this measure with one of control and allow for continued use of a statin that may not be on the "high or moderate intensity" level if the patient is well controlled.
UPMC Health Plan	In addition to the aforementioned Hospitalizations for Potentially Preventable Complications HEDIS 2016 measure, NCQA also developed a new metric to measure the use of statin therapy for patients with cardiovascular disease. The Agency has proposed to include this statin therapy measure on the 2017 display page and treat it as a Star Rating measure in 2018. Similar to the Hospitalizations for Potentially Preventable Complications measure, we are concerned that health plans will only have access to relevant

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	HEDIS data by the end of May 2016; thus, leaving plans with little time to understand and implement effective clinical interventions through coordination with our network physicians. This measure has also yet to be reported through the Center for Disease Control and Prevention's (CDC) Patient Safety Analysis Website, which serves as a valuable tool for health plans to compare their performance to overall averages and monitor their progress in improving their patient safety measures over time. For the foregoing reasons, we respectfully encourage that the Agency also consider keeping this measure on the display page for 2018.
VIVA Health, Inc.	The Plan proposes that newly introduced NCQA 2016 HEDIS measures be given at least one additional year of consideration before inclusion into the Star Ratings program. The measure requires two years of continuous enrollment for member eligibility. The Plan requests that the two years of member enrollment eligibility begin in 2016 since that is the first full year reflective of the HEDIS measure implementation. The Plan also has concerns on the clinical validity of this measure. We request additional documentation be provided by CMS to prove the clinical validity. The Plan also requests that members who are determined to be intolerant to Statin Therapy be excluded from the measure. The Plan also recommends this measure exclude members taking PCSK9 Inhibitors from the denominator. Research suggests that a combination of statin medications with PCSK9 Inhibitors can lead to a higher likelihood of complications in patients, resulting in discontinuation of therapy. Plans with large numbers of diabetics taking PCSK9 Inhibitors would thus show incorrectly low metric rates for this measure, due to member-specific qualities beyond the Plans' control. Also, the Plan questions the categorization of this measure as Part C. Despite different measure stewards, the specifications are very closely aligned with Statin Use in Persons with Diabetes SUPD, a Part D measure. Cardiovascular disease and diabetes occur as co-morbid conditions frequently. It is therefore highly probably that the same members will be included in the eligible populations for both proposed measures. The Plan believes this redundancy is unnecessary and should be considered. The Plan requests that the measure be included in the proposed adjustment factor for socio-economic disparity.
VNSNY CHOICE Healthplan	VNSNY CHOICE encourages CMS to leave certain measures that are new as display-only for several years, as their effectiveness and accuracy is tested and refined. In particular, VNSNY CHOICE suggests that the Part C measures, Hospitalization for Potentially Preventable Complications and Statin Therapy for Patients with Cardiovascular Disease be included only as a display measure for at least two years.

5. Asthma Measures (Part C)

Submitter	Response

Submitter	Response
Aetna	Aetna does not believe the Asthma measures are appropriate measures for inclusion in the Medicare Star Ratings system, as this is not a common condition in the Medicare population. Thus, we would also not recommend inclusion of these measures on the display page. Further, it will be helpful for CMS to provide more detail around how to exclude false positives and how to define persistent asthma.
Alliance of Community Health Plans	ACHP would like to reiterate the reservations we conveyed in our comments from last year about the asthma measures that will be included in the 2017 display page, and we ask that CMS carefully consider these concerns. There appear to be drawbacks to the measures for the under-65 population that are likely to apply to Medicare patients as well – and, in any case, insufficient testing of the measures in the over-65 population. We offer the following brief comments and urge CMS to continue to consult with clinical experts: - Asthma Medication Ratio: We understand that it is difficult to differentiate older patients with asthma from those with COPD, as both may exhibit a chronic obstruction. Applying the measure in the star ratings is likely to prompt expanded use of treatments that may not be appropriate for Medicare patients whose diagnosis is not straightforward. - Medication Management for People with Asthma: We understand that the measure does not reflect NIH recommendations for step-down asthma controller therapy or management of patients who exhibit seasonal variations. There are also questions about the effect of the measure on clinical outcomes for under-65 patients that are likely to apply to Medicare patients as well. Given questions about the clinical appropriateness and effectiveness of these asthma measures, and insufficient testing in the over-65 population, we recommend that this may not be the best avenue for assessing asthma care in the star ratings. Effective control of an enrollee's asthma in a way that allows the enrollee to function effectively and avoid having to go to the emergency department ER may be a preferable way to assess how well the health plan is taking care of asthma patients. We encourage CMS to continue to study the asthma issue and work with measure developers on approaches that better reflect how well the enrollee's asthma is controlled, rather than whether he or she is receiving certain medications.
AltaMed	AltaMed agrees it is the right time to include Asthma Measures (Part C) in the display measures. The National Committee for Quality Assurance (NCQA) is aware this measure is dependent on categorizing and documenting asthma severity, and the transition from ICD-9 to ICD-10 will make this much more realistic and prevalent across all health plans.
America's Health Insurance Plans	CMS is proposing to add two asthma measures (medication management for people with asthma and asthma medication ratio) to the 2017 display page and consider them for inclusion in Star Ratings for future years. We believe that before adding such

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	measures, CMS should consider other measures that focus on conditions with higher prevalence in the Medicare population (e.g., COPD). We further note that a 2015 published study indicates that the HEDIS Medication Management for People with Asthma measure did not correlate with improved outcomes. Due to these issues, we recommend that CMS not include these measures on the 2017 display page. [Reference: Crans Yoon, Angelina, et al. The HEDIS Medication Management for People with Asthma Measure is Not Related to Improved Asthma Outcomes. Journal of Allergy and Clinical Immunology, March 2015.]
Anthem, Inc	Anthem supports the inclusion of condition-specific measures in the Star Ratings, particularly measures that are focused on common, chronic conditions prevalent in the Medicare population. However, we are concerned that if the Star Ratings measures become too narrow in focus, there will be a significant number of contracts that do not have enough eligible members in order to be rated on the measures. This, in turn, raises concerns that such measures will introduce bias or inequity into the Star Ratings system if, for example, only half of contracts are rated on an asthma-specific measure. Therefore, Anthem encourages CMS to include measures for conditions with a high prevalence in the Medicare population in order to focus plans to direct quality improvement efforts to areas that will impact the greatest number of members. Should the Agency continue to include this measure on the Display Page, we request additional clarity. CMS states this measure includes the "percentage of members 5 to 85 years of age who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period (i.e., first prescription date through end of measurement year)." We request additional information as to what constitutes "remaining" on a medication.
Blue Cross and Blue Shield of Minnesota	BCBSMN urges CMS to delay inclusion of these measures in the 2017 display page and subsequent Star Ratings. Changes to the technical specifications (e.g., eligible population for the MRP measure) are substantial and are first year changes. For display data to be meaningful, even as benchmarks, plans must be given adequate notice to establish effective programs.
Blue Cross Blue Shield of Michigan	BCBSM has concerns about using these measures in the Medicare population, and recommends CMS reconsider its proposal. The majority of Medicare Advantage members are ages 65-85 and have progressed from asthma to other respiratory diseases like COPD, leading to a small denominator and potentially invalid results if these measures are used. If these measures are included on the 2017 display page, we recommend CMS consider categorizing by age (18-50 and 51-64). We also recommend CMS rely on ICD codes instead of drug claims. Since many drugs are approved for treating both asthma and COPD, drug claims are unlikely to provide as accurate a picture as ICD codes about a plan's membership with asthma.

Submitter	Response
Blue Shield of California	Most of our elders are not suffering Asthma but COPD. There might be need to review if the right population is been targeted.
BlueCross and BlueShield Association	CMS proposes two NCQA measures related to asthma for the 2017 Display Page and will consider their inclusion in the Star Ratings in future years. The first measure, Medication Management for People with Asthma, is the percentage of members, ages 5-85, who were identified as having persistent asthma and were dispensed appropriate medications that they remained on during the treatment period. The second measure, The Asthma Medication Ratio, is the percentage of members who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year. BCBSA and Plans support CMS's use of measures developed by the NCQA. We believe, however, that the measures related to asthma are inappropriate measures for Plan member populations, whose advanced age means that the rate of chronic obstructive pulmonary disease (COPD) far outpaces that of asthma. BCBSA and Plans anticipate that the sample size of members with asthma will be small and not likely to yield statistically significant results. Moreover, we note that many patients with an asthma diagnosis may already be on the medications and have them – especially the controller medications – at home. Finally, one Plan noted questions among stakeholders about the correlation between measure performance and clinical outcomes in the asthma context. Therefore, we believe that adding asthma measures to the Star Ratings would be of little value to beneficiaries and may detract from other efforts better targeted for the member population. If CMS does add an asthma measure to the Star Ratings, BCBSA and Plans recommend that the measure be based on ICD codes, as opposed to drug claims. Several of the same drugs are used to treat both asthma and COPD, meaning that drug claims would not provide an accurate picture of which members have been diagnosed with asthma. Recommendations: BCBSA and Plans recommend that CMS not include the NCQA measures Medication Management for People with Asthma and The

Submitter	Response
	Asthma Medication Ratio on the Display Page in 2017 or in future Star Ratings. Moreover, BCBSA and Plans recommend that CMS not include any measures regarding asthma on the Display Page or in the Star Ratings. Should CMS proceed with an inclusion of an asthma measure in the Star Ratings, BCBSA and Plans recommend that an asthma diagnoses be determined through review of ICD codes as opposed to drug claims.
BlueCross BlueShield of Tennessee	BCBST is concerned that this measure would target quality efforts on the wrong population and therefore disagrees with the addition of the Asthma measures Instead, BCBST suggests that CMS use and/or develop measures that align with Chronic Obstructive Pulmonary Disease (COPD) measures because this condition is more relevant to the Medicare beneficiaries due to advanced age. Should CMS choose to move forward with implementing the Asthma Measures, BCBST recommends that CMS consider adopting these metrics as Display measures in 2018 and no earlier than 2019 as a Star Rating to provide plan sponsors adequate time to ensure their prescribers are aware of these measure additions, understand the measure specifications, and to implement strategies.
Cambia Health Solutions	There are 2 submeasures – ratio of controller medications 50% of year and 75% of the year. Would like confirmation that CMS is considering the 50% submeasure for inclusion
Centene Corporation	Centene opposes including these measures for the Medicare population. These measures are primarily used in pediatric populations and have not been appropriately tested in the MA-PD population, making the validity of this measure in this population questionable. We encourage CMS to focus measures on conditions with a high prevalence in the Medicare population in order to encourage plans to direct quality improvement efforts to areas that impact the greatest number of members.
Cigna	We do not support the proposal to include Asthma as a Star Rating measure. We recommend that CMS focus on related conditions that are much more prevalent in the senior population and more likely to negatively impact quality of life and life expectancy, such as COPD and Emphysema. Doing so would align with CMS' goal of improving member health outcomes. Focusing on Asthma would negatively and disproportionately affect plans with a high percentage of dual-eligible members because this population has a higher prevalence of asthma and due to sociodemographic issues, is less likely to be compliant.
Commonwealth Care Alliance	CCA does not support inclusion of these measures on display page or in Star Ratings. Diagnostic data in claims for older adults is not reliable as to the diagnosis of asthma (vs COPD and other pulmonary conditions). In addition, recent studies have raised

Submitter	Response
	questions as to the connection between performance on these measures and improved outcomes.
GlaxoSmithKline	GSK supported NCQA's expansion of its asthma measures to include older adults. GSK supports CMS' plan to include the Medication Management for People with Asthma and the Asthma Medication Ratio measures on the 2017 display page and the consideration these measures for inclusion in Star Ratings for future years. GSK believes that including these measures could close a gap in care that currently exists for the older population which has a lifetime asthma prevalence percent of 10.4(1) and current prevalence of 7%(2) in people 65 years and older. Data also shows that asthma attack prevalence among those with current asthma is 37.8% in the 65 and older population(3). Therefore, extending these measures to this older population seems appropriate and necessary. (1) Current Asthma Prevalence Percents by Age, United States: National Health Interview Survey, 2012, http://www.cdc.gov/asthma/nhis/2012/table4-1.htm (2) Lifetime Asthma Prevalence Percents by Age, United States: National Health Interview Survey, 2012, http://www.cdc.gov/asthma/nhis/2012/table2-1.htm (3) Asthma Attack Prevalence Percents among those with Current Asthma by Age, United States: National Health Interview Survey, 2012, http://www.cdc.gov/asthma/nhis/2012/table6-1.htm#modalIdString_CDCTable_0
Health Net, Inc.	Recommend not including this measure in Stars Rating program as it is more specific to a pediatric vs. Medicare population; Greater impact to Plans who serve DSNP members;
Healthfirst	We support CMS's decision to include these measures on the display page for the 2017 and 2018 Star Ratings. However, we have concerns about the validity of this measure, including: Lack of evidence that this process measure is linked to better health outcomes. In a 2014 literature review (Iuga AO, McGuire MJ. Adherence and health care costs. Risk Manag Healthc Policy. 2014;7:35–44), it was found that studies that showed better medication adherence in asthma cohorts did not demonstrate improved health care costs (i.e. lower health care utilization). Furthermore, in an analysis of Healthfirst Medicaid members, we did not find a relationship between asthma medication adherence and preventable admissions related to asthma. ? Asthma is typically a younger person's disease state; therefore, inclusion of this measure poses a greater burden to plans with a larger proportion of younger Medicare members (e.g., dual eligible members, originally disabled members). Plans with higher proportions of originally disabled members (who tend to be younger and more likely to qualify for the measure) are at a disadvantage in performing well on this measure because disabled members may have challenges in handling multiple complex stimuli, memory problems, loss of coordination and muscle strength, and hearing and visual challenges that make it

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	difficult to use inhalers and adhere to asthma medication plans. Measures related to respiratory disease states relevant to older populations (e.g., COPD) are more relevant for use in the Medicare Star Ratings. The potential for drug interactions is greater in elderly patients with asthma because many of these members are on multiple medications for other conditions. Desired therapeutic and clinical outcomes may be more difficult to achieve in elderly patients with asthma. Normal lung function may either be unattainable or be attainable only with potentially dangerous, high pharmacologic doses. We recommend that CMS risk adjust this measure to account for socioeconomic disparities faced by a significant proportion of our members (including factors addressed above), many of whom live in areas with a high prevalence of asthma (e.g., Bronx, East Harlem).
HealthPartners	HealthPartners continues to have concerns about the clinical appropriateness and effectiveness of the asthma measures. There has not been adequate testing of beneficiaries age 65 and over. We encourage CMS to wait until additional studies have been completed prior to including on the display page.
Humana	Humana has concerns about this proposal and recommends ensuring that NCQA feedback is shared prior to CMS incorporating these as a Star measure for individuals over age 65 as there have been issues related to a diagnosis of Asthma compared to COPD in this population. As the Pharmacotherapy Management of COPD Exacerbation measure already exists, adding another measure that may potentially see a high diagnosis error rate, such as the Asthma Measure Suite, would not be appropriate for populations over age 65.
Independence Blue Cross	Asthma management is important for older adults: however there could be other comorbid conditions such as COPD and having more controller medication use at 0.50 higher than total asthma medications may be challenging to manage.
Kaiser Permanente	Kaiser Permanente is submitting comments regarding both Asthma measures. Medication Management for People with Asthma (MMA): - Based on our experience and research, Kaiser Permanente opposes the inclusion of the MMA measure, both for the 2017 Display Page and for future years' Star Ratings. We are in continuing conversations with the measure steward, NCQA, and expect them to address the following concerns regarding the validity and reliability of the MMA measure in the near future. - Available evidence suggests that this metric does not truly evaluate the effectiveness of asthma management. A recently published study found that compliance with the MMA metric does not correlate with improvement in asthma outcomes, including no improvement in asthma-related hospitalization rates, and no improvement in short-acting beta2-agonist dispensing. (See Footnote 1) - The MMA measure does not support the NIH-recommended step-down of asthma controller therapy for patients whose asthma has been well controlled for a

Submitter	Response
	period of months, nor does it support appropriate management of patients with seasonal asthma management (the NIH supports discontinuing controllers for patients with seasonal asthma). - The use of asthma controller medication in the amounts necessary to achieve compliance with this measure may place patients at increased risk of medication-related adverse effects without the benefit of improved asthma outcomes. (See Footnotes 2-5) - There is a cost to members and to society and the health care system when the use of expensive asthma controller medications is driven higher without a corresponding reduction in emergency department/hospital utilization or other adverse asthma outcomes. - Additional considerations for MMA include calculation of days' supply around end of year and for medications with an overlap. With MMA truncating the days' supply at the end of a calendar year, 90-day dispensing after October 1 is not appropriately accounted for, undervaluing the true controller compliance. Also, for many patients with seasonally exacerbated asthma, it may be appropriate to prescribe multiple different medications on one day with the intention of using the stronger controller during the pollen and stepping down to a lower potency controller for the remainder of the year. This strategy, based on NIH guidelines, is not considered in the current MMA measure, which gives credit for only one medication. Footnotes: 1. Yoon AC, Crawford W, Sheikh J, Nakahiro R, Gong A, Schatz M. The HEDIS Medication Management for People with Asthma Measure is Not Related to Improved Asthma Outcomes. J Allergy Clin Immunol Pract 2015 Jul-Aug; 3(4): 547-52. 2. Weldon D. The effects of corticosteroids on bone growth and bone density. Ann Allergy Asthma Immunol 2009; 103:3-11; quiz 11-3, 50. 3. Chauhan BF, Ducharme FM. Addition to inhaled corticosteroids of long-acting beta2-agonists versus anti-leukotrienes for chronic asthma. Cochrane Database of Systematic Reviews 2014; Issue 1: Art. No. CD003137. 4. Schumock GT, Stayner LT, Valuck RJ, Joo MJ, Gibbons RD, Lee TA. Risk of suicide attempt in asthmatic children and young adults prescribed leukotrienemodifying agents: a nested case-control study. J Allergy Clin Immunol 2012; 130:368-75. 5. Philip G, Hustad CM, Malice MP, Noonan G, Ezekowitz A, Reiss TF, et al. Analysis of behavior-related adverse experiences in clinical trials of montelukast. J Allergy Clin Immunol 2009; 124:699-706.e8. Asthma Medication Ratio We also do not support the inclusion of the Asthma Medication Ratio (AMR) measure on the Display Page or in the Star Ratings, due to the difficulty with reliably diagnosing asthma in the senior population. Asthma commonly begins before age 40 and the obstruction it causes is generally described as being fully reversible, while COPD is generally diagnosed later in life and, by definition, has a significant irreversible (chronic) component. With aging, environmental exposures (including cigarette smoke) and long term airway inflammation, obstruction in asthma can often develop a significant fixed obstruction that mimics COPD. Accurately identifying

Submitter	Response
	those members over 65 with 'pure' asthma and little to no chronic obstruction may be challenging. Therefore, we believe that using the AMR measure in the Medicare senior population may lead to inappropriate care for many older members with an unclear or mixed diagnosis.
Medica Health Plans	Medica supports this measure in concept, but is concerned about measures related to asthma in this population. Many times, elderly beneficiaries are lumped in with patients who have COPD and/or CHF in provider coding practices. This could lead to a lower denominator for a given population for the asthma cohort, and/or could also inaccurately include COPD or CHF beneficiaries in the denominator who require different treatment plans and prescriptions.
MetroPlus health Plan	MetroPlus believes that for both these measures, Medication Management for People with Asthma and the Asthma Medication Ratio, coding may pose a challenge for providers who view "persistent asthma" as seasonal. Once a patient is coded as "persistent" this designation may not be changed by the provider thereby skewing the measures. Therefore, we believe that coding will be an issue and providers should be given time to adjust to the newly implemented ICD-10 coding methods.
Molina Healthcare Inc.	Molina Healthcare requests that CMS re-evaluate the reporting of this measure for the Medicare population, especially for individuals who are 65 years and older. We are concerned about the application of these measures to older populations, in part due to concerns regarding the reliability of diagnoses of asthma in individuals over 65. Until recently, these measures have been used primarily for children and younger adults, and we are concerned that there is not enough experience with the validity of this measure in older populations to move forward with using this as a quality measure for older adults.
OutcomesMTM	OutcomesMTM supports the changes made to this measure by NCQA and the addition of this measure to the 2017 display page. Beneficiaries with asthma are often targeted for enrollment into MTM programs, so local pharmacies have already been responding to targeted medication reviews related to asthma medication adherence and can be a valuable partner for plan sponsors looking for innovative ways to manage beneficiaries with asthma.
PhRMA	PhRMA supports NCQA's expansion of its asthma measures to include older adults. It is important to include older adults in these measures to ensure that their conditions are also being adequately managed and complications are thus avoided.
RxAnte	RxAnte supports the additional therapy areas you are considering for 2018 and commends CMS for pushing forward these quality initiatives.
SNP Alliance	5. Asthma Measures (Part C) In general, we encourage CMS to focus measures on conditions with a high prevalence in the Medicare population in order to encourage plans to direct quality improvement efforts to areas that impact the greatest number of members. More specifically, we are concerned about the application of these

Submitter	Response
	measures to older populations, in part due to concerns regarding the reliability of diagnoses of asthma in individuals over 65. Until recently, these measures have been used primarily for children and younger adults, and we are concerned that there is not enough experience with the validity of this measure in older populations to move forward with using this as a quality measure for older adults. Although these measures may warrant consideration conceptually, we believe more time and experience are needed to ensure that they yield meaningful results when applied to older adults in comparison to younger people.
Triple S Advantage, Inc	TSA suggest is too early to include this measure. In addition, Asthma is not a high prevalence disease among those over the age of 65; COPD has a higher prevalence and measures related to this disease already are a part of the Star Ratings
UCare	UCare questions the validity of this measure in the elderly population, as it does not always align with best practice.
VIVA Health, Inc.	To our knowledge, there is little established medical documentation to suggest that compliance to these measure specifications correlate to better outcomes for members. The Plan believes that more research is needed into the clinical validity of these measures before their inclusion into the Star Ratings. Also, due to the younger age of typical asthma patients, these measures will put additional pressure on plans with a high percentage of LIS/DE members. If this measure is included, the Plan requests it be added to the list of measures included in the analytical adjustment for Socio-economic disparity. Please also consider that the same medications used for asthma are also used for COPD in older populations. Finally, the language in the Request for Comments around inclusion of asthma measures into the Star Ratings is ambiguous. The Plan welcomes more clarification.
WellCare	WellCare supports this measure, but we have concerns about the timing. Specifically, CMS plans to post results of this measure in 2017 on the display page. However, this is a new HEDIS measure, and the data will not be publicly reported on NCQA's Quality Compass until after 2017. We ask CMS to delay publication of the data on the display page until 2018, so as to align with NCQA's publication schedule.

6. Statin Use in Persons with Diabetes (SUPD) (Part D)

Submitter	Response
Academy of Managed Care Pharmacy (AMCP)	AMCP supports CMS' recommendation to add the SUPD measure to the 2017 display page. AMCP, however, recommends the measure exclude from the denominator patients who have a documented contraindication to statin therapy as plans should not be penalized for patient-specific characteristics that are out of their control and that may vary significantly across different plans. AMCP also recommends that prior to finalizing this measure for the 2018 Star Ratings, CMS develop a mechanism for measuring not only whether

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	a patient is on the correct intensity of a statin, but also include a companion measure to determine whether the patient is adherent to the appropriate medication and taking the medication as prescribed.
American Pharmacists Association	APhA supports CMS' proposal to add four new Part C and one new Part D measure to the 2017 Display Measures: the Medication Reconciliation Post Discharge (Part C), the Hospitalizations for Potentially Preventable Complications (Part C), the Statin Therapy for Patients with Cardiovascular Disease (Part C), the Asthma Measures (Part C), and the PQA-endorsed Statin Use in Persons with Diabetes (SUPD) measure (Part D). These measures address important health care issues where there is opportunity improve the quality of care. APhA would support moving these measures to Star Ratings measures in the future if experience and assessment merit their inclusion in the Star Ratings program.
America's Health Insurance Plans	CMS is proposing to add the new PQA-endorsed measure, Statin Use in Persons with Diabetes, to the 2017 display page and consider this measure for the 2018 Star Ratings. This measure is used to assess the percentage of patients ages 40 to 75 years who received at least two diabetes medication fills and received a statin medication during the measurement period. We reiterate our comments above for the new HEDIS measure on Hospitalizations for Potentially Preventable Complications, that CMS should provide at least two years for plans to gain experience with reporting new measures prior to considering them for inclusion on the display page. This would enable plans and providers time to work with the specifications for the new measure and report on any issues during the initial years of implementation. Therefore, we recommend that CMS delay inclusion of this measure on the display page for 2017.
Anthem, Inc	Anthem supports the inclusion of the new SUPD measure on the 2017 display page, and agrees with CMS' proposal to exclude beneficiaries in hospice from the denominator of the measure for the entire year.
Blue Cross and Blue Shield of Minnesota	BCBSMN notes that treating diabetic individuals with statins is a recommendation to physicians and is not yet a widely accepted practice. We recommend that CMS delay consideration of statin therapy measures until such treatment becomes the standard of care among physicians.
Blue Cross Blue Shield of Michigan	BCBSM recommends using ICD codes to determine the diagnosis of diabetes for this new, PQA-endorsed measure, as opposed to drug claims, since certain diabetes drugs are used to treat conditions other than diabetes (e.g., weight loss, pre-diabetes). ICD codes will be a more accurate indicator of members with a diagnosis of diabetes.
Blue Shield of California	We would like for CMS to take take into consideration patients with contraindications to statins.
BlueCross and BlueShield Association	CMS proposes to include the Statin Use in Persons with Diabetes (SUPD) measure on the 2017 Display Page and in the 2018 Star Ratings. This measure would assess the percentage of patients,

Submitter	Response
	ages 40-75, who received at least two diabetes medication fills as well as a statin medication during the measurement period. CMS proposes to exclude beneficiaries in hospice according to the Enrollment Database from the denominator of the SUPD measure for the entire year. BCBSA and Plans request that CMS also exclude those patients who cannot use statins. For example, one Plan noted that treating diabetic individuals with statins is not yet a widely accepted practice among physicians and it remains a suggestion – not a requirement – for clinicians. If CMS decides to include the measure in 2017 or in the future, BCBSA and Plans recommend that the Agency use ICD codes to determine which members have diabetes. Reliance on drug claims can yield false information, as certain diabetes drugs are used to treat other conditions (e.g., weight loss, pre-diabetes). BCBSA and Plans also recommend that CMS exclude those patients taking PCSK9 inhibitors. In one Plans' experience, these patients are more likely to experience adverse effects with statins and may discontinue therapy as a result. Recommendations: BCBSA and Plans recommend that CMS exclude from the Statin Use in Persons with Diabetes measure those patients who cannot use statins. BCBSA and Plans recommend that CMS determine which members have diabetes by looking at ICD codes rather than drug claims. Finally, BCBSA and Plans recommend that CMS exclude those patients taking PCSK9 inhibitors.
BlueCross BlueShield of SC	Recommend not making the statin use in persons with diabetes measure an actual measure in 2018. This would be a measure similar to the use of ACE/ARB/RAS inhibitors in diabetic patients that was removed as a star measure. There is documented that about 10-15% of patients are statin intolerant. Also from looking at individual data the adherence to statins is always the lowest for our plan. It also appears to be low across the board when looking at the cut-points for the adherence measures and statin targets are 3-4% less than diabetes and ACE/ARB/RAS. The use of statins in diabetes patients should be encouraged. However if the member can't take the medication or is prescribed the medication but is not

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	adherent we will not achieve the clinical outcomes of decreased cardiovascular incidents which is the main reason for using the statin in the first place.
BlueCross BlueShield of Tennessee	BCBST is concerned that Diabetic patients may be wrongly diagnosed with Diabetes without having diagnosis data included in the measure's specifications. Also, many patients cannot take statins due to substantial side effects. Will specifications include exclusions for individuals with adverse reactions to statin drugs?
CareSource Management Group	We encourage CMS to leave certain measures that are new as display-only for several years, as their effectiveness and accuracy is tested and refined. In particular, Part C measures, Hospitalization for Potentially Preventable Complications and Statin Therapy for Patients with Cardiovascular Disease are included only as a display measure for at least two years. PQA has developed and endorsed a new measure which recommends moderate- to high-intensity statin therapy for primary prevention for patients aged 40-75 years of age with diabetes. We support CMS's decision to add this measure to the Star Ratings program, which aligns with current American College of Cardiology (ACC)/American Heart Association (AHA) guidelines, to the 2017 display page (using 2015 data), as well as to the 2018 Star Ratings (using 2016 data). We recommend that this measure exclude from its denominator those patients taking the recently approved PCSK9 Inhibitors. While these drugs are indicated for use in adjunct to the maximally tolerated statin therapy, our experience with this class of medication demonstrates patients taking PCSK9 Inhibitors are more likely to have experienced adverse effects to statins, which require them to discontinue therapy. Plans with a higher number of diabetic patients on PCSK9 inhibitors would therefore have falsely lower metric scores on this star measure, based on patient-specific characteristics out of their control.
Cigna	Can CMS please clarify the eligible population for this measure? Additionally, we would like to understand how CMS will define the denominator. Recommendations: 1. CMS establish the same age criteria for this measure as the proposed criteria for Statin Therapy for Patients with Cardiovascular Disease because the proposed age limit supports health care quality. 2. CMS share monthly data with plans. 3. CMS remove patients with true contraindications to statins from this measure, thus allowing for rating accuracy. If requested, we would be willing to assist CMS with the development of these exclusions.
Commonwealth Care Alliance	See comment related to Statin therapy in CVD.
CVS Health	PQA has developed and endorsed a new measure which recommends moderate- to high-intensity Statin therapy for primary prevention for patients aged 40-75 years of age with diabetes. We support CMS's decision to add this measure to the Star Ratings program, which aligns with current American College of Cardiology (ACC)/American Heart Association (AHA) guidelines, to the 2017

Submitter	Response
	display page (using 2015 data), as well as to the 2018 Star Ratings (using 2016 data). We recommend that this measure exclude from its denominator those patients taking the recently approved PCSK9 Inhibitors. While these drugs are indicated for use in adjunct to the maximally tolerated Statin therapy, our experience with this class of medication demonstrates patients taking PCSK9 Inhibitors are more likely to have experienced adverse effects to Statins, which require them to discontinue therapy. Plans with a higher number of diabetic patients on PCSK9 inhibitors would therefore have falsely lower metric scores on this star measure, based on patient-specific characteristics out of their control.
Fresenius Health Plans	Current ESRD clinical practice guidelines recommend against starting lipid lowering agents in beneficiaries with ESRD. We request that CMS consider the fact that ESRD patients are a different population from the rest of Medicare beneficiaries and be excluded from this measurement's calculations.
Health Care Service Corporation	CMS proposes "adding the SUPD measure to the 2018 Star Ratings (using 2016 data)." This measure relies on the inference that a person filling a diabetes medication is diabetic; however metformin, a diabetes medication, may be used for other conditions such as pre-diabetes or polycystic ovarian syndrome (PCOS). If members with these conditions are included in the contract, they would be added to the denominator when they do not meet the definition of the measure since they are not diabetic. Additional exclusions should be considered for members that do not want to start a statin (e.g., to avoid muscle pains, etc.) and members that cannot tolerate statin therapy. Exclusions for members in the denominator should include (1) those taking gemfibrozil, which also is used to impact the lipid profile, but is contraindicated (i.e. not recommended) with statin use; and (2) those taking the new PCSK9 agents, which while recommended to be used with statin, also can be used without a statin to lower the lipid profile in persons intolerant to statin therapy.
Health Net, Inc.	Request that any proposed Star measures be included on display page for a minimum of two rating periods.
Healthfirst	We support the evidence-based guidelines that recommend the use of statins in patients with diabetes. The guidelines seem appropriate for a broad population; however, there are challenges that Healthfirst and other plans currently face around the cholesterol adherence Star measure. Healthfirst has a large LIS population, and many of our LIS members encounter social and financial stress in their lives, which can make it difficult for them to adhere to their medications. This in turn negatively impacts medication adherence in our population. We recommend that CMS risk adjust this measure to account for the socioeconomic determinants of health that contribute to performance disparities on this measure. Factors include: Behavioral challenges around statin adherence Cultural biases Literacy and understanding of their disease Fear of side effects Unwillingness to change social habits Transient population, difficult

Submitter	Response
	to contact and outreach Additionally, we have some concerns regarding the place in therapy of PCSK9 inhibitors and how this class of drugs will affect this measure. Plans with a higher number of diabetic patients on PCSK9 inhibitors, may experience lower scores on this measure, as patients who take PCSK9 Inhibitors commonly have to stop statin therapy due to adverse events and failed therapy. We recommend that CMS takes this into account as well as other reasons why a member may not be on a statin, including inability to tolerate and failed therapy. While we agree with the guideline recommending that patients with diabetes are on a statin, there are clinically acceptable reasons for which a diabetic member may discontinue statin use. We recommend that such members be excluded from the measure denominator. Further, because the health plan does not have the health history of members new to the plan (including reasons for statin discontinuation), we recommend that members must have at least 12 months of continuous enrollment with the plan before being included in the measure.
Humana	Humana supports the adoption of the PQA Measure: Statin Use in Patients with Diabetes as a 2015 data year display measure and 2016 data year Star measure. This measure aligns with clinical guidelines that support statin therapy for primary prevention in diabetics and this specific measure would enable use in both MAPD and PDP populations, allowing for quality care and outreach related to appropriate statin treatment for all Medicare members. Prevention of primary cardiovascular events is essential to decrease future co-morbidities for diabetic members and this measure will further improvement in the care of patients.
Kaiser Permanente	Kaiser Permanente recommends that CMS use diagnosis codes or registry data, instead of prescription claims, to determine the presence of diabetes for purposes of this measure. Metformin, as a stand-alone agent, can be used to treat prediabetes and other conditions, thereby introducing many potential false positives into the denominator of the measure. Prediabetes and polycystic ovarian syndrome (PCOS), for which metformin is used, are not qualifying conditions for statins and this flaw in the metric may drive inappropriate over-treatment. As the prevalence of prediabetes increases over time, the measure will become increasingly flawed. Additionally, we recommend the ages of inclusion be 50-75 for females, as there are many potentially fertile women aged 40-50, and removing them from the denominator would help reduce their risk of inappropriate statin treatment during pregnancy.
Medica Health Plans	Medica supports inclusion of this measure in the display measure set.
Molina Healthcare Inc.	Molina Healthcare is concerned that CMS is moving too quickly in considering this measure for the 2018 Star Ratings. More experience with this measure is needed.
Novo Nordisk	Novo Nordisk supports the addition of the Statin Use in Persons with Diabetes (SUPD) measure to the Star Ratings program, which was

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	recently developed and endorsed by the Pharmacy Quality Alliance (PQA). The measure aligns with the 2013 American College of Cardiology/American Heart Association guideline for the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults, which recommends statin use for primary prevention for patients with diabetes 40 to 75 years of age. The recommendation is supported by three randomized controlled trials looking exclusively at primary prevention. This measure is also aligned with the American Diabetes Association recommendation, that "for patients of all ages with diabetes and overt CVD, high-intensity statin therapy should be added to lifestyle therapy." Finally, the SUPD measure complements existing measures already included in the Star Ratings program focused on improving care for patients with diabetes (eye care, blood sugar control, and adherence to diabetes medications). Novo Nordisk supports CMS in its efforts to continue to enhance the care delivered to MA and PDP enrollees with diabetes through the addition of this measure.
OutcomesMTM	OutcomesMTM supports the addition of this measure to the 2017 display page and 2018 Star Ratings. Beneficiaries with diabetes are often targeted for enrollment into MTM programs, so local pharmacies have already been responding to targeted medication reviews related to this measure and can be a valuable partner for plan sponsors looking for innovative ways to manage beneficiaries with diabetes.
PCMA	6. Statin Use in Persons with Diabetes (SUPD) (Part D) – CMS states it will add the SUPD measure to the 2017 display page and proposes adding the measure to the 2018 Star Ratings. The PQA-endorsed SUPD measure does not take into account the availability of new statin alternatives, such as PCSK9 inhibitors. PCMA is concerned that plans which chose to make statin alternative therapies readily available to members may be negatively affected if these therapies are not factored into the statin therapy measure. We are concerned that patients taking PCSK9 inhibitors are more likely to have experienced adverse effects from statin use which required them to discontinue therapy. Plans with a higher number of diabetic patients on PCSK9 inhibitors could have falsely lower metric scores on this Star measure, based on patient-specific characteristics that are beyond their control. While PCMA supports adding the new SUPD measure for patients with diabetes to the display page, we request that CMS clarify how the new statin alternatives will be taken into account going forward and adjust the measure accordingly. PCMA Recommendation: PCMA supports the addition of this measure for patients with diabetes to the 2017 display page, but we request that CMS clarify how the new statin alternatives, such as PCSK9 inhibitors, will be taken into account in the measure. We recommend that CMS address this issue prior to adding the measure to the 2018 Star Ratings.
Pfizer	Description of the Issue or Question: PQA has endorsed a new

Submitter	Response
	measure for statin use among patients with diabetes (Statin Use in Persons with Diabetes [SUPD] [Part D]). CMS has selected this measure for inclusion in the display for 2017 and within Star Ratings for 2018. Suggested Revisions/Comments: Pfizer supports the inclusion of the SUPD measure within the Star Ratings program and encourages CMS to develop and include additional statin measures that fully incorporate all populations for which statins are recommended in the guidelines.
PhRMA	PhRMA supports addition of the PQA-endorsed measure for statin use in persons with diabetes as a complement to the existing statin adherence measure. However, we remain concerned that the new measure is not sufficient to fill the gap created by retirement of the previous cholesterol screening and control measures for persons with diabetes. This measure captures one aspect of treatment for patients with diabetes, who have elevated cardiovascular risk, however, it does not address other important aspects of care like screening and ongoing monitoring of LDL levels as specified by the 2013 ACC/AHA guidelines. Unlike the retired cholesterol control measure, this measure also does not address the outcomes of treatment. We encourage CMS to work with measure developers to enhance its measurement of cardiovascular care for patients with diabetes to include screening, monitoring, and the outcomes of treatment.
PQA	We agree with the CMS proposal to add the PQA-endorsed SUPD measure to the: • 2017 Part D display page (using 2015 data); and • 2018 Part D Star Ratings (using 2016 data).
PrescribeWellness	We support this display measure and have added to our solutions for 2016 so pharmacists can target this patient population.
RxAnte	RxAnte supports the Statin Use in Persons with Diabetes (SUPD) measure for inclusion in the 2017 display measures and 2018 Star Ratings. This measure was created and adopted by consensus PQA stakeholders and has strong clinical rationale.
SCAN Health Plan	E. 6 Statin Use in Persons with Diabetes (SUPD) (Part D). New PQA endorsed measure will be added to the 2017 display page (using 2015 data) and proposed to be added to 2018 Star Ratings (using 2016 data). SCAN Comment: Moderate to high intensity statin therapy is recommended for primary prevention in persons aged 40-75 years with diabetes. This recommendation is included in the ACC/AHA guidelines. We agree with the guidelines and the proposal to add the SUPD measure to the 2018 Star Ratings (using 2016 data) to ensure that beneficiaries are receiving appropriate therapy.
SMT, Inc	The expectation that following recommendations in the AHA/ACC 2013 guidelines will result in reduced ASCVD events is predicated on the simple recommendation that the level of care and the intensity of treatment matches the patient's level of ASCVD risk. The intention of the guidelines is not to just prescribe any statin at any dose, as evidenced by the specificity of intensity of dosing by patient population and the grouping of drugs with dosing into the different

Submitter	Response
	intensity recommendations. This measure will accept any dose of statin to satisfy the measure, This will not be sufficient to assess whether the patient was on the appropriate intensity of statin treatment which is a key to reducing ASCVD events, which is the ultimate goal of the guidelines and related performance measures. Our concern is that this measure will give a passing mark to everyone who orders a statin for a patient and will not have the intended effect of providing patients with the intensity of therapy appropriate for their level of risk which is what is required to achieve maximum reduction in ASCVD risk, which means it will not achieve the desired long-term effect or it will not be possible to determine whether or not the measure had any effect on future ASCVD event rates.. This measure needs to accept only high intensity care within the denominator to ensure appropriate care has been provided. This is particularly true for patients with diabetes, where most require higher intensity of dosing. Quality measures serve as a safety net for patients and support appropriate care. Patient engagement is a critical element in improving healthcare. Measures need to be easily understood, actionable and provide the transparency necessary for provider selection. Because of the lack of connection between the dose of the statin and patient level of risk, drug plans which show compliance with the measure will not be equated with appropriate patient care. Patients cannot rely upon the proposed measure by itself as written to determine if they are being adequately treated. Development of additional measures should be entertained to address the issue of appropriate care, matching dose with risk level and monitoring response to insure adequate treatment. To ensure the measure addresses the sub-populations who require more than statins to manage their hypercholestolemia. In reviewing the measure specification, the measure denominator does not include the new FDA approved PCSK-9 therapies, PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C. The, IMPROVE-IT (Improved Reduction of Outcomes: Vytorin Efficacy International Trial) trial found a direct correlation: lower LDLs were associated with improved patient outcomes and lower risk for strokes, MIs, revascularization and heart attacks. A more recent study, Impact of Dual Lipid-Lowering Strategy with Ezetimibe and Atorvastatin on Coronary Plaque Regression in Patients with Percutaneous Coronary Intervention, JACC Vol 66 added evidence to the IMPROVE IT study. Dr. Sabina Murphy, Reduction in Total (First Recurrent Cardiovascular Events With Intensive Lipid-Lowering Statin Therapy Compared With Moderate Lipid Lowering Satin therapy After Acute Coronary Syndromes, study used a Poisson regression-analysis found lipid lowering therapy improved clinical efficacy with reductions

Submitter	Response
	in total primary endpoints events, driven by reductions in MI, strokes, and urgent revascularization. Taking into account total events more than doubled the number of events prevented by these lipid lowering therapies and statins in combination. Because of the need for combination therapy to achieve therapeutic results and the time lag in incorporating new evidence and drugs in the guidelines, the addition of "statins and other lipid-lowering drugs" would allow the measure to be timely as new evidence and drugs become available. The measure specifications also do not recognize use of non-statins alone as an element in the denominator. Intolerance to statins has been recognized as an important element in cardiovascular care. There is an additional unintended consequence of not recognizing nonstatins therapy. There is significant misunderstanding about the importance of nonstatins as a result of the 2013 ACC/AHA guidelines. Although statins are recognized as first line of therapy for the majority of patients, nonstatins are recognized in the 2013 ACC/AHA guidelines the NLA recommendations and others, as important for subpopulations of patients in order to achieve control and reduce their risk for ASCVD events. Failure to recognize them in a performance measure aimed at patient adherence to treatment for elevated cholesterol gives the impression that they are not recognized by CMS and by other payers. This translates into restricting access in the pharmacy benefit. Neither the statin measure associated with ASCVD nor this one address the need to monitor treatment response, which requires testing the LDL-C levels. There is the misperception that monitoring LDL-C levels for response is no longer needed. The data shows that there is already a trend to reduced LDL-C testing. This will have serious long-term consequences. Accenture's 'Predictive Health Intelligence Environment' data base with over 315 billion clinical, financial, and operational data elements, spanning 50 million unique patients across multiple therapeutic areas, 360 hospitals, and over 317,000 providers from 26 major integrated healthcare systems. We conducted a study on the rate of LDL-C testing with 14.5 million patients in 3 time periods who are either diabetic or at risk of getting a diagnosed with diabetes. Three periods were identified for conducting the study – 1) Pre guideline update – Jan 2012 to June 2012 compared to Jan 2013 to June 2013 2) Post guideline update Jan 2013 to June 2013 compared to Jan 2014 to June 2014 3) Post retirement NCQA and CMS LDL-C screening, monitoring and LDL-C <100 Jan 2014 to June 2014 compared to Jan 2015 to June 2015. We are observing a 10% increase in LDL test ordered prior to ACC guideline update, 0% change post ACC guideline and a 17% reduction after the LDL intermediate outcome quality measure retirement. In 2016, ACC will be convening a panel to update the 2013 guidelines. We expect the update will include new evidence as well as addressing the myths and gaps related to the guideline recommendations and their application in daily clinical practice. It is

Submitter	Response
	anticipated that they will address two major controversies, the need for and use of LDL-C levels in treatment management and the importance and acceptance of nonstatin therapy in achieving therapeutic goals.
SNP Alliance	6. Statin Use in Persons with Diabetes (SUPD) (Part D) As in the case of the measure Statin Therapy for Patients with Cardiovascular Disease, we are concerned that CMS is moving too quickly in considering this measure for the 2018 Star Ratings. More experience with this measure is needed.
Tenet Healthcare	The plan agrees with CMS's decision to add Statin Use in Persons with Diabetes measure to the Star Ratings program in 2018. This measure is endorsed by PQA and supports current ACC/AHA guidelines. While we agree with the decision we ask that this measure exclude from its denominator patients utilizing PCSK9 Inhibitors. PCSK9 Inhibitors are indicated for use as adjunct therapy to maximally tolerated statin use. Patients taking PCSK9 Inhibitors are more likely to have experienced adverse effects to statins, which may require them to discontinue therapy. Plans could have falsely lower metric scores on this star measure as a result of statin discontinuation.
Triple S Advantage, Inc	TSA suggest is too early to include this measure. Further research should address the requirements of the measure. Selection of therapy should be individualized to patient's clinical presentation. Not all patients can tolerate statin therapy. Additional comment: TSA suggest is too early to include this measure. Further research should address the requirements of the measure. For these patients there are other therapy methods which are more effective and proposed fewer risks for the patient.
UnitedHealthcare	As CMS considers adding this measure as a Star measure for 2018, UnitedHealth respectfully asks that CMS also how contraindications to statins and other clinical information indicating instances that statins may not be clinically appropriate for a member (for example a member with limited life expectancy <1 yr, dementia, metastatic cancer, patient refusal, inability to tolerate statins, etc.) may be factored into the measure. Since the measure is solely based off PDE data and may be missing critical clinical information, we ask that CMS consider accepting supplemental data or consider having some way of accounting for these types of instances if it becomes a Star measure. The American College of Cardiology/American Heart Association (ACC/AHA) guidelines recommend statin therapy for primary prevention for persons aged 40-75 years with diabetes (LDL 70-189mg/dL)). For patients, whose LDL-C is <70 mg/dL, the guidelines recommend that statin therapy should be individualized on the basis of considerations of ASCVD risk-reduction benefits, the potential for adverse effects, drug–drug interactions, and patient preferences. In using PDE data alone to determine plan performance on this measure, neither LDL values, nor any of the above would be taken into consideration for those members who

Submitter	Response
	have diabetes but may not be candidates for a statin-- including instances where patients with diabetes, having LDL in the 70-80 mg/dL range may chose not take statins since the guidelines do not provide clear direction on how low an LDL would be considered safe in patients.
VIVA Health, Inc.	The Plan requests that this newly introduced PQA measure be given at least one additional year of consideration before inclusion as a Star Ratings measure. The Plan has concerns on the clinical validity of this measure. We request appropriate documentation be provided by CMS around this measure to demonstrate sufficient medical validity insomuch to deem appropriate to include in the Star Ratings program. The Plan recommends the members with intolerance to Statin Therapy be excluded from this measure. Additionally, the Plan recommends this measure exclude members taking PCSK9 Inhibitors from the denominator. Research suggests that a combination of statin medications with PCSK9 Inhibitors can lead to a higher likelihood of complications in patients, resulting in discontinuation of therapy. Plans large numbers of diabetics taking PCSK9 Inhibitors would thus show incorrectly low metric rates for this measure, due to member-specific qualities beyond Plans' control. The Plan also notes the similarity of this measure to the proposed Statin Therapy for Patients with Cardiovascular Disease (Part C). Due to the frequency of co-morbid occurrence of diabetes and cardiovascular disease, it is highly likely that members will fall into both measures. The Plan believes this redundancy in member inclusion in such similar measures is unnecessary and should be considered. In the event CMS does not delay adding this measure for Star year 2018, the Plan requests that the measure be included in in the adjustment factor for socio-economic disparity.

F. New Measures

1. Care Coordination Measures (Part C)

Submitter	Response
American Pharmacists Association	APhA is encouraged by CMS efforts to identify meaningful care coordination measures. As CMS considers the activities that best represent care coordination, APhA requests that CMS consider examining the contributions of pharmacists to appropriate care coordination, especially as it relates to optimizing medication therapies. Medication-related problems often occur due to lack of care coordination, and pharmacists can play an important role in managing medications across multiple providers, communicating medication information, and exchanging reconciled medication lists. APhA recommends that the activities of pharmacists be included in the exploration of new care coordination measures. APhA believes that the additional measure topics being explored for 2018 and beyond represent important areas of quality measurement focus for

Submitter	Response
	CMS.
America's Health Insurance Plans	CMS describes its work to identify and develop potential new care coordination measures and indicates that as part of this work, the agency is considering use of various data sources including MA encounter data. It will be important for CMS to ensure measure development in this area consider the full range and variety of care coordination programs and activities that are employed by MA plans and their network providers, and we strongly recommend that the agency carefully assess whether use of MA encounter data would be the most appropriate vehicle to capture and reflect these practices. In addition, we note that implementation of encounter data collection via CMS' Encounter Data System (EDS) has required ongoing systems development and modifications on the part of the agency and plans, and has resulted in challenges in data submission and acceptance. We reiterate our longstanding position that it will be critical for CMS to validate over a sustained period of time that the data from EDS are complete and accurate before relying on these data for any purpose. We appreciate and support CMS' intention to continue to update the industry as work in this area continues and recommend that the agency also actively engage the industry throughout this process to take advantage of plans' practical experience with care coordination.
Anthem, Inc	Anthem supports CMS' initiative to develop care coordination measures that more comprehensively assess key elements of care management, particularly given our ongoing concern that the CAHPS survey serves as the primary data source for CMS' assessment of plans' care coordination efforts. The survey data present a number of limitations, some of which disproportionately impact SNPs. For example, the existing measures do not adequately consider the appropriate role of non-physician members of the care team. In addition, members may be more likely to find the measure language confusing, resulting in inaccurate responses. Finally, some of the measures request member comment on plan processes that they cannot reasonably be expected to assess (e.g., whether their primary doctor is fully informed on their specialty care). As CMS considers measure development related to care coordination, Anthem offers the following recommendations. First, we encourage CMS to rely on encounter data to the extent possible, due to its administrative simplicity. However, CMS should assess whether using encounter data is likely to capture the full clinical picture. The Agency should also ensure that any measures take into account the full range and variety of care coordination practices that plans employ. Second, we encourage CMS to review existing SNP Model of Care requirements to determine whether they may also be applied to evaluating care coordination (e.g., number of members eligible for care management services versus number of members receiving care management services). We also note that appropriately adjusted outcome measures could play a role in assessing care

Submitter	Response
	coordination, but should not be used as substitutes for measures that directly assess care coordination activities and programs. Finally, given that there already are significant reporting requirements in care coordination and care transitions, Anthem recommends that any future care coordination measures build upon those existing requirements.
Association for Community Affiliated Plans	CMS was not specific in the exact changes the agency proposes to make in these areas. Instead, CMS listed broad issue areas it hopes to address in future years, including care coordination, depression and pain management. CMS should put specific measures and changes to the measures out for public comment before these measures become display measures or included in stars.
Blue Shield of California	Must be focused on encounter data and not another chart.
BlueCross and BlueShield Association	BCBSA and Plans appreciate CMS's commitment to developing measures that reflect effective care coordination efforts and agree that, in general, effective care coordination contributes to improved health outcomes. We are concerned, however, that the concept of care coordination is difficult to define, much less quantify. As such, BCBSA and Plans caution CMS to carefully consider whether there is one particular aspect of care coordination that can be concretely defined and measured, while recognizing that Plans employ a wide range and variety of care coordination practices. We submit that any measure related to care coordination should be – to the extent possible – based on encounter data as opposed to medical chart review, although we acknowledge that not all aspects of care coordination will be present in encounter data. Finally, BCBSA and Plans recommend that any care coordination measure be developed from existing reporting requirements related to care coordination and care transitions, so as to minimize any additional administrative burden. Recommendations: BCBSA and Plans encourage CMS to proceed slowly and thoughtfully with the development and implementation of any measure related to care coordination. BCBSA and Plans recommend that any such measure be directed at one particular aspect of care coordination that can be measured with encounter data.
BlueCross BlueShield of Tennessee	BCBST requests that CMS define care coordination and what the expectation for plans is as it relates to care coordination. Reasonable standards need to be developed. Please define the efforts needed to be considered effective. BCBST agrees that development of such measures should be based on encounter data

Submitter	Response
	and not chart review data or member perception as is the case with CAHPS questions. BCBST suggests to CMS that the Care Coordination measures are reflective of a plan's process rather than performance and recommends that CMS work with NCQA to incorporate it into NCQA Quality Improvement Standards.
Cambia Health Solutions	We would like to see this as an encounter based measure
CAPG	Summary Recommendations: • CMS should develop an incentive to encourage health plans to enter capitated, delegated contracts with physician organizations. This should be done through the Star Rating program, for example adding stars credit for MAOs with a significant portion of their downstream contract revenue paid through capitated, delegated arrangements. • CMS should directly incent physician organizations that take "more than nominal financial risk" from health plans in Medicare Advantage. Background: Medicare Advantage is Critical to Delivery System Reform MA is growing in popularity and enrollment among seniors, particularly baby boomers. Today the program makes up nearly one-third of Medicare enrollment. The combination of appropriately aligned financial incentives and the program's flexibility to innovate to improve care make MA an ever-growing, popular option for our patients. In addition to being a high value option for seniors, Medicare Advantage plays a critical role in delivery system reform. Physician relationships with MA plans are on the same trajectory from volume to value as physician relationships in traditional Medicare, except that in MA, the relationships have reached the goal of percent of premium capitation. In some areas, this risk-bearing alternative payment model (percent of premium capitation) is widespread. For example, in California, this model is the norm. In these areas, we see substantially better quality and resource use performance, all of which directly benefits patients. Research shows that Medicare Advantage, when offered through an integrated, capitated APM provides higher quality for seniors than traditional Medicare. The quality difference is striking. For example, some CAPG members have readmission rates as low as six or eight percent as compared to a fee-for-service average readmission rate that hovers around 18 percent. Attached you will find a summary of a recent Integrated Healthcare Association study showing striking differences in quality performance between Medicare Advantage and fee-for-service Medicare. Beyond the role that MA plays in improving care for MA seniors, evidence suggests that a strong coordinated care infrastructure in MA supports the development of an advanced delivery system across payer types. A recent PwC report shows that "early ACO formation often has occurred in communities with successful Medicare Advantage programs, piggybacking onto the established market norms. Data provided by CMS show clusters in communities such as healthcare-rich New England, where ACO and bundled payment efforts co-exist with a high density of Medicare Advantage patients." These findings support our recommendation

Submitter	Response
	that CMS take a whole Medicare (MA and traditional Medicare) approach to delivery system reform. Investments in Medicare Advantage translate to a stronger delivery system overall and advancements in the very "alternative payment models" CMS seeks to build and spread in traditional Medicare. More should be done to Rapidly Transition Medicare to a Value-Based Delivery System Some CAPG members currently participate in two-sided risk arrangements, including capitation, with health plans in MA. Other CAPG members are actively seeking out these relationships. But there are still large swaths of the United States where these types of risk-bearing relationships do not exist and should be encouraged. CAPG has tried to gather information about what percentage of MA is tied to risk-bearing or capitated arrangements, but has not been able to determine the percentage with certainty. We estimate that less than 20 percent of MA is currently capitated when considering the relationship between the health plan and the physician group. This represents substantial opportunity to improve care for seniors. Current efforts to transition the nation's healthcare system overlook the critical role of MA. For example, under the Medicare Access and CHIP Reauthorization Act (MACRA), MA APMs are included only in the all-payer threshold beginning in 2021, whereas incentives for traditional Medicare's APMs begin in 2019, two years earlier. MA's inclusion in the All-Payer Threshold is an important step but does not go far enough to recognize the value and importance of this program in achieving high quality, risk-based coordinated care. Physician groups should be able to qualify for APM incentives based on their participation in Medicare Advantage APMs for 2019 to 2024. We encourage three important steps to remedy the problem: First, rather than a Medicare Part B threshold, organizations should be able to qualify based on a Medicare threshold (Medicare Part B and Medicare Advantage). MA contracts that include payment with more than nominal financial risk should count toward achieving the Medicare threshold for 2019-2024. APM contracts between MA plans and physician organizations where the physician group takes more than nominal financial risk, including capitation, should then explicitly count toward achieving this Medicare threshold. Second, the same financial incentives for risk in traditional Medicare should be available for physician groups taking risk in MA. That is to say, for a group that participates in MA, the APM incentive should apply to their MA revenue for physician services, not just their Part B revenue. This incentive should be paid directly to the physician or physician group taking the risk. The structure should be the same as MACRA: once a physician organization exceeds the threshold for risk, bonuses should be paid equally for both traditional Medicare and Medicare Advantage. The amount of the bonus should be adjusted to account for the financial incentives for health plans (our third recommendation). Third, financial incentives should be available to health plans that enter into two-sided risk arrangements with

Submitter	Response
	physician groups. With increasing frequency, CAPG hears from its members—among the most sophisticated risk-bearing physician organizations in the country—that many health plans are unwilling to offer risk-bearing arrangements to capable physician groups. Therefore, we encourage you to consider incentives for plans that enter capitated, delegated arrangements with physician groups. We believe that this type of incentive should be achieved through the Star Ratings program. In this year's rate notice, we encourage CMS to implement the necessary changes to incentivize the movement from volume to value in MA.
Centene Corporation	Centene Corporation requests more detail to provide substantive comment. We are interested in further elaboration of the NCQA testing parameters including specific information regarding administrative data under development by NCQA and the other cited contract. Centene has concerns regarding the use of medical records as a primary source of data as it contributes to provider abrasion, increases dependencies on provider office staff to incorporate unfamiliar documentation into the medical record, and is associated with increased administrative costs. Our concern is that care coordination measures are not truly linked to improved outcomes, putting plans in the position of having to devote resources to improving performance in areas that do not lead to improved outcomes. In addition, we encourage CMS to review existing SNP Model of Care requirements to determine whether they may also be applied to evaluating care coordination (e.g., number of members eligible for versus those receiving care management services).
Centers Plan for Healthy Living, LLC	We support the following measure stated on page 19 of the 11/12/15 memo: "follow-up with PCP/Specialist following hospital discharge or emergency department visit." We also advocate follow-up with PCP/Specialist, or other comprehensive clinical assessment following hospital discharge. Plans should not be assessed on the timeliness of their communication with the member's PCP/Specialist regarding inpatient admissions based on the admission date, but rather based on the date that the plan was notified of the admission; as quite often, neither the plan nor the PCP/Specialist are notified of the patient's admission until after the fact.
Cigna	We agree with CMS' decision to have this measure reported via HEDIS, by NCQA, as it would provide a true-accounting of a plan's performance. We look forward to receiving additional information concerning this measure. Does CMS intend to include encounter data that closes gaps for this measure from internal and/or external sources?
Commonwealth Care Alliance	CCA supports the development and testing of valid measures of coordination of care that can be demonstrated to be related to outcomes. CCA looks forward to seeing the results of testing of these measures. Testing that demonstrates feasibility, low burden, and a direct relationship to improved outcomes must be completed before such measures can be endorsed. Measures that do not

Submitter	Response
	require chart review should be a priority.
EmblemHealth	This measure is dependent on PCP participation. PPO members do not have an assigned PCP. Members without a PCP who have encounter data for inpatient admission/discharge, specialist visit, etc., should be assessed for care coordination via referral to Plan's internal case management for transitional care coordination, and/or assessed for services.
Health Care Service Corporation	CMS proposes to identify new care coordination measures and states that "NCQA, using administrative and medical record data, will begin testing the following proposed measures using 2015 data: primary care provider (PCP) notification of inpatient admissions, summary of care record in PCP chart, follow-up with PCP/specialist following hospital discharge or emergency department visit, and in the ambulatory setting whether there is a comprehensive assessment performed and documented by the PCP/specialist and whether there is a specialist visit summary in the PCP chart. Additionally, CMS has recently awarded another contract to develop care coordination measures using administrative data, including MA encounter data and Part D data." HCSC supports CMS' efforts to consider various options to assessing care coordination. We recommend that CMS focus on measures that do not involve chart review as this is a cumbersome and costly approach to gathering relevant data.
Health Net, Inc.	Concerns that this will result in a high burden to providers to capture data. Feel care coordination is already reflected in PCR measure and Care Coordination CAHPS measures.
Healthfirst	We advocate for first year NCQA HEDIS measures to be placed on the display page for at least two years prior to being included in the Star Ratings. This provides plans with the opportunity to evaluate performance given the characteristics of their membership and assess measure validity. We believe care coordination is an important aspect of quality of care. However, we do not support measures to be included in the Star Ratings that requires data to be collected primarily via chart review. This would greatly increase administrative burden and cost on the health plan and divert from other potentially more impactful activities.
HealthPartners	HealthPartners supports care coordination and point out that it can be carried out and paid for in a number of ways. We caution CMS in using encounter data to evaluate care coordination as it measures at the care system/care delivery level only. There is an assumption that plans will pay for care coordination using a code or contract in ways it can be measured. Care coordination activities done by plan staff or paid to providers outside the claims system (i.e., bonus payments) would not be accounted for in a measure based on encounter data only.
Kaiser Permanente	Kaiser Permanente supports the use of care coordination measures. As CMS continues its work in this area, we urge the agency to ensure that any measures of care coordination take into account

Submitter	Response
	visits and other provider-patient interactions that are conducted remotely, including by telephone and video. Certain follow-up visits, in particular, may be done as effectively by telephone or video conferencing as they are through in-person visits and can often improve the convenience and accessibility for the patient, thereby helping ensure the visit takes place. Plan sponsors that provide such access options to their members should not be penalized by any care coordination measures ultimately developed.
Magellan Health	Magellan advocates that for individuals who are seriously mentally ill (SMI) and/or those with a level of mental health disability, that the measure accommodate that a mental health provider may be primary and best positioned to coordinate that individual's care. There may also be certain challenges in sharing mental health diagnoses with an individual's medical provider that need to be considered in the measurement. (https://pcmh.ahrq.gov/sites/default/files/attachments/Integrating%20Mental%20Health%20and%20Substance%20Use%20Treatment%20in%20the%20PCMH.pdf)
Medica Health Plans	Medica has some concerns about how MA encounter data could be used to identify enrollees receiving Part A or SNF services who did not receive information about LTSS in a community setting. In our model of care, this is the role of the Care Coordinator, but would not be captured in encounter data. We are also concerned about the electronic exchange of health information. Minnesota privacy laws would not allow this level of data to be exchanged. Additionally, Cost plans moving to Medicare Advantage will need resources and time to build the type of support needed for the highest quality care management and transition support.
Molina Healthcare Inc.	Molina Healthcare agrees with CMS that care coordination for Medicare members is critical to ensuring members receive timely and appropriate health care and services. Our concern however is that CMS may inadvertently move forward with care coordination measures that are not truly linked to improved outcomes, putting plans in the position of having to devote resources to improving performance in areas that do not lead to improved outcomes. In reviewing the list of care coordination measures that NCQA is testing in 2015, we are concerned about the measures being tested that include additional review of medical records. We instead encourage CMS to pursue the development of measures that will allow for the use of administrative data as much as possible. We ask that proposed measures focus on follow-up with Primary Care Physicians and specialists after hospital discharge or emergency department visits. These two measures could be reported using administrative data. We also ask that CMS incorporate a population-based approach to care coordination performance measurement. Care management approaches should vary depending on the specific populations enrolled to avoid a one-size-fits-all approach.
Novo Nordisk	Novo Nordisk supports CMS' plans to explore the development and

Submitter	Response
	implementation of measures addressing care coordination in the Star Ratings program, given the need for measures to improve care for patients with co-morbidities. Care coordination has been recognized by several healthcare stakeholders as a priority area for care improvement. For example, one of the priority domains of the National Quality Strategy, "Effective Communication and Care Coordination", recognizes the importance of improved care coordination for optimizing patient outcomes and improving efficiency within the healthcare system. Measures addressing cross-cutting topics including care coordination complement existing measures addressing effective clinical care (e.g., adherence to diabetes medications) by driving a shift towards a more patient-centered, coordinated healthcare system. As CMS considers the implementation of measures that address care coordination for specific disease areas, Novo Nordisk encourages CMS to consider high-impact conditions, especially chronic conditions like cardiovascular disease and diabetes, as coordination is pivotal in these populations.
PhRMA	PhRMA supports the idea of exploring ways to evaluate care coordination. We believe that care coordination is an important aspect of ensuring patients receive appropriate diagnosis, treatment, and ongoing care.
Senior Whole Health	In general, we would encourage CMS to identify and commit to a core group of valid, tested measures and maintain them over a number of years. As much as CMS wants the plans to focus on "all the measures all the time," there are some very real constraints on a plan's ability to do performance improvement, particularly when the services that need to be improved are sourced from the delivery system, not directly from the plan. Reports have to be designed, incentive models need to be developed, contracts need to be changed. And the provider groups can be confused by a constantly shifting set of measures every year. True embedded QI can happen, but it takes time. A measurement set can evolve, but any new Star measure should be tested and proven, and only a small proportion of the set should change in any given year. Having a stable set of measures allows a plan to focus and commit a broad set of resources -- clinical and non-clinical staff, population health programs, delivery system and other community resources -- to the topic and achieve the performance improvement.
SNP Alliance	1. Care Coordination Measures (Part C) The SNP Alliance strongly supports CMS' efforts to develop care coordination measures that are shown to improve beneficiaries' quality of care. While we agree with CMS that it is possible that 5-Star contracts' performance is related to their ability to effectively coordinate care, we encourage CMS to undertake additional research to determine more definitively what makes 5-star plans successful. A more studied approach to understanding the factors that contribute to these plans' success will undoubtedly help CMS to better understand how care coordination

Submitter	Response
	improves outcomes and lead to the development of appropriate care coordination measures. Our concern is that CMS inadvertently move forward with care coordination measures that are not truly linked to improved outcomes, putting plans in the position of having to devote resources to improving performance in areas that do not lead to improved outcomes. In addition, we encourage CMS to review existing SNP Model of Care requirements to determine whether they may also be applied to evaluating care coordination (e.g., number of members eligible for versus receiving care management services). A population-based approach to performance measurement is critical, in particular in the area of care coordination. Care management approaches should vary depending on the specific populations enrolled, e.g. frail elders, individuals with different types of disabilities, individuals with multiple and complex medical conditions such as ESRD, individuals with mental illness, etc. Care coordination measures must take this into account and avoid a one-size-fits-all approach. With regard to data sources for care coordination measures, we share CMS' concerns regarding limitations of CAHPS survey data to assess the effectiveness of plans' care management approaches for reasons outlined in Section G.4 of our response to CMS' RFC. We also are concerned about the administrative burden associated with medical record review, both for health plans and on providers. For this reason, we support CMS' efforts to consider encounter data as a source of data for these measures. One challenge with respect to using encounter data, however, is that plans employ a variety of care coordination practices and, increasingly, are engaging in alternative payment arrangements that may make encounter data an inadequate source of data on plans' care coordination activities. For example, plans may be combining primary care and care coordination functions under per member per month (pmpm) payment arrangements that will not allow for encounter data to provide a full accounting of plans' care coordination activities. As plans are increasingly employing value-based purchasing arrangements and moving away from fee-for-service reimbursement structures in order to improve quality and cost effectiveness, encounter data may increasingly underrepresent plans' care coordination efforts. We strongly recommend that CMS' contract to develop care coordination measures using administrative data take this into consideration. Another key consideration in developing care coordination measures for the Star Rating system is that these measures are aligned with care coordination measures used in the Medicaid program and build on existing requirements. This is especially important for integrated plans subject to both Medicare and Medicaid requirements. We look forward to CMS making additional information available on these measures as it becomes known and on having the opportunity to provide input. It is not clear, based on their current state of development, that care coordination measures will be ready for either Star ratings or the

Submitter	Response
	display page as soon as 2018. It is important that these measures are adequately vetted.
Triple S Advantage, Inc	TSA suggest for the component of the Care Coordination to become an administrative measure and have the main source of data to be claims and encounters. We support more research related to this measure and sources of data.
UnitedHealthcare	UnitedHealth believes that care coordination should be agnostic to the setting or provider that provided the service. UnitedHealth recommends that CMS include multiple provider types so that the measure addresses whether a member who felt they needed care coordination received it.
VIVA Health, Inc.	The Plan agrees on the importance of effective care coordination and is supportive of further development of meaningful measurements. The Plan recommends CMS continue to take into consideration the impact of these new measures on high percentage Dual/LIS/Disabled plans, as coordinating care for this population may be intrinsically more difficult. Additionally, transmission of data across providers remains largely disparate due to significant variability among provider electronic data exchange capabilities. For example, some rural parts of the state still lack the broad-band infrastructure necessary to implement modern data sharing capabilities, which are foundational to many care coordination & notification strategies. Measure construction should account for situations where establishment of the Member/PCP relationship is impacted by PCP physician shortages. Lack of timely access to Primary Care Physicians due to such shortages across many areas of the country is a current national issue. The Plan asks CMS to consider the impact of these situations carefully as measures are constructed.
WellCare	WellCare supports CMS' desire to expand measurement in the care coordination realm. CMS requested comments on measures that could be developed using MA encounter data. WellCare recommends the development of a measure examining the placement of a member after discharge from an inpatient stay. Additionally, WellCare recommends a measure examining the percent of members readmitted to an inpatient setting more immediately after discharge from an acute inpatient admission. This would demonstrate poor discharge planning or show which members were discharged too early from the hospital.

2. Depression Measures (Part C)

Submitter	Response
Aetna	Aetna submits the following for the Depression Remission or Response at Six Months measure: o While the prevalence of various types of depressive disorders is certainly significant (studies suggest upwards of almost 20%, with the prevalence of co-morbid depression for those with chronic medical conditions being greater), the actual diagnosis of such disorders recorded by physicians is

Submitter	Response
	much lower. Therefore, if this measure were focused specifically on individuals with a recorded diagnosis, it would only include a minority of members who are actually receiving treatment for these conditions. o The identification and recording of symptoms by treating physicians is a challenge (as is the actual diagnosis, as indicated above). In order to record a baseline and to identify quantifiable improvement in symptoms, there would need to be a consistent approach to the process – likely utilizing a validated instrument (such as the Patient Health Questionnaire-9 or the Geriatric Depression Scale). Typically, these types of instruments are not deployed as standard procedure by the physician community. Therefore, identification of remission and improvement in symptoms in any consistent way would be elusive. o An better approach to address depression might be to focus specifically on those individuals being engaged in case/disease management programs. The measure could incorporate certain of these four components: (1) The percentage of engaged members being screened for depressive disorders (due to the high prevalence of co-morbid depression, this could be a high risk subgroup of all members); (2) The percentage of screened members referred for further evaluation of depressive disorders (evaluation by specialized behavioral health case management teams); (3) The percentage of those members evaluated as positive for depressive disorders referred for treatment (treatment by either behavioral health care providers and/or non-BH physicians); (4) The percentage of those members referred for treatment who are re-evaluated for symptom level by either treating physicians or specialized behavioral health case management teams.
Alliance of Community Health Plans	ACHP supports efforts to appropriately recognize plans that effectively manage depression and reduce its symptoms, but we have concerns about the Depression Remission or Response in Adolescents and Adults (DRR) measure. We are concerned that the measure may over-emphasize the ability of plans to negotiate with providers the exchange of PHQ-9 data via electronic clinical systems, as opposed to accurately assessing the reduction of depression symptoms. As CMS continues to examine depression measures, CMS should consider approaches that measure reductions in MCS scores from the HOS for members with high baseline scores.
Blue Shield of California	Need a screening measure first before it is used an outcome measure. Some of the providers don't have the CMR system to transfer the data.
BlueCross and BlueShield Association	BCBSA and Plans understand that CMS is considering the addition of the NCQA's Depression Remission or Response in Adolescents and Adults (DRR) measure in future Star Ratings. The DRR measure assesses the percentage of individuals ages 12 and older with depression and an elevated PHQ-9 score (greater than 9) who achieve a PHQ-9 score of less than 5 at six months or have a 50%

Submitter	Response
	reduction in their PHQ-9 score. BCBSA and Plans appreciate CMS's efforts to incorporate a measure reflecting the treatment of depression. Plans have concerns regarding the appropriateness of this metric. At the most, Plans recommend that any first step be limited to using a measure to assess depression screening. The DRR measure is based on treatment outcomes, and Plans note that beginning to measure performance with a screening metric will allow Plans to engage providers more effectively in order to focus on appropriate care for depression. To the extent that a depression-related measure relies on data from electronic clinical data systems (as the DRR measure is purported to do), BCBSA and Plans request that CMS provide sufficient lead time between the announcement of the measure and its incorporation in either the Display Page or the Star Ratings. Plans note that some providers are not prepared to transmit this data electronically, and this capability will require some time to develop and operationalize. Recommendations: BCBSA and Plans recommend that any measure related to depression focus on screening, rather than treatment outcomes. If CMS elects to use a measure that depends on electronically submitted data, BCBSA and Plans urge CMS to provide sufficient notice so that providers can develop the capability to transmit this data.
BlueCross BlueShield of Tennessee	BCSBT recommends that CMS place this measure on the display page for the first 1-2 years following HEDIS approval to ensure that plans have time to understand performance and adapt processes and strategies. For instance, a screening needs to be completed first rather than jumping straight into a measure of outcome and Plans need time to help providers set up processes to support inclusion of the PHQ-9 into office work flows.
Cambia Health Solutions	We would like to see this first as a process measure and then progress to outcomes based measure Would this be for integrated health plans or all health plans?
Centene Corporation	Centene Corporation supports the addition of a depression management measure. We recommend that the follow-up outcome assessment be included into the required annual assessment and updating of the care plan.
Cigna	We request that this measure be studied for multiple measure years before being considered to move from display to a Star Rating.

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Clover Health	Clover Health supports this measure, critical in the evaluation of the proper management of depression, a condition that affects a significant proportion of our members.
Commonwealth Care Alliance	CCA looks forward to seeing tests of the feasibility and validity of this measure. CCA is very concerned about the addition of any measures that are based on member self-report via survey as well as any measures that would have specifications allowing for data to be drawn from multiple types of electronic data systems due to validity issues.
EmblemHealth	It is less likely that members with chronic depression will show the kinds of improvement on a PHQ9 or other assessment tool that a newly diagnosed member would demonstrate. At the chronic stage, the emphasis is on maintenance, preventing decline, and medication monitoring. The Plan recommends establishing a specific time period of newly diagnosed members and/or members who resumed psychological services, after a period of not receiving, in the calendar year. If a member falls into this timeframe, then they can be assessed for progress in their mental health interventions.
Fresenius Health Plans	Please reconsider the limitation to PHQ-9 for monitoring depressive symptoms, and instead include other recognized methods in this measurement. CESD-10 and PHQ-9 are both widely accepted and recognized for producing results. The CESD-10 is the depression screening tool used by the Dialysis Outcomes Practice Patterns and Study Program (DOPPS). The DOPPS is a study of hemodialysis practices that begun in 1996 and is now in place in over twenty countries. The program collects observational longitudinal data from around the world to identify clinical practices with the most benefit for patients.
Health Alliance	•Depression—In order to comment further on gathering this information, our plan requests clarification on the new data collection methodology for HEDIS. In the past any medical record review connected with mental health has been difficult due to privacy concerns. Will this be taken into account?
Health Care Service Corporation	CMS states, "NCQA has adapted a provider-level depression outcome measure developed by Minnesota Community Measurement for use in HEDIS." CMS indicates that, "If approved, the new measure would be published in HEDIS 2017." CMS also states that these measures would be under consideration for the Star ratings or display measures for 2018 and beyond. HCSC supports measures that address depression, one of the common conditions in the Medicare population. However, we believe it is premature to focus on an outcomes measure at this time. HCSC has recommended in the past that CMS include a measure focused on depression screening. In working with providers, it is more effective to begin with increasing screening rates and developing treatment plans, before measuring outcomes. We recommend that as CMS continues to monitor development of measures for depression, that the agency start with screening measures well before moving to

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	outcomes measures. In addition, we find that behavioral health providers generally are not as advanced in utilizing EMR systems for reporting data. Most labs do not consistently use Logical Observation Identifiers Names and Codes (LOINC codes), which are needed to capture data for depression measures. Overcoming these impediments will entail a long lead time before successful reporting of depression data can occur. HCSC recommends that CMS evaluate the readiness of behavioral health providers to utilize LOINC codes and report data via EMRs before including these new requirements on the display page or in the Star Ratings.
Health Net, Inc.	Measure impact on Plans which low SES membership. Request that any proposed Star measures be included on display page for a minimum of two rating periods.
Healthfirst	We advocate for first year NCQA HEDIS measures to be placed on the display page for at least two years prior to being included in the Star Ratings. This provides plans with the opportunity to evaluate performance given the characteristics of their membership and assess measure validity. This measure is being piloted by NCQA and should not be included in Medicare Stars as a display measure until the results of that pilot are known and public commenting has been conducted. Additionally, many plans do not have the capability of capturing the electronic data in the way that this measure specifies.
HealthPlus	This measure uses a minimally tested new methodology created by NCQA and focuses on healthplans with significantly integrated data exchanges for reporting the measure. The measure is too new to accurately reflect the level of depression assessment, scope of care provided and improvement outcomes.
Humana	Humana is concerned that the 6-month measurement window may not be appropriate to demonstrate impact. There is evidence of considerable variation in treatment response trajectories. Moreover, it is common for clinicians to wait for 6–12 weeks before considering a switch to a different medication when there is evidence of nonresponse to the initial antidepressant therapy. We also note, that medical record reviews demonstrate on average only about 25-30% of providers using PHQ-9 regularly. Reference 1. Kudlow, Paul A., Roger S. McIntyre, and Raymond W. Lam. ""Early switching strategies in antidepressant non-responders: current evidence and future research directions."" CNS drugs 28.7 (2014): 601-609."
Kaiser Permanente	Kaiser Permanente strongly supports the development of better behavioral health measures—including measures of depression screening and symptom improvement—than currently exist in the HEDIS dataset. We strongly support and participate in the NCQA behavioral health learning collaborative, from which we hope better behavioral health measures will eventually be developed. We are concerned, however, that while the patient health questionnaire, PHQ-9, is an important tool to screen for, assess and monitor depression symptoms, few health plan sponsors currently have

Submitter	Response
	access to electronic PHQ-9 data for the majority of their members with new episodes of depression. We look forward to working with NCQA through the behavioral health learning collaborative to help develop, test, refine and adopt better measures in future, which with demonstrated validity and reliability, will become candidates for inclusion in the Star Ratings.
Medica Health Plans	Medica supports CMS in their endorsement of the Minnesota Community Measure's Depression remission or response measure as this is a way to address a condition thought to be underdiagnosed in most elder populations. We are looking forward to working with CMS and the measure steward to support enrollees who require diagnosis and treatment for depression. We do have a concern about the ability of Medicare plan sponsors to request and receive data via electronic health records to support the HEDIS process. Minnesota provider groups currently report this measure to the data steward in a timeframe that would not allow for access to the data during the HEDIS timeframe and prior to the audits completed by MNCM. The data submission from providers is the most complicated to report to the steward given the index event/remission response cycles for this measure steward. Additionally, Minnesota providers have been reluctant to share electronic health record information with plan sponsors citing HIPPA and Minnesota privacy laws. Medica would like to do all we can to support the timely acquisition of these data to support our beneficiaries, but we wanted to highlight these known current challenges related to report.
MetroPlus health Plan	MetroPlus believes that this measure should be open to other validated depression screening tools other than the PHQ-9.
Molina Healthcare Inc.	Molina Healthcare requests that CMS evaluate the impact of data collection and reporting of the measure and how it will impact Medicare Advantage and Medicare-Medicaid Program plans prior to implementation. Collecting patient-reported information from providers about depression outcomes will be difficult, as the data will need to come from the medical record. We also ask that CMS consider adopting an initial depression screening measure before focusing on outcomes.
OutcomesMTM	OutcomesMTM supports the addition of these measures to the 2018 display page and would encourage plan sponsors to leverage relationships with local pharmacy networks to administer the PHQ-9 tool. The accessibility of pharmacies for beneficiaries coupled with the new data collection methodology for HEDIS, through electronic clinical data systems, positions pharmacies providing MTM services very well to help assess depression symptom control and coordinate care with physicians for this population.
PhRMA	PhRMA supports adoption of NCQA's patient-reported outcome measure for depression remission or response in adolescents and adults in future Star Ratings. This measure is based on the PHQ-9 tool, which has a strong evidence base as a disease management tool for assessing whether patients with depression have achieved

Submitter	Response
	remission or have experienced a change in symptoms. As a patient-reported outcome measure, this measure can ascertain the patient's view of his or her condition and possible improvement as a result of treatment and serves as a valuable indicator for quality from the patient perspective.
RxAnte	RxAnte supports the additional therapy areas you are considering for 2018 and commends CMS for pushing forward these quality initiatives.
SNP Alliance	2. Depression Measures (Part C) While the SNP Alliance appreciates the need to evaluate the ability of plans to address members' mental health needs, we are concerned about CMS' proposal to utilize a patient-reported outcome measure that would require plans to survey their members. This would place considerable administrative burden on plans. Further, regardless of how the survey is administered, we have expressed concerns regarding the appropriateness of survey-based measures for the populations enrolled in SNPs. Among SNP enrollees, we have concerns regarding response rates and the ability of frail older adults and others with intellectual or cognitive disabilities to report data yielding valid measures. Rather than moving immediately to an outcome measures for depression, we recommend that CMS initially consider a screening measure. From our members' perspective, this would be an appropriate first step in working with providers. We also need additional information regarding the new data collection methodology for HEDIS that is referenced in CMS' Request for Comment. It appears complex and raises concerns regarding the consistency with which data would be collected. Further, SNP Alliance members' experience suggests that providers in the behavioral health arena may not be equipped to provide data electronically on a consistent basis. We look forward to the results of testing on the use of this new methodology.
Triple S Advantage, Inc	TSA suggest is too early to consider including this measure as part of the Star Rating. It could be appropriate to wait for the results of the HIE pilot
Tufts Health Plan	F.2. Depression Measures (Part C) Although we support CMS' efforts to lessen depressive symptoms for those diagnosed with depression, we have strong concerns about the challenges in collecting relevant PHQ-9 scores for the measure in question (DRR). The measure's design does not appear to reward plans that are able to manage depression and reduce its symptoms as much as it rewards plans that are able to contractually negotiate the exchange of electronic clinical data regarding PHQ-9 scores with providers. Additionally, behavioral health providers, who tend to be more independent, seldom have the resources to integrate an EHR with a health plan. CMS may wish to encourage more data exchange between payors and providers, but we believe this could be done more directly, instead of under the guise of reducing depressive symptoms. If CMS wants to create a measure that assesses the

Submitter	Response
	reduction of those with depressive symptoms, it could consider measuring reduction in MCS scores (from the Health Outcomes Survey) for members who had particularly high baseline MCS scores.
UnitedHealthcare	Depression is a complex disease, and for many, medication alone cannot bring about remission and behavioral therapies may reasonably take longer before remission is achieved. UnitedHealth recommends that this measure be leveled consistent with that of CMS MSSP, which measures remission at 12 months.
VIVA Health, Inc.	Accurate and complete data collection for these measures may be very difficult or overly burdensome for many plans. Behavioral health providers generally have less experience with EMR use and procedures, and many practices still lack the necessary infrastructure necessary to efficiently support such a measure. The Plan recommends CMS consider the complications this measure's specific data collection methodology would pose for many plans. These measures may also be impacted by socio-economic status, and the suggested clinical goals in the 6 month time frame may be unrealistic.
WellCare	WellCare supports the addition of the depression measures to the Star Ratings. Adding a behavioral health measure fills a measurement gap, as there are relatively few measures that address behavioral health processes and outcomes. However, WellCare has concerns about the instrument used to gather the data. WellCare agrees that adults should be measured using the PHQ-9, a reliable and valid measure of depression severity, but we think adolescents should be measured using the PHQ-A, a slightly modified version designed for use in adolescents.

3. Appropriate Pain Management (Part C)

Submitter	Response
BlueCross and BlueShield Association	BCBSA and Plans understand that CMS may, in the future, include a measure related to appropriate pain management and that the Agency is monitoring the NCQA's efforts to develop a measure to assess the quality of pain management and treatment. CMS notes that there is no definite timeline for the development of this measure. BCBSA and Plans appreciate CMS's focus on pain management and request that the Agency provide sufficient detail to allow stakeholders the opportunity to provide meaningful comment. Recommendations: Should CMS propose a measure of pain management, BCBSA and Plans request that CMS provide Plans with enough information about the measure to enable Plans to fully analyze the measure and provide meaningful comments to the Agency. (See also Key

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	Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.)
BlueCross BlueShield of Tennessee	BCBST commends CMS for following progress on measure development by NCQA. However, since pain is managed differently depending on the condition or situation, BCBST recommends that CMS continue to monitor development of this measure and provide additional information regarding the metric related to this measure as soon as possible. BCBST urges CMS, that once this measure is clearly defined, to incorporate it into the Display Page for 1-2 years to allow plans time to understand performance and adapt processes and strategies.
Cambia Health Solutions	We would welcome any information on how this is intended to be measured
Centene Corporation	Centene Corporation looks forward to comment when the measure is fully developed.
Cigna	Pain management is highly subjective and variable, and dependent on comorbidities, which need to be considered in development of this measure. The measure should be limited to specific categories of pain management to facilitate level comparisons across contracts.
Commonwealth Care Alliance	CCA endorses CMS efforts in this important area.
Health Net, Inc.	Measure impact on Plans which low SES membership. Request that any proposed Star measures be included on display page for a minimum of two rating periods.
Healthfirst	We advocate for first year NCQA HEDIS measures to be placed on the display page for at least two years prior to being included in the Star Ratings. This provides plans with the opportunity to evaluate performance given the characteristics of their membership and assess measure validity. Additionally, we are unable to fully comment on this measure without being provided the specifications of this measure, including the data collection methodology.
Independence Blue Cross	This is subjective with individuals and may vary at stage of condition that causes the pain. Would there be exclusions for RA, cancer, gout and other multiple debilitating conditions? Members who transition to an MA plan may have a history of pain management treatment whilst in another plan (example: opioid use).
Kaiser Permanente	Kaiser Permanente recognizes the importance of appropriate pain management, and looks forward to learning more about NCQA's efforts to develop and test pain management measures. As with all measures derived from clinical data sources, we expect that CMS will adopt only those measures which are NQF-endorsed. We also caution that "appropriate pain management" can be at odds with controlling/monitoring opiate use from a measurement standpoint. We advise CMS to take this into account as pain management measures are developed.
Medica Health Plans	Medica would like more specific information about the proposed measures before commenting, but would like CMS to consider

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	medications and alternative treatments for managing pain.
Pfizer	Description of the Issue or Question: CMS notes that the National Committee for Quality Assurance (NCQA) continues to explore measure development in this area, with the intent to assess the quality of pain management and treatment. Suggested Revisions/Comments: Pfizer urges CMS to continue to pursue incorporating new pain measures into the Star Ratings program. We are encouraged by your statement that NCQA is intending to develop new measures related to the management of chronic pain. Chronic pain is a disabling condition associated with increased healthcare resource utilization and loss of productivity. However, given the lack of standardized pain assessment questions, physicians struggle to systematically assess, document, and monitor information and data related to their patients with chronic pain. As such, Pfizer encourages CMS and NCQA to consider new measures related to the screening and evaluation of patients with chronic pain. Similar to measures for depression, Pfizer encourages the use of a standardized screening tool in the evaluation of a patient's chronic pain status. The routine use of a standardized tool would enable physicians to consistently monitor treatment plan's impact on pain severity and patient's functioning and evaluate whether current plans are yielding adequate pain relief and improvement for the patient. It will also allow CMS to more accurately compare measure results across providers. Pfizer has recently developed an electronic 14-item instrument to capture patient-reported data and outcomes associated with chronic pain. This Electronic Chronic Pain Questions module (eCPQ) is based on existing guidelines and scientific and medical literature, and was developed for use in clinical practice. The aim of the eCPQ is to help physicians assess, manage, and monitor patients with chronic pain in either the primary care or specialty setting. The eCPQ has been found to be valid and reliable in identifying and monitoring patients with chronic pain with minimal staff disruption and administration time. Pfizer encourages CMS and NCQA to consider the use of this tool in a measure related to requiring physicians to assess, document and monitor improvements for patients who present with chronic pain. We would be happy to discuss this tool with the agency and present the research to validate and, next, assess the impact of use of the tool. IOM. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington, DC: The National Academies Press; 2011. Coyne K, et al. Psychometric Validation of the Electronic Chronic Pain Questions (eCPQ) in a Primary Care Setting. PainWeek 2015 Conference, September 8-12 2015, Las Vegas NV

4. Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer (Part D)

Submitter	Response
Academy of Managed	AMCP appreciates CMS' focus on developing measures to help curb

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Care Pharmacy (AMCP)	the abuse of opioid medications among Medicare beneficiaries. AMCP, however, has several concerns with the proposed measures and urges CMS to provide clarification on the questions outlined below prior to finalizing these measures: • CMS must clarify the timeframe for Measure 2 (Multiple Prescribers and Multiple Pharmacies) and Measure 3 (Multi-Provider, High Dosage). Dependent upon the timeframe, it may be reasonable that a patient receives prescriptions for opioids from four or more prescribers and four or more pharmacies. Therefore, defining a timeframe to accompany the measures is necessary to alleviate both false positives and false negatives. • Are the measures based only upon claims data available to plans, and how will patients who choose to pay cash for their prescriptions or physician visits be factored in to the measures? While forty-nine states and the District of Columbia have Prescription Drug Monitoring Programs (PDMPs) that collect dispensing data for all opioid medications, including prescriptions paid for by insurance and cash, only five states provide PDMP access to Medicare plan sponsors and three states to commercial third-party payers. The current legislative scheme at the state-level is a barrier to Part D sponsors being able to properly assess the true opioid overutilization of their members. If the measure is limited to adjudicated prescription claims data only, CMS risks falsely rewarding plans for their high measure score while in reality many of their patients may be opioid over-utilizers but appear as a false negative due to limitations in data availability. Prior to finalizing these measures, CMS must address how patients paying cash for their prescriptions and physician visits, and the inability of plan sponsors to access this information, will be factored into these measures. • How do these measures differ from the Overutilization Monitoring System (OMS)? In addition, AMCP encourages CMS to advocate for legislative changes to the Part D program allowing sponsors to enroll patients identified as high-risk for opioid overutilization in a pharmacy and/or prescriber restriction program, also known as lock-in programs. Lock-in programs have successfully been used by state Medicaid programs and commercial plans for years, but are currently prohibited under Medicare Part D. Prescriber and pharmacy restricted access programs help to mitigate the issues associated with doctor or pharmacy poly-shopping and may reduce the number of inappropriate controlled substance prescriptions. In 2009, the Oklahoma Medicaid department found that its lock-in program reduced doctor shopping, utilization rates of controlled substances, and emergency room visits with an average savings of $600 per person in costs. As demonstrated in Medicaid and other programs, and recommended by the General Accountability Office in 2011, CMS should consider restricted access to certain prescribers and pharmacies for Medicare beneficiaries to reduce incidence of doctor or pharmacy shopping. References: A. Alexander GC, Frattaroli S, Gielen AC, eds. The Prescription Opioid Epidemic: An Evidence-

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	Based Approach. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015 B. Academy of Managed Care Pharmacy. Role of Managed Care Pharmacy in Managing Controlled Substances for Medicare Part D Beneficiaries. 2014. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18556. (Accessed December 8, 2015).
Anthem, Inc	Anthem continues to have considerable concerns with the validity of the Opioid Overutilization measure. While PQA's three opioid metrics propose to evaluate overutilization individually, it will be difficult for current programs to monitor the metrics separately, since they are a composite process. Anthem is concerned that tracking the measures separately will create significant additional burden with unclear gains. Additionally, we are concerned that introducing these measures could create an incentive for plans to discriminate against potential over-utilizers. These unintended consequences are contrary to the intent of the Star Rating system and, thus, we recommend that CMS reevaluate its proposal. As CMS evaluates the Opioid Overutilization measure, Anthem recommends that the measure align with CMS' opioid drug utilization review (DUR) requirements, which do not indicate case management for PQA's Measure 1 (Opioid High Dosage) and Measure 2 (Multiple Prescribers and Multiple Pharmacies). The DUR requirement and the quarterly Overutilization Monitoring System (OMS) report utilize Measure 3 (Multi-Provider, High Dosage) as the criteria for reporting—this then feeds into subsequent member case management. Anthem believes that Measure 1 and Measure 2 will only assess demographic information—rather than the true quality of a plan's Opioid Overutilization prevention strategies—since the measure rates are determined by the population that a plan enrolls. The intent of any Opioid Overutilization measure should be to measure how a plan performs in managing the cases that trigger an opioid DUR (and the resulting outcomes), not how many cases are triggered.
BlueCross and BlueShield Association	CMS proposes to add three opioid overutilization measures – Opioid High Dosage, Multiple Prescribers and Multiple Pharmacies, and Multi-Provider, High Dosage – to the Display Page in 2018. BCBSA and Plans appreciate CMS's efforts to address the overutilization of opioids and are committed to working to reduce the incidence of such overutilization. We also appreciate CMS's intentions to develop new patient safety opioid overutilization measure reports to provide Part D Plans with additional information about their performance. BCBSA and Plans encourage CMS to continue researching opioid overutilization and how to most effectively measure plan efforts and outcomes. We submit that any such measure should focus on Plan performance. (See Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.)

Submitter	Response
	Recommendations: BCBSA and Plans recommend that CMS continue to investigate opioid overutilization. If CMS decides to include an opioid overutilization measure in the Star Ratings, we request that the Agency provide stakeholders with detailed information about the measure. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.)
BlueCross BlueShield of SC	Measure one for use of opioids should not be considered a measure because it is currently addressed thru the Overutilization Monitoring System. From the cases that we have had those with high doses were either approved from a coverage determination with a legitimate diagnosis or once investigated the prescribing physician(s) stopped therapy due to other prescribers providing duplicate prescriptions. Measure two and three would be better measures because they would combat more fraud or abuse opioid cases and not those that are seeing one prescriber for high doses for a clinically appropriate reason as with measure one.
BlueCross BlueShield of Tennessee	BCBST is concerned that the proposed measures do not translate to plan performance for opioid management. CMS' Overutilization Monitoring System (OMS) enables plans to monitor and perform case management for potential opioid over-utilizers. Under the OMS system, members considered potential over-utilizers are those that are identified as receiving prescriptions for opioids greater than 120mg (MED) for 90 consecutive days or longer AND have received their prescriptions from 4 or more prescribers AND 4 or more pharmacies (Measure 3). As shown through the case management activities post-identification, plan sponsors have found that not all members identified by these targeting criteria are actual opioids over- utilizers requiring intervention. BCSBT supports CMS' stance to not include the Use of Opioids measures into the Star Ratings program and recognizes the need for continued research in the development of these measures. BCBST urges CMS to not assume that a correlation exists between these targeting measures and actual over-utilization of opioids. In addition, BCBST also encourages CMS to further evaluate and address the following concerns, identifying timely cancer and accurate diagnoses, targeting 4 or more prescribers and 4 or more pharmacies (taking into account prescribers at the same office or pharmacies within the same chain), and the prevalence of members who meet this criteria across plans. BCBST requests clarification as to whether plans will be measured on the number of members with opioid prescriptions with more than 4 pharmacies or prescribers. If so, CMS should consider allowing plans to impact the measure through lock-in

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	activities. Lastly, BCBST encourages CMS to consider alternate Opioids Use-related metrics that more directly measure actual opioids overutilization and plans' efforts to case-manage these members. A change such as this would require a transition from process measurement – as proposed here – to actual outcome measures post case-management and intervention.
Centene Corporation	Centene Corporation requests a rationale for including this measure on the display page when it has been stated that it is not a valid measure for star ratings.
Cigna	CMS' goal to better manage opioid utilization aligns with our goals. Opioid use in persons without cancer is complex: subsets of members are critically and chronically ill and require opioids to manage their pain and improve their quality of life. There is also a subset of members who are intentionally misleading providers to prescribe opioids, using multiple pharmacies and paying cash to avoid detection. There are also geographic prescribing patterns. If higher prescribing rates are observed in a geographic region there is a limitation on the part of the health plan to contract with physicians based on network adequacy requirements.
Commonwealth Care Alliance	CCA does not support adding these measures to display page as it is unclear as to the purpose of doing so. These are not useful population care quality measures. Patient level data IS USEFUL for targeting interventions to improve the care and outcomes of individuals.
CVS Health	SilverScript supports the inclusion of a composite measure to evaluate opioid overutilization as a Display measure.
Group Health Cooperative	Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D) Group Health understands the reasoning behind the Pharmacy Quality Alliance (PQA) endorsed metric; however, we also believe that CMS should allow plans to do more to adequately reduce high opioid overutilization. Group Health also believes that closed formulary plans will in a better position to score higher on this metric than plans who utilize an open formulary; such variation should be accounted or adjusted for in the measure. Additionally, Group Health believes regional differences in utilization should be considered and accounted for in the metric
Health Net, Inc.	Recommend delay adding to Stars until measure has been tested.
Healthfirst	We do not support the inclusion of this measure in the Star Rating program. Although endorsed by PQA, we do not believe that each one of these three measures accurately identifies inappropriate opioid utilization. Currently, there are no FDA approved max doses for opioids, and there are situations where members are using above the 120mg MED for a medically necessary diagnosis besides cancer pain. We believe that only using 120mg MED to identify over utilizers is not targeted enough to detect a high percentage of fraud and abuse cases. We also feel that assessing for multiple providers and multiple pharmacies may not take into account prescribers in the same practice and different branches of a chain pharmacy.

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	Additionally, if we do detect fraud or abuse from a member using multiple prescribers and pharmacies, we are not permitted by the Part D program to lock-in a member to a particular pharmacy or prescriber. We do agree that the measure that combines high dosage opioids and multiple providers is better positioned to detect inappropriate behavior; however, we are not sure how this is different from the Overutilization Monitoring System. Through OMS, we are best able to review patient behavior and implement measures to prevent opioid overutilization in real time using point of sale edits and quantity limits.
Humana	Humana supports the addition of these opioid measures to the 2018 Part D Display measure and we are aligned with CMS with respect to concerns regarding adding these measures to the Star Ratings at this time. Humana suggests allowing response to outliers to remain within the OMS component process.
Medica Health Plans	Medica supports this measure and has conducted audits around opioid use in the recent past.
MetroPlus health Plan	MetroPlus supports the development of this measure as long as CMS develops programmatic changes to restrict these recipients similar to how New York State handles the Medicaid population.
Molina Healthcare Inc.	Molina Healthcare agrees with the Agency's recommendation not to add these measures to the Star Ratings until the concerns about lack of evidence-based guidelines and data sources for appropriate diagnoses can be addressed. We also recommend that CMS not add the measure results to the display page until these concerns can be addressed and a full cycle of reporting can be completed and measurement analysis is performed.
PCMA	4. Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D) – CMS proposes to add the three PQA-endorsed opioid measures to the 2018 Part D display page but does not recommend adding them to the Star Ratings at this time. PCMA has ongoing concerns with these measures: a) we doubt that the PQA-endorsed measures will result in improved plan performance for opioid management, and b) we believe CMS should investigate alternative measures that allow plan sponsors to case manage opioid abusers. We urge CMS to refocus its opioid use efforts on outcome measures rather than process measures. We believe CMS could have far greater impact on improving outcomes from opioid abuse interventions if it would allow sponsors to restrict members with abusive opioid use profiles to one pharmacy and/or one prescriber for all their opioid medications. PCMA Recommendation: PCMA urges CMS to refocus its opioid use measures on clinical outcomes and allow plan sponsors to limit members with abusive opioid use profiles to one pharmacy and/or one prescriber for all opioid medications.
PhRMA	CMS proposes to develop new patient safety opioid overutilization measure reports using three PQA developed and endorsed measures previously noted in the 2016 Call Letter. CMS proposes

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	providing these reports through the Patient Safety Analysis website to allow sponsors to track their performance and allow for contract level trending and outlier analyses. These measures are proposed to be added to the 2018 Part D display page, but are not proposed for inclusion in the Star Ratings at this time. PhRMA believes that medications should be used appropriately and safely, and we support measures that aim to support these goals. However, we have concerns with activities that evaluate opioid overutilization in a manner that could lead to limitations on access to needed pain medication. We also share CMS' concern regarding the current lack of consensus clinical guidelines for the use of opioids to treat chronic, non-cancer pain and the need to develop potential exceptions due to medical necessity. We support CMS' decision not to add these measures to the Star Ratings at this time. We would appreciate the opportunity to review and provide comment about any changes to the measures or any recommendation to include them in the Star Ratings in the future.
PQA	PQA supports the development and provision of opioid overutilization measure reports to Part D sponsors and the addition of the three opioid measures to the display page (using 2016 data). We encourage CMS to assess whether plans are able to utilize the measure reports to decrease overutilization as PQA is interested in sharing best practices and understanding how these measures can be used to achieve this goal.
PrescribeWellness	We support focus and development in this critical area which should also include a Part C measure to ensure clinical outcomes so everyone on the healthcare team is held responsible.
RxAnte	• RxAnte supports the adoption of the opioid measures to the patient safety reports and OMS without incorporating them as Star Ratings at this time due to current clinical guideline ambiguity. o However, given the major national epidemic of unsafe opioid use, RxAnte encourages CMS to do more than just require or encourage plans to report on the opioid measures. Our concern stems from the fact that the CMS measures likely do not by and large identify patients for possible intervention before patients experience harm from these medications. A patient who seeks medications from multiple prescribers and/or multiple pharmacies may already be experiencing (or have experienced) harm or may be seeking undue access to medications for inappropriate reasons. In our view, CMS should encourage plans to report on these measures, but also to continue developing alternative approaches to identifying candidates for care management intervention besides merely waiting until patients seek prescriptions from multiple prescribers or pharmacies. o Outcomes-based opioid measurement could measure opioid overdose episodes, specifically fewer ED/Inpatient visits related to opioid overdose or proportion of those identified with an opioid abuse/dependence diagnosis who are receiving addiction treatment such as Medication Assisted Treatment (MAT) therapy or treatment

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	center attendance. o For high-risk patients, we need to know who is at risk of future unsafe use of opioid medications earlier in therapy and why. Then we (CMS, plans, providers, others) need to use that information to inform smarter prescribing, patient management, care coordination, patient and caregiver engagement strategies. There is a role for all stakeholders here. But simply identifying patients for care management once they have met the current criteria is not enough to prevent the further manifestation of this important epidemic.
SCAN Health Plan	F.4 Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D). Three opioid overutilization measures endorsed by PQA in May 2015 will be added to the 2018 Part D display page (using 2016 data). CMS does not recommend adding these measures to the Star Ratings at this time. CMS will provide to Part D sponsors new patient safety opioid overutilization measure reports through the Patient Safety Analysis website. The website also includes the OMS. SCAN Comment: We believe that the three measures should not be applied to the Display Page. Measure 1 may identify false positives in which members may be appropriately on proper treatment (MED >120mg) prescribed by one provider and filled at one pharmacy. This may result in falsely implying that the plan has a higher proportion of members using opioids inappropriately. Measure 2 does not include a specific timeframe. This extends the timeframe which increases the likelihood of members getting prescriptions at different pharmacies within the same chain or visiting different providers within the same pain clinic, falsely implying excessive opioid use/abuse as the timeframe is extended. Measure 3 is a combination of the two and may also imply misuse even though treatment may be medically necessary given the member's circumstance. The memo indicated that poor scores on display measures are subject to compliance actions by CMS. These three measures may cause a plan to score poorly even though treatment may be appropriate. Overall, we recognize the need for, and support CMS efforts to, better understand and manage overutilization of opioids. However, in doing so, CMS may wish to consider modifying the measure technical specifications such that identification of false positives is minimized.
SNP Alliance	4. Use of Opioids from Multiple Providers or at High Dosage in Persons without Cancer (Part D) We are not clear on the rationale for placing these measures on the display page in light of concerns about adding these measures to the Star Ratings. Until the concerns related to adding these measures to the Star Ratings are addressed, we object to these measures being placed on the 2018 Part D display page. At a minimum, if CMS proceeds to include the opioid measures on the display page we believe that CMS should also provide accompanying information that describes the concerns related to these measures, i.e. (1) current lack of consensus clinical guidelines for the use of opioids to treat chronic, non-cancer pain

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	and potential exceptions due to medical necessity, and (2) pending additional analysis on diagnosis data sources which are used to identify exclusions for certain cancer conditions. Unless this is done, those reviewing the data will not be fully knowledgeable about the information presented. We also are concerned that although these measures can be helpful in treating individual patients, they are not appropriate for evaluating plans' population management efforts. We suggest that CMS does have the option of limiting the use of these measures to the new patient safety opioid overutilization measure reports at this time. As CMS points out, these reports will allow plans to track their performance over time and allow for contract level trending and outlier analyses. In this way, CMS has opportunities to monitor members' use of these drugs while delaying making the results of these measures public until important concerns with them are addressed. With respect to the development of new patient safety opioid overutilization measure reports, we are concerned, however, that SNPs may trigger significant numbers of CAPs that are not indicative of inappropriate care but are related to the characteristics and needs of the populations they serve. For example, for plans that serve disproportionate numbers of members with physical disabilities, or with severe or chronic pain, the dosage in Measure 1 (Opioid High Dosage) may not be excessive. We are concerned that the effort and resources required to respond to these CAPS will be considerable and not lead to improvements in care.
Transamerica Life Insurance Company	While we are in agreement that this is a good area to focus on, we have little impact on providers as a Part D only contract. We have no access to provider information other than claims adjudication info. We hope the letters we send and additional outreach we make to providers is effective, but beyond that there's not much more we can do to alter their behavior.
UnitedHealthcare	UnitedHealth appreciates CMS' attention to this issue and agrees that CMS should not add this as a Star measure at this time. UnitedHealth respectfully suggests that PQA measures will not add additional benefit beyond what is already being managed and monitored. The measure criteria identify potential overutilizers of opioids that would benefit from case management activity, and is not a good indicator or metric for plan quality or performance. In addition, since the PQA measures are based solely off claims paid at the pharmacy, it does not take into account those members where the provider has indicated the medication is medically necessary or those for whom opioid restrictions may have been placed moving forward. The Overutilization Monitoring System (OMS) and case management process has already been established within plans and continues to be enhanced, and appears to be working to ensure that members are being monitored appropriately. Therefore, UnitedHealth asks that CMS continue to monitor opioid overutilization via the OMS as opposed to PQA endorsed measures. UnitedHealth would also like to note that "Measure 1 (Opioid High

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	Dosage)" can be problematic as greater than 120 mg morphine equivalent dose is too low to avoid false positives. In addition, Measure 1 and 2 individually do not provide plans with actionable insight around reducing opioid overutilization.
VIVA Health, Inc.	While the Plan supports the inclusion of a composite measure to evaluate opioid overutilization as a display measure, the Plan continues to have concerns about the lack of clinical guidelines, standard exceptions, and resulting impact on medically necessary access. There may be cases where high medication doses are clinically appropriate. The Plan recommends these measures be developed further with consensus clinical guidelines for appropriate opioid use before inclusion in Star Ratings.
WellCare	WellCare agrees with the Agency's position about the lack of consensus clinical guidelines for the use of opioids. It is important to note that not every measure PQA develops should be used in the Star Rating program. Some measures are appropriate for comparisons across like populations, but are not appropriate measures for the entire industry. We applaud CMS' desire to use opioids cautiously, and support CMS' decision to withhold these measures from the Star Ratings.

5. Antipsychotic Use in Persons with Dementia (APD) (Part D)

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Aetna	We recognize that CMS is not proposing adding this measure to the Star Ratings program at this time pending additional research. However, we note as CMS moves forward that given CMS policy on protected class drugs where utilization management is only allowed for beneficiaries who are new to the treatment regimen, it is challenging for plan sponsors to deploy effective interventions to manage inappropriate utilization through retrospective interventions.
America's Health Insurance Plans	CMS is considering a potential new measure, Antipsychotic Use on Persons with Dementia, for the 2018 Part D display page which would replace the current Part D display measure, the Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes. CMS notes the agency is developing new patient safety APD measure reports and will provide these reports to Part D plan sponsors monthly via the Patient Safety website beginning with the year of service 2016. CMS is also conducting additional research regarding diagnosis data sources. We agree with CMS' proposal to pursue additional research. We recommend that the agency also share its research findings prior to considering the inclusion of this measure on the display page.
Anthem, Inc	Anthem agrees with CMS' decision to replace the Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes display measure with the new APD measure. We believe this measure offers a more targeted approach to address inappropriate antipsychotic use in the elderly population, particularly around inappropriate indications. Anthem also supports CMS' decision to

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	continue monitoring and gathering data on the APD measure before implementing it as a Star Ratings measure. If the APD measure were to become an actual Star Ratings measure, we request that CMS provide sufficient notice so that plans can make appropriate preparations, including implementation of point of sale edits and/or clinical programs. As CMS considers moving forward with the APD measure, Anthem also recommends that it ultimately align with surveyor guidance regarding antipsychotic use in long-term care (LTC) facilities, so that both plans and LTC facilities are working towards the same goals.
BlueCross and BlueShield Association	CMS proposes to include the PQA-endorsed Antipsychotic Use in Persons with Dementia (APD) measure on the 2018 Display Page to measure the inappropriate use of antipsychotics in nursing home and community settings. CMS intends for this measure to replace the Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes measure. BCBSA and Plans share CMS's concern regarding the unnecessary use of antipsychotic drugs in nursing homes and community settings, and are committed to helping the Agency develop and/or refine an appropriate measure of Plan performance related to such inappropriate use. BCBSA and Plans have concerns about the APD measure, however, and urge CMS to consider leaving the measure off of the Display Page until such issues are addressed. For example, BCBSA and Plans note that the APD measure, as interpreted by CMS, requires the separation of members into various populations, including those in community settings and those in nursing homes. As CMS stated in the Request for Comments, members were classified based on diagnosis data. BCBSA and Plans request clarification as to how CMS identified members based on diagnosis data and caution that – to the extent the Agency is looking to particular drugs that are prescribed – providers may be treating members for off-label uses, thus leading to potential confusion and miscategorization. We also note that Part D Sponsors do not have access to all diagnosis data. Should CMS decide to include the APD measure in future Star Ratings, BCBSA and Plans request that CMS provide Plans with sufficient notice such that they are able to make appropriate preparations such as point of sale edits or clinical programs. Recommendations:

Submitter	Response
	BCBSA and Plans request that CMS provide additional information about how the Agency classifies members based on diagnosis data. If CMS decides to include the APD measure in the Star Ratings, BCBSA and Plans request that CMS provide sufficient lead time to allow Plans to make the appropriate adjustments.
BlueCross BlueShield of SC	I agree that antipsychotic use in persons with dementia should be discouraged and maybe even a star measure. However in order for plans to be able to manage the measure I would ask that CMS allow prior authorizations on these medications to be implemented. Currently the only PA that is allowed on antipsychotics because it is in a protected class is one that is applied to new starts only. In order to most effectively identify the antipsychotic medications being used inappropriately in a nursing home resident is to apply a PA and request a diagnosis. Systematically this could be approved to only apply to LTC residents. Often times these medications are fronted by the nursing home dispensing pharmacy and not withheld from the patient because of a PA. In order for the nursing home pharmacy to be paid they would then have to get the physician to complete the PA. Another point to make here is CMS allows the use of antipsychotics in elderly residents with dementia but only after other environmental causes of behaviors have been identified and addressed given that the medication is prescribed in a low dose and gradually reduced and reviewed. If this has already occurred then plans would then again be penalized in a measure which we could not clinically impact.
BlueCross BlueShield of Tennessee	BCBST requests that CMS work with the industry to ensure the patient safety reporting developed and provided includes the information necessary for plans to adequately address this concern. Because of the importance of having the patient's diagnosis, BCBST agrees with CMS's recommendation that additional research on diagnosis data sources, such as newly available encounter data for Medicare Part C, should be completed and timing issues of RAPS file updates must be resolved before adoption as a Star Rating can be considered. Moreover, BCSBT recommends that CMS provide plan sponsors with adequate time to work with their contracted care providers to ensure awareness of this concern and understanding of the measure specification.
Cambia Health Solutions	Is there consideration on splitting this measure out from the Drug Disease Interaction measure?
Centene Corporation	Centene agrees with CMS' assertion that this is not a recommended addition to the star measure set. Centene looks forward to reviewing the outcomes of CMS' research on diagnosis data sources. We further recommend that accountability for skilled nursing facilities should not reside with the health plans as there are already state and federal nursing home surveys and a nursing home compare

Submitter	Response
	measurement system. This measurement would be more appropriate in that rating system rather than in the Stars ratings.
Cigna	We do not support the proposal to add this measure for MA-PD plans. We believe this measure should be used as part of the SNF performance measurement system as it is rooted in a ST/LTC setting. In order to provide CMS with a well-formed comment, we would like to better understand how CMS' defines short term, long term, and assisted living. Additionally, we would like to understand how CMS will account for state behavioral health agencies that may be involved in a member's ST/LT/AS care management and may not pass that data along to the MA plan.
Clover Health	Clover Health supports the provision of new monthly Antipsychotic Use in Persons with Dementia (APD) patient safety reports in 2016, as well as the addition of the APD measure to the 2018 Part D display measure set. The alarming rate of antipsychotic use among older adults with dementia despite the FDA's black box warning that antipsychotics may cause an increased risk of death in this population must be monitored more closely. However, it will be very difficult for MAPD plans to improve upon this measure without the necessary diagnosis data used to identify patients in the numerator and denominator. While breaking out the measure rates by community-only residents, short-term nursing home residents, and long-term nursing home stay residents for the 2018 display page will aid in surveillance among unique beneficiaries, it will not aid in the optimal targeting needed to improve quality of care by plans. Like CMS, we do not support the addition of this measure to the Star Ratings at this time, as diagnosis data that is necessary to develop quality improvement plans and calculate the rate is not yet available.
Commonwealth Care Alliance	CCA supports this plan.
CVS Health	SilverScript supports the provision of new monthly Antipsychotic Use in Persons with Dementia (APD) patient safety reports in 2016, as well as the addition of the APD measure to the 2018 Part D display measure set. The alarming rate of antipsychotic use among older adults with dementia despite the FDA's black box warning that antipsychotics may cause an increased risk of death in this population must be monitored more closely. However, it will be very difficult for Part D plans and PBMs to improve upon this measure without the necessary diagnosis data used to identify patients in the numerator and denominator. While breaking out the measure rates by community-only residents, short-term nursing home residents, and long-term nursing home stay residents for the 2018 display page will aid in surveillance among unique beneficiaries, it will not aid in the optimal targeting needed to improve quality of care by plans. Like CMS, we do not support the addition of this measure to the Star Ratings at this time, as diagnosis data that is necessary to develop quality improvement plans and calculate the rate as specified by PQA is not yet available to Part D sponsors.

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EmblemHealth	A similar measure is already part of Nursing Home Five-Star Quality Rating System - The rating now includes information about nursing homes' use of antipsychotic medications in both long-stay and short-stay residents. This information is collected by the nursing home for all residents. Since nursing homes would be reporting this data, it would be duplication to ask health plans to report on the same information.
Health Care Service Corporation	CMS states, "We will develop new patient safety APD measure reports to provide to Part D sponsors on a monthly basis through the Patient Safety Analysis website beginning with year of service 2016. We also recommend adding the overall APD measure plus breakout rates for community-only residents, short-term nursing home residents, and long-term nursing home stay residents to the 2018 Part D display measure set (using 2016 data) to continue to draw attention to the inappropriate use of antipsychotics in persons with dementia without an appropriate mental health diagnosis in both the community and nursing home settings. The APD measure will replace the Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes display measure. However, we do not recommend adding this measure to the Star Ratings pending additional research on diagnosis data sources, such as newly available encounter data for Medicare Part C and resolving timing issues of RAPS file updates." HCSC believes this is an important measure and agrees with CMS' proposal to continue conducting additional research on the identified topics before adding the measure to the Star Ratings.
Health Net, Inc.	Recommend adding to Rating System for Nursing Homes
Healthfirst	We agree with the recommendation to add APD to the Part D display measure set, to help curb the inappropriate use of antipsychotics in members with dementia. Additionally, we agree with the recommendation to not add this measure as a Star Ratings measure at this time.
Humana	Humana supports the proposed addition of the Antipsychotic Use in Persons with Dementia as a replacement for "Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes" measure in the Part D Display Ratings. Humana believes the PQA measure adequately reflects clinically appropriate recommendations and is a priority program of focus due to detrimental impact to medical outcomes. Further, Humana supports the addition of reporting regarding the overall APD measure along with the suggested breakout rates.
Independence Blue Cross	Nursing homes should be accountable for the Star ratings at the facility and not the health plan. This is so varied based of the level of dementia, and also family and facility pressure may influence the treating physician to prescribe these medications.
Kaiser Permanente	Kaiser Permanente supports the gradual adoption of this measure, beginning with the dependency of reliable reporting in the 2017 plan year. We agree that additional research on diagnosis data sources

Submitter	Response
	(e.g. Medicare Advantage encounter data) and resolving timing issues of Risk Adjustment Processing System (RAPS) file updates are necessary steps prior to adoption of this measure as a Star Ratings measure.
Magellan Health	Magellan supports the importance of this measure for all the reasons cited in the RFC, and also, the CMS recommendation to use it as a display measure initially.
Medica Health Plans	Medica supports the provision of the best care for our beneficiaries who suffer from dementia and we look forward to findings from current and future studies. Dementia is becoming more prevalent and we need to evaluate and support evidence based treatments. We will comment further as the measures are developed.
Molina Healthcare Inc.	Molina Healthcare agrees with the Agency's direction in focusing on the inappropriate use of antipsychotic medications for individuals with dementia. However, we ask that CMS first review the data collected using the proposed breakout rates for sub-populations prior to reporting. By reporting this measure for community-only residents, short-term and long-term nursing home stay residents, we are concerned whether there will be enough populations to have fully reported data. We also ask that CMS fully define and allow health plans to provide feedback on any draft patient safety measure reports prior to finalization. This will allow plans to comment before final rates are published.
PCMA	5. Antipsychotic Use in Persons with Dementia (APD) (Part D) – CMS recommends adding the recently endorsed PQA measure, Antipsychotic Use in Persons with Dementia, for community-only residents, short-term nursing home residents, and long-term nursing home residents to the 2018 display measure set, replacing the current antipsychotic display measure. PCMA supports the addition of this new measure to the 2018 Part D display page, but we note it will be very difficult for Part D plans and PBMs to improve upon this measure without the necessary diagnosis data used to identify patients in the numerator and the denominator. Like CMS, we do not support adding this measure to the Star Ratings at this time because diagnosis data needed to develop quality improvement plans and calculate the rate as specified by PQA are not available to Part D sponsors. PCMA Recommendation: PCMA supports CMS's recommendation regarding APD.
PQA	PQA is pleased that CMS has conducted extensive testing of the APD measure and supports the proposal to develop new patient safety APD measure reports for Part D sponsors. We also support the reporting of the measure in the 2018 Part D display measure set including the following four rates: o Overall population o Community-only residents o Short-term nursing home residents o Long-term nursing home residents As the measure steward, we look forward to seeing the testing results for this measure, stratification rates, and details of the diagnosis data used for the numerator and denominator. PQA agrees this measure will be valuable in improving

Submitter	Response
	care for patients with dementia, and that the measure should not be added to the Star Ratings before additional research is conducted on diagnosis data sources.
PrescribeWellness	We support this measure to ensure better health outcomes in this vulnerable patient population.
SNP Alliance	5. Antipsychotic Use in Persons with Dementia (APD) (Part D) We support CMS' efforts to undertake additional research on diagnosis data sources before the measure is added to the Star Ratings.
Triple S Advantage, Inc	TSA agrees with further research for this measure; at first it does not seems as a Part D measure. Also further details are needed. Even if it is contraindicated use, need to take into consideration physician's clinical judgement. Plan sponsor is not in absolute control of these determinations.
UnitedHealthcare	UnitedHealth supports new patient safety APD measure reports and adding the breakout rates to the 2018 Part D display measure set. UnitedHealth also agrees that this should not be a Star measure until further research is completed.
VIVA Health, Inc.	The Plan supports the addition of this measure to the Display measures in the future, but does not yet support the addition of this measure to the Star Ratings. Diagnosis information necessary to calculate the rate as specified by the measure steward is not yet available. In addition, while separating measure rates by long-term nursing home stay residents, short-term nursing home residents, and community-only residents for the Display page will help in observation among unique members, it will not support the optimal targeting necessary to improve the quality of care by plans. The Plan recommends the data standards for the measure include members in skilled nursing facilities only.
WellCare	WellCare supports CMS' recommendation not to add this measure to the Star Ratings. While there are benefits in using these drugs, there can be difficulty in identifying circumstances in which utilization is appropriate. WellCare encourages CMS to continue to research diagnosis data sources and to propose a measure that does not penalize the appropriate utilization of these medications for the appropriate population.

G. Changes to Existing Star Ratings and Display Measures and Potential Future

1. Colorectal Cancer Screening (Part C Star Rating)

Submitter	Response
Blue Cross and Blue Shield of Minnesota	BCBSMN notes that the evidence cited for extending screening to patients age 76-85 in the USPSTF draft recommendation released for public comment is C-level. We recommend no change to the age limit to this measure.
BlueCross and BlueShield Association	CMS notes that the NCQA may change the Colorectal Cancer Screening (COL) measure, which assesses the percentage of adults, ages 50-75, who had appropriate screening for colorectal cancer,

Submitter	Response
	based on potential updates to the U.S. Preventative Services Task Force's (USPSTF) guidelines. BCBSA and Plans appreciate CMS's attention to evolving standards of care and support the Agency's efforts to update the Star Ratings to reflect such changes. We request that CMS provide us – in advance of implementing any changes to the Star Ratings – with additional detail about the proposed recommendations. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.) For example, BCBSA and Plans would want to know what about the metric is changing and the timing of that change for purposes of the Star Ratings. Recommendations: BCBSA and Plans request that CMS provide additional information about the potential changes to the COL measure. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.)
BlueCross BlueShield of Tennessee	BCBST supports NCQA and CMS' decision to follow and adhere to the USPSTF guidelines for colorectal cancer screening.
Cigna	We would like to see Cologaurd added to the specifications for 1-year compliance. Also, the USPSTF recommendation is not likely to occur until late 2016, which may not be enough time to include in HEDIS 2016 specification updates. Therefore, recommend CMS include changes to this measure and potential Star rating to 2017 as the measurement year (2019 Star rating).
Commonwealth Care Alliance	CCA looks forward to future communications on this topic.
Exact Sciences	On behalf of Exact Sciences, we appreciate the opportunity to comment on enhancements to the Star Ratings for 2017 and beyond. On November 12, 2015, the Centers for Medicare and Medicaid Services (CMS), released a Request for stakeholder comment and feedback (R4C) on the proposed methodology enhancements and changes for the 2017 Star Ratings for the Medicare Advantage (MA) and Prescription Drug Plans (PDP) in advance of the 2017 Call Letter. The memo also included advanced notice of potential changes to the Star Ratings for 2018 and beyond. CMS has stated that the goal of the Star Ratings system is to influence beneficiaries' plan choices and also drive organizations and sponsors toward higher quality and more efficient care. The Cologuard test complements CMS's intentions and should be included in the Star ratings system.

Submitter	Response
	Exact Sciences is the manufacturer of Cologuard, the first noninvasive screening test for colorectal cancer, with U.S. headquarters located in Madison, WI. Our diagnostic test was also the very first technology to successfully complete the CMS and U.S. Food and Drug Administration (FDA) Parallel Review process, resulting in the development of an affirmative National Coverage Determination (NCD) (CAG-00440N). Our organizational objectives are aligned with the CMS' intent for the Star Ratings system as we are focused on developing diagnostic tests that lead to quality healthcare decision making and encourage more efficient use of healthcare resources. At present our targeted focus is driving toward the eradication of colorectal cancer. Changes to Existing Star Ratings and Display Measures and Potential Future Changes: Colorectal Cancer Screening (Part C Star Rating) In the R4C, the agency states that it has discussed the updates to the USPSTF colorectal cancer screening guideline with the USPSTF and that the final release is not likely to occur until late 2016, at which point NCQA will consider revisions to the Colorectal Cancer Screening measure currently being used in the Star Ratings program. Exact Sciences strongly supports the continued inclusion of the Colorectal Cancer Screening measure in the Star Ratings program; however, though existing evidence supports the use of FIT-DNA (Cologuard) and CT colonography, and the draft USPSTF recommendation include FIT-DNA and CT colonography, the current measure includes only FOBT and FIT, Flexible Sigmoidoscopy combined with FIT, and colonoscopy as options to satisfy the measure. Exact implores CMS and NCQA to update this measure to include all colorectal cancer screening modalities which are evidenced and included in the draft USPSTF recommendation as options to satisfy the measure as expeditiously as possible to increase patient access to colorectal cancer screening. Over the past decade, intense research has shown the underlying basis of colorectal cancer to be an accumulation of genetic alterations. According to the American Cancer Society, approximately 75% of colorectal cancers are not inherited, but disease of the genome, meaning every cancerous cell has some genetic alteration. This knowledge of genomics forms the basis of a new method of colorectal cancer screening, allowing for identification of known DNA alterations associated with screening relevant neoplasia. Cologuard, works by detecting specific, altered DNA sequences in cells that are shed from the lining of the colon into the stool from pre-cancerous or cancerous lesions. The test also includes a hemoglobin

Submitter	Response
	detection component which identifies the presence of blood in the stool – another possible indicator of colorectal cancer. In a large clinical study, Cologuard found more cancers and precancers than the fecal immunochemical test (FIT), a commonly used non-invasive screening test that detects blood in the stool. I The clinical study results showed that Cologuard found 92 percent of colorectal cancers and 69 percent of high-risk precancers. Colon cancer is one of the most preventable, yet least prevented, cancers in the US today. It is the third most diagnosed cancer, and second leading cause of cancer deaths in both men and women 50 years of age and older. Despite these facts, colon cancer is one of the most treatable cancers if it is found early through screening; however, 1 in 3 adults 50 years of age or older is still not getting screened as recommended. Cologuard serves as an easy to use, noninvasive colon cancer screening test that can be used by men and women 50 years of age and older who are at average risk for colon cancer. Given the evidence for the effectiveness of Cologuard's stool DNA-based colorectal cancer screening test, we encourage the Agency to include stool DNA-based colorectal cancer screening tests in the numerator as an option for satisfying the Colorectal Cancer Screening measure used in the Star Ratings program as expeditiously as possible. Exact Sciences appreciates the opportunity to comment on the measure specification and thresholds for colorectal cancer screening in advance of the 2017 Call Letter and would welcome an opportunity to meet with the Star Ratings team to further discuss Cologuard as it relates to the colorectal cancer screening measure prior to the agency's publication of the 2017 Call Letter. In the interim, should the CMS need additional information concerning Cologuard, or our request, please feel to contact me directly via email: dmjohnson@exactsciences.com or by phone: (330) 559-3944.
Fresenius Health Plans	This is a quality of life question for ESRD beneficiaries. Compared with the general population, the ERSD population has a substantially reduced life expectancy, which does not support universal screening for colon cancer, but to screen instead for acquired cystic kidney disease due to elevated risk for renal cell carcinoma in this population.
Humana	Humana believes this to be a very important measure and one that is needed to keep to incentivize provider and patient compliance. Humana also recommends that CMS recognize Cologuard. After launching an FDA/CMS parallel review of this test and subsequent FDA approval and CMS NCD with payment established every 3 years, Medicare Advantage plans are required to cover Cologuard

Submitter	Response
	for their patients, yet they are not receiving appropriate HEDIS/STARS credit for Cologuard. Cologuard is included in the guidelines for colorectal cancer screening of the American Cancer Society (ACS) with indication for use every three years as well as included in the guidelines of the American College of Gastroenterology (ACG) for use every three years. Cologuard was also included in the recent draft guideline published by USPSTF as an alternative test. There are at least 17 states that require coverage of Cologuard through state mandated legislation. Health plans are in a difficult position of not receiving appropriate quality credit for performing this screening. Cologuard represents a major advancement in colorectal cancer screening quality and is addressing vexing compliance issues. As shown in a 10,000-patient study, Cologuard is superior to the FIT test at detecting both cancer and pre-cancerous lesions. In an important second study published in October in Mayo Clinic Proceedings, Cologuard's performance advantage was even greater. Cologuard is the only colorectal cancer screening test that is FDA-approved and is subject to the FDA's highest level of quality oversight, is performed and provided uniformly nationwide so all patients receive the same quality test, and is supported by an embedded nationwide patient navigation system to help clinicians and patients achieve successful screening.
Medica Health Plans	Medica supports CMS in the decision to wait for the findings of the U.S. Preventative Task Force on the evidence based methods of screening for colorectal cancer.
MetroPlus health Plan	MetroPlus supports these changes and requests that Plans not be held accountable for these changes prior to the revisions and is given ample time to implement the changes in the network and membership.
Triple S Advantage, Inc	TSA suggest a timeline from NCQA for the expected changes. Most times changes to measures are presented too late in the year for MAs to be able to educate members and providers in time. We understand that is changes are made; the measure might be move to the Display Page for that year.
UnitedHealthcare	UnitedHealth is concerned with how this measure would address changes made during the measurement year. For example, will flexible sigmoid completed in previous years be addressed in regards to gap closures? UnitedHealth recommends that if NCQA modifies this measure, it should become effective in January 1, 2017, for Star year 2019.

2. Fall Risk Management (Part C Star Rating)

Submitter	Response
Blue Shield of California	Not strong data regarding Vitamin D to prevent falls.
BlueCross and BlueShield Association	BCBSA and Plans appreciate the notice that the NCQA is proposing changes to the Fall Risk Management (FRM) measure. As CMS notes in the Request for Comments, the NCQA is proposing to (1) revise the denominator of the Discussing Fall Risk indicator to

Submitter	Response
	include all Medicare members 65 and older, and (2) revise the numerator for the Managing Fall Risk indicator to include use of Vitamin D and remove vision or hearing test or taking of postural blood pressure. BCBSA and Plans note that providers are not always consistent in the interventions they employ to reduce falls, and appreciate that CMS is considering including additional interventions in the Managing Fall Risk indicator. We are concerned, however, that there is not sufficient clinical evidence supporting Vitamin D as an effective intervention. We encourage CMS to reconsider whether its inclusion would signal good Plan performance. Additionally, BCBSA and Plans request additional information as to when CMS plans to incorporate any changes into the Star Ratings. We encourage the Agency to provide MAOs with sufficient time to adjust to any changes. Recommendations: BCBSA and Plans recommend that CMS refrain from including the use of Vitamin D as an intervention included in the Managing Fall Risk indicator. BCBSA and Plans request that CMS provide MAOs with advance notice of any changes made to the FRM measure.
BlueCross BlueShield of Tennessee	BCBST supports NCQA and CMS' decision to follow and adhere to the USPSTF guidelines for Fall Risk Management. BCBST also recommends that CMS consider moving this measure to the Display Page for one year upon implementation due to the significance of the changes being made to the survey.
Cigna	Use of Vitamin D is not an exclusive indicator of fall risk management. If included should also include use of MVI w/Vit D
Commonwealth Care Alliance	CCA looks forward to future communications on this topic.
EmblemHealth	Research continues to support use of vision and hearing testing, and postural blood pressure as interventions/ screening tools for fall risk management. The Plan recommends that CMS not remove vision and hearing testing, and postural blood pressure, as numerator-qualifying interventions. Doing so could exclude members who've had appropriate intervention/ fall risk screening. While vision,

Submitter	Response
	hearing, or blood pressure intervention/screenings alone may not indicate fall risk, either can be a significant contributing factor.
Fresenius Health Plans	Around 80% of the ESRD population receives a vitamin D analogue during dialysis. These meds are prescribed to treat secondary hyperparathyroidism and its sequlae, metabolic bone disease. Adding oral vitamin D in this scenario creates a substantial risk for the development of hypercalcemia, which is not only bad news for patients, but avoiding hypercalcemia is one of the current dialysis facility 5 star measures. Again, it is not meaningful to compare the top 1-2% sickest population to the entire Medicare population. We recommend either a carve-out for the ESRD population or for there to be ERSD-specific measurements in place for ESRD C-SNPs. In addition, due to the fact that many ESRD patients become Medicare C-SNP eligible due to his/her health condition, rather than age, this measure is not conducive to measuring the ESRD C-SNP population, as this measurement would not be applicable to many beneficiaries in our population. We recommend either a carve out for the ESRD population or for there to be ERSD-specific measurements put in place for ESRD SNPs.
Humana	Humana supports alignment to the US Preventative Services Task Force guidelines.
Innovacare	Adding the compliance with the administration of Vitamin D among the members 65 y/o will change the perspective/focus of this measure to another one related to Pharmacy (part D) and eliminate its principal focus of prevention of falls among members by eliminating physical barriers.
Medica Health Plans	Medica supports evidence based encounters and treatments to help prevent falls and fractures for our beneficiaries. We will hold on further comments until NCQA and USPTF have shared their findings and recommendations.
MetroPlus health Plan	MetroPlus requests that Plans be given adequate time to roll out this measure if the proposed changes are approved.
Molina Healthcare Inc.	Molina Healthcare agrees with the Agency's direction to review revisions in current scientific evidence prior to finalizing the measure. We ask that CMS reconsider whether this measure is valid and reliable for use in comparing health plans.
National Council on Aging	The National Council on Aging (NCOA) has been a national leader on falls prevention issues for over a decade, through our NCOA Falls Free® Initiative and role as the National Falls Prevention Resource Center, which supports the implementation and dissemination of evidence-based falls prevention programs and strategies across the nation. To assist us in providing comments on the Fall Risk Management (FRM) measure, we consulted with our representative members of the American Occupational Therapy Association and the American Physical Therapy Association; members who are actively practicing physical and occupational therapists specializing in balance and fall prevention and who fall under these star ratings. While the USPSTF guidelines are built upon research findings, we

Submitter	Response
	believe the more valuable application guidelines used by the American and British Geriatric Societies and translated into practical user protocols by the CDC as the STEADI (Stopping Elderly Accidents, Deaths and Injuries) should be considered. The American Board of Internal Medicine also recognizes these guidelines and uses the STEADI in recertification. The CDC is offering a variety of online STEADI training options and toolkits to further adoption. Applying those guidelines, we submit the following comments: 1) Pertaining to Fall Risk assessments, all older adults age 65 years of age and older should be screened for fall risk annually and provided education about fall risk. A positive screen is based on the following: fall in the past year, fear of falling, self-reported difficulties with mobility, problems with balance or walking with their current practitioner, feels unsteady when standing or walking, or worry about falling and received fall risk intervention. All positive screens per STEADI guidelines should lead to an assessment and an intervention. 2) Pertaining to Fall Risk management, all older members 65 years of age and older who fell in past year, feel unsteady when standing or walking, or worry about falling should receive a fall risk intervention from their current practitioner; the fall risk intervention is defined as a functional mobility assessment for all positive screens. As a minimum, patients screening positive should also receive: 1) fall prevention education, and 2) a referral for a community-based exercise or fall prevention program or a referral to physical therapy. Refer to: AGS/BGS Clinical Practice Guideline: Prevention of Falls in Older Persons http://www.americangeriatrics.org/health_care_professionals/clinical_practice/clinical_guidelines_recommendations/prevention_of_falls_summary_of_recommendations CDC STEADI http://www.cdc.gov/steadi/materials.html Prevent Falls in Older Patients, Provider Pocket Guide http://www.cdc.gov/steadi/pdf/preventing_falls_in_older_patients_provider_pocket_guide_2015-a.pdf
Triple S Advantage, Inc	TSA suggest further research for the changes in methodology.
UnitedHealthcare	UnitedHealth supports CMS' proposed the changes to the numerator, including the indicator to recommend vitamin D. This aligns with clinical practice guidelines from the American Geriatrics Society and others.

3. Pneumococcal Vaccination Status for Older Adults (Part C Display)

Submitter	Response
America's Health Insurance Plans	CMS indicates that NCQA is considering changes to this Part C display measure in order to align it with the most current guidelines. We are concerned that reliance on patients' responses to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey question regarding receipt of a pneumococcal vaccine for this measure does not produce the most reliable and valid data. We recommend that CMS work with the industry, identify

Submitter	Response
	and consider more reliable data source(s).
Blue Cross and Blue Shield of Minnesota	Due to the complexity of these vaccines, BCBSMN recommends that data collection and reporting use medical claims, not member reporting.
Blue Shield of California	Must be done through claims data.
BlueCross and BlueShield Association	CMS notes that NCQA is considering updating the Pneumococcal Vaccination Status for Older Adults (PNU) measure according to new recommendations from the Advisory Committee on Immunization Practices. The PNU measure assesses the percentage of Medicare members, ages 65 and older, who have received a pneumococcal vaccination. The changes would reflect the recommendation that all adults, ages 65 and older, should receive sequential administration of both PCV13 and PPSV23. BCBSA and Plans are committed to ensuring that all adults, as appropriate, receive the most effective PNU vaccinations and appreciate CMS's attention to changing recommendations. We are concerned, however, that the measure, which is currently on the Display Page, is based on data collected through the CAHPS survey and is member-reported. It is Plans' experience that members have a difficult time recalling whether they have received a specific vaccination – a problem that is compounded if the measure is updated to reflect the recommendation that individuals receive two vaccine administrations. Recommendations: BCBSA and Plans recommend that CMS revise the PNU measure to be based on claims data and not rely upon member recall. (See also Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.)
BlueCross BlueShield of Tennessee	BCBST supports the alignment of this measure with the new ACIP guidelines. In addition, BCBST encourages CMS to offer guidance on how to monitor compliance when members move from plan to plan, and more so in general, how historical vaccinations could/should be incorporated.
Cambia Health Solutions	Is NCQA considering moving this to an administrative or hybrid measure? We believe this will be difficult to measure on a survey
Centene Corporation	Centene Corporation would like to voice concern with the methodology of this measure; specifically, Centene is concerned that an outcome measure that relies on a beneficiary's ability to recall a series of multiple injections would not accurately capture compliance. Additionally, this measure would be difficult for MCOs with a large membership in long term care or nursing facilities, as the

Submitter	Response
	pneumococcal vaccination is included as part of standard care and cannot easily be extracted using claims data. Thus, we recommend that this be a hybrid measure that includes an administrative data collection component in addition to the proposed CAHPS survey with lower cut points. We also recommend that the CAHPS survey question address whether or not the vaccine was received, with a supplemental question about sequential administration for data purposes.
Cigna	This measure was previously a Star Rating and removed because it was unreliable. Based on this, would like to understand more from CMS as to why CMS is bringing this measure back. If this measure is returned, we recommend that claims data be used to validate compliance because members may not be able to recall an immunization they received in the remote past, making survey data unreliable for this measure. To ensure accuracy we also recommend that CMS use a 5-10 year timespan to identify vaccinations.
Commonwealth Care Alliance	CCA looks forward to future communications on this topic.
Fresenius Health Plans	This measure is not conducive to our Model of Care and the ESRD population for a couple of reasons. For one, our model of care has nephrologists as PCPs rather than regular PCPs. Secondly, a majority of ESRD patients will receive flu vaccines at the Dialysis Center and not at their PCP office or pharmacy, as beneficiaries with ESRD requiring dialysis must receive treatment three times a week, each of which typically last four hours. We recommend measurement be based on claims data to ensure accurate numbers.
Health Care Service Corporation	We appreciate the summary of new and proposed changes to this measure. We continue to have concerns that the CAHPS survey, which relies on self-reported data is lacking in accuracy. We also acknowledge that claims data are incomplete, but believe they may be a more accurate indicator than the CAHPS survey. HCSC recommends that CMS continue to work with NCQA to evaluate the best approaches to getting more accurate data for this measure.
Health Net, Inc.	Recommend measure not added to Stars Rating due to identified issues w/ accurate reporting
Humana	Humana supports the incorporation of a quality measure related to pneumococcal vaccinations in the efforts to increase preventative activity and vaccination rates. However, Humana would suggest that this measure's validity and reliability be fully tested and that it be included as a display measure for several years, while this is tested. Humana believes many people may not be able to remember previous vaccinations, especially those who received vaccinations several years in the past. Humana requests that CMS study the responses and compare those to claims history for these vaccinations to ensure member responses align to what is occurring clinically as the measure should be accurately measuring clinical treatment. Humana would also support the development of a claims

Submitter	Response
	or registry based vaccination measure to accurate measure vaccination status.
Medica Health Plans	Since the current guideline is for beneficiaries to receive the vaccination one time for life, the length of time can be a barrier to recall of whether or not the beneficiary received the vaccination(s). Medica would like to to see measures around vaccinations based on claims versus beneficiary recall over several years. Also, not every beneficiary who ages in to Medicare coverage receives this vaccination at age 65, and there may be a 2-3 year delay, if the member received the shot at 64, as he or she may wait five years before getting an additional dose.
Molina Healthcare Inc.	Molina Healthcare agrees with the Agency's direction not to include this measure in the Star Ratings until the current evidence is reviewed. In addition, Molina has concerns as to whether this measure is appropriate for use in Star Ratings. Members may have a difficult time remembering whether they received a pneumococcal vaccination.
Pfizer	Description of the Issue or Question: CMS notes that the Pneumococcal Vaccination Status for Older Adults (PNU) measure (currently a Medicare Advantage display measure), collected through the Medicare CAHPS survey, assesses the percentage of Medicare members 65 years of age and older who have ever received a pneumococcal vaccination. The agency also notes that NCQA is considering changes to the PNU measure. These changes will reflect the updated Advisory Committee on Immunization Practices (ACIP) recommendation that all adults 65 years of age and older receive sequential administration of both PCV13 and PPSV23. Suggested Revisions/Comments: Pfizer supports NCQA's efforts to update the PNU measure to reflect the most recent ACIP recommendations. According to estimates from the National Health Interview Survey (US 2012), pneumococcal vaccination rates are still suboptimal. In 2013, pneumococcal vaccination coverage of adults over the age 64 was still at only 60 percent, and only 49 percent and 39 percent of blacks and Hispanics, respectively, received pneumococcal vaccination. There is clear evidence demonstrating the impact of quality measures on vaccination rates. Following the inclusion of quality measures evaluating the percentage of inpatient individuals assessed for pneumococcal vaccination, large increases in vaccination rates have been observed; between 2006 (when CMS first began reporting quality measure data assessing pneumococcal vaccination) and 2011, the percentage of pneumonia patients who were assessed for a pneumococcal vaccine increased from 74.3 to 95.4 percent. In the absence of optimal vaccination rates, pneumonia will continue to exert a significant economic burden on the healthcare system. In 2012, total costs for Medicare beneficiaries during and one year following a pneumonia hospitalization were approximately $15,682 higher than those patients without pneumonia. In recent years, pneumonia caused an

Submitter	Response
	estimated four million illness episodes, which resulted in direct medical costs of $3.5 billion, as well as other costs such as lost productivity and diminished quality of life. Appropriate vaccination could reduce the incidence of pneumonia and avoid the costs of the condition. Due to the suboptimal rate of pneumococcal vaccination and the continuing burden and prevalence of pneumonia in the 65 and older population, Pfizer further encourages CMS to consider moving the pneumococcal vaccine status measures from the Display page and incorporate it into the Star Ratings calculation. While the measure's appearance on the Display page is certainly beneficial for the collection of data from those plans choosing to voluntarily report on the measure, incorporation in the Star Ratings calculation will help provide the necessary incentive to ensure health plans are striving for comprehensive vaccination across their membership. Centers for Disease Control and Prevention. Summary Health Statistics for the U.S. Population: National health Interview Survey, 2012. Available at http://www.cdc.gov/nchs/data/series/sr_10/sr10_259.pdf. Williams, W et al, Vaccination Coverage Among Adults, Excluding Influenza Vaccination-United States 2014, MMWR Feb 6, 2015. From the CDC website: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6404a6.htm?s_cid =mm6404a6_w. Centers for Medicare & Medicaid Services. 2015 National Impact Assessment of Centers for Medicare & Medicaid Services (CMS) Quality Measures Report. March 2015. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/2015-National-Impact-Assessment-Report.pdf. pp. 180. Thomas CP. et al. Incidence and Cost of Pneumonia in Medicare Beneficiaries. Chest. 2012. Oct; 142(4):973-81. National Foundation for Infectious Diseases. "Pneumococcal Disease Call to Action." April 2012.
SNP Alliance	G. Changes to Existing Star Ratings and Display Measures and Potential Future Changes For all the measures in this section, the SNP Alliance looks forward to future communications and updates, and the ability to comment on specific recommendations related to these measures' inclusion in Star Ratings or on the display page. 3. Pneumococcal Vaccination Status for Older Adults (Part C Display) In general, we are concerned about the reliability of the patient-reported survey data for this measure. It may be difficult for patients to know whether they had the specific vaccination and whether it was administered in a given year. This is an issue that is even more of a concern for the populations enrolled in SNPs. Our preference would be to utilize claims data for this measure and to lower the measure's cut points, realizing that not all vaccinations will be captured in claims.
Triple S Advantage, Inc	TSA suggests considering a change in the source for the measure given the new indications.
UCare	Having older adults self-report on receipt of vaccinations can be

Submitter	Response
	problematic. In addition, many members confuse this vaccine with the flu vaccine when self-reporting.

4. CAHPS measures (Part C & D)

Submitter	Response
Anthem, Inc	Anthem continues to believe that the Star Ratings system should include more outcomes measures that focus on improvements in beneficiaries' health. In order to avoid restrictions on how members access services and disincentives for health plans to implement innovative approaches to disease and care management, the Star Ratings should be measures of outcomes, rather than measures of process. We encourage CMS to select outcomes measures with more direct linkage to the actions and influence of a plan rather than those that have a broad focus and are influenced by an infinite number of external variables outside the immediate control of the plan. In particular, we suggest that CMS attribute greater weight to data-driven measures developed based on rigorous scientific and evidence-based information than to measures that are constructed from enrollee surveys, which are subjective responses subject to recall from beneficiaries. Ensuring that the Star Ratings truly measure plan value and performance will, in turn, make the plan ratings a more useful and meaningful tool for beneficiaries to employ when selecting a MA or Part D plan. CMS notes that it also is considering changing the sampling for CAHPS when a contract is listed in HPMS as associated with a consolidation, merger, or novation between July of the prior year and January of the current year when the CAHPS sample is drawn. Specifically, CMS is considering changing the sampling frame for the surviving contract to include the enrollees for all members of all contracts involved if the two or more contracts merging, consolidating or novating are under the same parent organization. Anthem disagrees with this approach and requests that CMS not change the sampling for CAHPS in these situations. Circumstances of the former plan, such as a different network or different benefits—factors that may even be the catalyst of the novation or consolidation—suggest that the experience of the novated/consolidated member could be very different from the experience of the member who was enrolled in the contract in the previous year. Therefore, Anthem believes it is inappropriate to include novated/consolidated members—who by definition were in another plan during the survey eligibility period—in the CAHPS survey sample.
Association for Community Affiliated Plans	For any changes CMS is considering making to display measures, CAHPs, and CMMI, ACAP requests that CMS identify the specific modifications to be made and give plans ample time to review the changes and prepare for them. For example, if the Medicare Plan Finder Price Accuracy measure were to be changed mid-2016, issuers would have insufficient time to account for those changes, and 2018 Star Ratings would be adversely impacted. If CMS is

Submitter	Response
	unable to give plans sufficient time to prepare, then CMS should hold off on making changes to measures for an additional year or more.
BlueCross and BlueShield Association	CMS proposes to update the CAHPS measures to reflect the changes developed for the CAHPS 5.0 Health Plan Survey. Because three measures – Getting Care Quickly, Customer Service, and Care Coordination – require changes to the wording in the CAHPS survey and CMS's tests showed that scores using the new measure were significantly different, CMS proposes to exclude the measures from the Part C Improvement Measure for the 2018 Star Ratings. In general, BCBSA and Plans agree with the changes to the CAHPS survey, and thus the Star Ratings measures, although Plans note that it is difficult to adjust when measures are removed from the Improvement Measure without notice before the measurement period. We appreciate, however, that CMS recognizes the need to take such action because the underlying metrics have changed. CMS also proposes to change the sample for CAHPS when a contract is listed in HPMS as associated with a consolidation, merger, or novation between July of the prior year and January of the current year when the CAHPS sample is drawn. As stated in the Request for Comments, CMS is considering using the enrollees for all members of all contracts involved if the two or more contracts which are merging, consolidating, or novating are under the same parent organization. BCBSA and Plans request that CMS provide stakeholders with additional detail about this proposal. Recommendations: BCBSA and Plans request that CMS provide additional detail about its proposal to adjust the sample used for the CAHPS survey measures. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.)
BlueCross BlueShield of Tennessee	BCBST agrees that the survey verbiage changes should have a year over year comparison and therefore should be excluded from the improvement measure calculation as proposed by CMS.
Centene Corporation	Centene Corporation recommends that steps be taken to shorten the survey with the objective of increasing members' response rates so that responses are more representative of members' experience overall. The length of the current survey leads to a disproportionate number of responses from members that are either very pleased or

Submitter	Response
	very displeased with various aspects of plans performance, resulting in a sampling of responses that are not representative of members' satisfaction overall. Based on our experience, response rates would improve significantly if the survey were shortened considerably. In order to reduce the number of survey questions, we suggest that the survey is not an appropriate source of information on plan/provider reminders and operations. CMS should consider alternative ways of evaluating these aspects of plan performance. We suggest that the CAHPS survey be more limited to questions related to consumer satisfaction. We also feel that the use of proxy does not reflect the members overall experience with their Medicare program. Additionally, CMS's method for relying on the survey vendor to assign a disposition code to exclude members from the survey who are institutionalized or residing in a group home or institution (hospice, nursing home) is unreliable. Centene feels that if these beneficiaries are to be excluded then a more reliable source should be to exclude these beneficiaries from the survey sample based off of Plan enrollment data prior to sending the sample to the survey vendor.
Centers Plan for Healthy Living, LLC	These measures are still highly subjective as they are based on the member's perception/recollection of events. Recognizing that there is often a discrepancy between a Member's perception of urgency and when a Member's condition might actually dictate attention, we might recommend that the language of such survey questions be modified to acknowledge that some contact with the Provider's office may have occurred to mitigate concerns the Member may be having with regard to being evaluated for their condition (i.e. a conversation with the on-call doctor might be sufficient to address a Member's needs such that the Member's perception of an urgent need for an appointment might be dispelled); thus, we would recommend that respondents be asked "...if they were able to get an appointment or speak with their physician/provider as soon as they needed..."; Survey measures that attempt to capture (from the Member) whether a specific vaccine was administered are inherently flawed; responses are necessarily limited to Member recall and Member recall for the receipt of a vaccination would not be expected to be able to reliably discern whether the vaccination received was for pneumococcal pneumonia, influenza or any other vaccine. Measurement of such an important dimension of preventive care should be based upon by more objective parameters, as might be accomplished through capturing claims-based encounters for these types of services.
Cigna	We recommend CMS exclude from the CAHPS sample set members who are part of a consolidated, merged, or novated plan. Also - the changing of the wording from "how often" was it easy to get appointments with specialists to "did respondents get" an appointment as soon as they needed could encourage the respondents to answer more unfavorably based on factors out of the health plan's control. With the original wording, more emphasis is

Submitter	Response
	placed on the health plan's actions of making it easy for a member to get an appointment with a specialist (i.e., easy referral process). Specialists' offices often take months to get an appointment with, regardless of the health plan or member.
Commonwealth Care Alliance	CCA supports this plan.
EmblemHealth	Annual flu vaccine measure should be based on actual administrative encounter data rather than patient perception on the CAHPS survey. The recall bias leads to a false assessment of the vaccination rate and the use of claims data would not only help with a more accurate rate.
Healthfirst	We have several concerns about the CAHPS measures and urge CMS to consider down weighting them or, at minimum, removing them from the calculation of the Part C and D Improvement Scores. Our concerns: 1. CAHPS measures are case-mix adjusted for beneficiary-level characteristics, but do not account for macro-environmental factors like Health Professional Shortage Areas (HPSAs) and benchmark rate changes. HPSAs: HPSAs are not included in the CAHPS case-mix adjustment methodology, despite the fact that several CAHPS measures are directly impacted by provider availability (Getting Appointments and Care Quickly, Getting Needed Care). Affordable Care Act Benchmark Cuts Affecting CAHPS Performance: Mandatory changes to benchmark rates differ by county. As our benchmark rate continues to decline to 95% of FFS, these mandatory cuts have forced us to increase cost sharing - co-pays/premiums for members. Rising out-of-pocket costs play a significant role in members' satisfaction with their health plan and providers. We brought this concern about the relationship of benchmark rate changes and CAHPS measure performance to CMS earlier this year. We were informed that CMS examined the impact of decreasing benchmarks on each CAHPS measure, and that this analysis identified a systematic relationship between changes in CAHPS scores and declining benchmarks. We request that CMS releases its study on the relationship of declining benchmark rates and changes to CAHPS scores. 2. CAHPS Sample Size and Small Differences in Star Cut Points Because the CAHPS survey has a small sample size, it is difficult to reliably distinguish performance between star cut points. For example, Healthfirst had 411 respondents to the CAHPS survey, which results in a 3.9% margin of error at a 95% level of confidence. CAHPS cut points are very close with most measures have a 1-3% difference between adjacent star cut points; as such, most cut point differences (1-3%) are less than our 3.9% margin of error. A considerably larger sample (n=> 1000) is necessary to reduce the margin of error such that performance at adjacent cut points can be reliably distinguished. 3. Provider-driven CAHPS measures on the MA Survey have a significant impact on the overall star rating, but providers themselves aren't consistently and directly evaluated on these measures. Inconsistency in

Submitter	Response
	Wording - The CAHPS Clinician & Group Survey is administered to patients to report on their experiences with doctors and their staff. The phrasing of the questions pertaining to Getting Timely Appointments, Care, and Information differs between the CAHPS Clinician & Group Survey and the MA CAHPS survey. Questions regarding provider access and availability should be consistent among provider-driven measures in the CAHPS surveys. While CMS is planning to update the MA & PDP CAHPS Survey to be more consistent with the Clinician and Group Survey, this update will not be implemented until the 2017 survey, impacting the 2018 Star Rating. Inconsistency in Importance - The MA CAHPS survey asks members, "In the last 6 months, how often did you see the provider within 15 minutes of your appointment time?" This question is counted toward the scoring for CAHPS in the Star Ratings. However, this same question is just a supplemental question on the CAHPS Clinician & Group Survey – providers are not being held accountable on this measure. We recommend that CMS remove this question from the CAHPS composite measure, Getting Appointments and Care Quickly, as questions regarding provider access and availability should be consistent among provider-driven measures on the CAHPS surveys. For the reasons outlined above, it is clear that there is noise associated with the CAHPS measures that make them less reliable for quality measurement. We urge CMS to downweight the CAHPS measures until these concerns are addressed. At minimum, they should be removed from the calculation of the Part C and Part D Improvement Scores.
HealthPartners	We recommend that CMS shorten the length of the CAHPS survey. We have seen our response rate decline over time and believe it is due to the growing length of the survey. The survey is over 90 questions in length and results in a disproportionate number of responses from members who are either very pleased or very displeased with the plan. We suggest that the CAHPS survey be more limited to questions related to consumer satisfaction.
Medica Health Plans	Media supports the proposed changes at this time.
Molina Healthcare Inc.	Molina Healthcare agrees with CMS's direction to move forward with the CAHPS version 5.0 survey. In regard to survey administration, CMS should follow NCQA's guidelines so that all requirements are consistent across all organizations and programs.
PCMA	4. CAHPS Measures (Part C & D) – CMS proposes to update the MA and PDP CAHPS Survey to reflect AHRQ's CAHPS 5.0 Health Plan Survey, taking effect for the 2017 survey administration and affecting 2018 Star Ratings. PCMA Recommendation: PCMA supports the proposed update.
SNP Alliance	4. CAPHS measures (Part C & D) We do not have any specific concerns related to CMS' proposal to update the MA & PDP CAHPS Survey to reflect AHRQ's CAHPS 5.0 Health Plan Survey, We would, however, like to reiterate several comments regarding the CAHPS Survey that the SNP Alliance has made in the past and request

Submitter	Response
	CMS' consideration of these: ?--In general, we believe that CMS should attribute greater weight to data-driven measures where development is based more on rigorous scientific and evidence-based information than on measures that are constructed from enrollee surveys that contain subjective responses and are subject to recall from beneficiaries. As we have commented in the past, we are especially concerned about the validity of self-reported data provided by certain subsets of Medicare beneficiaries that are disproportionately served by SNPs, including persons with cognitive impairments, intellectual and developmental disabilities, and serious mental health issues. We recommend that these individuals be excluded from the denominator unless a "qualified" responsible party is available to serve as a proxy respondent. ? --We recommend that steps be taken to shorten the survey with the objective of increasing members' response rates so that responses are more representative of members' experience overall. The length of the current survey results in a disproportionate number of responses from members that are either very pleased or very displeased with various aspects of plans performance such that the responses are not representative of members' satisfaction overall. It is our belief that response rates would improve significantly if the survey were shortened considerably; and, in order to reduce the number of survey questions, we suggest that the survey is not an appropriate source of information on plan/provider reminders and operations. CMS should consider alternative ways of evaluating these aspects of plan performance. We suggest that the CAHPS survey be more limited to questions related to consumer satisfaction. ? --Currently, the CAHPS survey methodology does not allow for many non-English speaking members to participate. Many SNP Alliance members' plans serve significant proportions of beneficiaries who speak languages other than English, Spanish or Chinese and whose experiences are not included in survey results. We recommend that CMS increase the number of languages into which the survey is translated and set forth a consistent proxy methodology that would allow for higher participation rates among non-English speaking populations.
UnitedHealthcare	UnitedHealth requests that CMS provide plans with the methodology used to determine the exclusion of measure from the improvement score due to significant methodology changes, including what constitutes a "significantly different" score. We suggest that this methodology be provided via the Technical Notes. UnitedHealth also requests that CMS clarify whether this determination will be applied to other measures that have proposed methodology changes such as Colorectal Cancer Screening, Fall Risk Management, MPF Price Accuracy, and CAHPS consolidation/merger/novation adjustment.
WellCare	WellCare supports the move to the CAHPS 5.0. We appreciate the testing and development that was considered prior to this change and the close monitoring that CMS will provide following the change.

Submitter	Response
	By simplifying and shortening the CAHPS survey and questions, members may feel less overwhelmed when they receive the CAHPS survey in the mail and may be more likely to complete the survey, especially those with lower educational attainment and lower socioeconomic status. With regard to the question addressing how often it was easy to get appointments with specialists, we ask CMS to clarify whether this will now be a yes/no question or if the question will be worded with the standard options: always, usually, sometimes, or never.

5. Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating)

Submitter	Response
Aetna	Aetna supports exclusion of Entresto in the measure.
Anthem, Inc	Due to the complex dose titration and newly approved status of sacubitril/valsartan, Anthem agrees with CMS' decision to exclude these newly-available therapies from the RAS Antagonists adherence measure.
Blue Cross and Blue Shield of Minnesota	BCBSMN notes that the HEDIS measures related to the three medication adherence measure centering on treatment for diabetes, cardiovascular disease (specifically high cholesterol), and hypertension have key differences to the Acumen adherence measures. Specifically, the scope of the data used to identify members for the measure and the breadth of the exclusions invoked vary across the two measure types. All three of the HEDIS measures have upper age limits; the Acumen measures are not defined. We recommend implementation of upper age limits for these reasons: 1) Clinical trials do not include the very old, so the scientific evidence for inclusion is not proven. 2) When determining the risk/benefit ratio of prescribing a medication for a member, the benefit of possibly preventing a condition that may develop in 20 years or more cannot offset the possibility of creating a risk of the member falling. 3) Working with our PBM, we performed an analysis of 1.3 million MAPD members in the adherence measures to calculate adherence rates for members by age bands. We found that adherence fell significantly with age and are happy to provide this data upon request. In the absence of clinical evidence through published literature of efficacy of the treatment in the very old, we believe that this statistically significant observation of a decline in use in the older age bands provides empirical evidence that use of these medications is not supported in members above specific age thresholds. BCBSMN recommends establishing upper age limits for the three adherence measures, based on the corresponding HEDIS measures: Diabetes & Statin capped at age 75 and hypertension capped at age 85.
BlueCross and BlueShield Association	Consistent with PQA's specification change, CMS proposes to exclude from the denominator those patients with one or more claims for sacubitril/valsartan. BCBSA and Plans support this change and encourage CMS to implement it as proposed. Additionally, BCBSA

Submitter	Response
	and Plans recommend that CMS also exclude those patients who are over 85 years old, as such individuals are not included in the research on medication adherence. More generally, BCBSA and Plans recommend that CMS consider implementing upper age limits on all three medication adherence measures: Medication Adherence for Hypertension (RAS Antagonists); Medication Adherence for Cholesterol (Statins); and Medication Adherence for Diabetes Medications. One Plan noted that the related Healthcare Effectiveness Data and Information Set (HEDIS) measures have such age limits. Recommendations: BCBSA and Plans recommend that CMS implement the change to the Medication Adherence for Hypertension (RAS Antagonists) as proposed. BCBSA and Plans recommend that CMS revise the measure to also exclude patients who are over 85 years old, because they are excluded from clinical studies. BCBSA and Plans recommend that CMS consider adding upper age limits to all three of the medication adherence measures: Medication Adherence for Hypertension (RAS Antagonists); Medication Adherence for Cholesterol (Statins); and Medication Adherence for Diabetes Medications.
BlueCross BlueShield of Tennessee	BCBST agrees with CMS' proposed change.
Cambia Health Solutions	We would support this move. Would like confirmation on when CMS will begin excluding these members from the denominator
Commonwealth Care Alliance	CCA supports excluding from the denominator those patients with one or more claims for sacubitril/valsartan. This star measure should not apply to dual plans where members have $0 cost sharing.
CVS Health	SilverScript supports the exclusion of sacubitril/valsartan.
Fresenius Health Plans	We request that emphasis and specification be added that beneficiaries with ESRD will continue to be excluded from the denominators of these measures, as stated in the 2016 Call Later.
Healthfirst	We support the exclusion of Sacubitril/Valsartan from this measure. Since Sacubitril/Valsartan is only FDA approved for heart failure and does not have an indication for hypertension, it should not be included in the hypertension adherence measure.
Medica Health Plans	Media supports.
MetroPlus health Plan	MetroPlus also supports the exclusion of these medications.
PCMA	5. Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating) – CMS states the measure will exclude from the denominator those patients with one or more claims for sacubitril/valsartan. PCMA Recommendation: PCMA supports this

Submitter	Response
	exclusion.
PQA	PQA agrees with the CMS proposal to include the PQA specification change to exclude from the denominator those patients with one or more claims for sacubitril/valsartan.
RxAnte	• RxAnte supports the exclusion of sacbutril/valsartan from Medication Adherence for Hypertension measure for the reasons stated by CMS in proposing this change.
SCAN Health Plan	G.5 Changes to Existing Star Ratings and Display Measures and Potential Future Changes: Medication Adherence for RAS Antagonists (Part D Star Rating). Based on PQA specification change, the measure will exclude from the denominator those patients with one or more claims for sacubitril/valsartan. SCAN Comment: Agree with PQA specification change to exclude those with one or more claims of sacubitril/valsartan.
SNP Alliance	5. Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating) We support excluding patients with one or more claims for sacubitril/valsartan from the measure's denominator.
UnitedHealthcare	United requests that CMS clarify whether the proposed changes for Medication Adherence for Hypertension will impact Star year 2017 or 2018.

6. MPF Price Accuracy (Part D Star Rating)

Submitter	Response
Aetna	Aetna believes the Medicare Plan Finder Accuracy measure should be removed from the Star Ratings program and moved to the display page. Through written guidance, CMS has previously described its intention to move measures from the Stars program to the display page when plans have achieved high- quality performance, and where the results do not allow for differentiation among plans. In the 2016 Star Ratings results: MA plans achieved an average rating of 98% MA plan 4-star cut-point was set at 99% and 5 stars at 100% PDP plans achieved an average rating of 99% PDP plan 4-star cut-point was set at 98% and 5 stars at 99% (with no plans at 1 to 3 stars). Based on these results and in line with CMS' policy to retire high-performing measures, we believe the MPF Price Accuracy measure should be retired and moved to the Display Page.
America's Health Insurance Plans	CMS is proposing changes to the existing MPF Price Accuracy measure for the 2018 Star Ratings. We understand that plans continue to have a challenging time analyzing data in order to determine the distinction between cut points for this measure. This makes it difficult for them to evaluate their performance and set internal performance targets. We continue to urge the agency to evaluate these concerns and consider stakeholder input on this measure.
Anthem, Inc	Anthem appreciates CMS' efforts to improve Price Accuracy Scores. However, we recommend that the Agency retain the existing MPF Price Accuracy measure methodology for 2017 and mimic its proposed changes on the display page. This would ensure that plans

Submitter	Response
	have clear visibility into how CMS' contemplated methodological changes would work, as well as sufficient time to review the impact on performance. Similar to our concerns with the MTM Program Completion Rate for CMR measure, Anthem believes that the 2016 cut points for the MPF Price Accuracy measure are not supported by the data reporting and submission timelines associated with this measure. In 2016, plans had to achieve a rate of greater than or equal to 99% to receive a 4 Star, or 100% or greater to receive a 5 Star on this measure. However, while CMS requires plans to update source Average Wholesale Price (AWP) information at least every seven days, the pricing files are only submitted to Plan Finder via CMS' subcontractor every two weeks. This disconnect in data timing, which is outside of the plan's control, makes the MPF Price Accuracy measure 4 and 5 Star cut points extremely hard to meet—even when plans are reporting accurate information according to the Agency's standards.
Association for Community Affiliated Plans	CMS is considering updates to the Medicare Plan Finder Price Accuracy measure, including how current methodology is limited to 30-day claims filled at pharmacies reported by sponsors as retail only or retail and limited access only. If CMS pursues this, then the quality measure will differ from how pricing information is displayed on Medicare Plan Finder. As such, we request that CMS change plan finder submissions to allow plans to submit pricing data for 30 days.
Blue Cross and Blue Shield of Minnesota	BCBSMN worked with our PBM to quantify the difference in the detail data CMS provided from the MPF measure and our PDE data. We found that 60% of the claims had a difference between the PDE and the MPF of $1.00 or less (17% of the file was $0.05 or less). In addition, the majority of the errors were related to differences in the update schedule between the AWP and MAC pricing (weekly) and the MPF updates (every two weeks). BCBSMN notes that the Star thresholds for this measure are very tight and therefore the measure is unable to demonstrate meaningful differences across plans. Because the measure reflects a point in time, the data points are unlikely to represent the actual experience of beneficiaries and because plans are not able to reproduce the results in a timely manner, the ability to impact and improve these results does not exist.
BlueCross and BlueShield Association	CMS proposes to make two changes to the MPF Price Accuracy measure. First, CMS proposes to expand the universe of claims used to evaluate price accuracy to include those claims with 28-34 day supplies, those claims with 60-62 day supplies, those claims with 90-93 day supplies, and all retail claims (including those filed by retail pharmacies that are also long term care, mail order, or home infusion pharmacies). Second, CMS proposes to include a Claim Percentage Score in the MPF Price Accuracy measure to account for the frequency of inaccuracy (i.e., the percent of claims where PDE cost is greater than MPF cost).

Submitter	Response
	BCBSA and Plans generally do not support measures that evaluate the PDE cost relative to MPF costs, as there are too many variables that affect the analysis that are outside of Plans' control and because administrative/oversight measures are unrelated to quality of care. We also note that the measure reflects performance at a fixed point in time and may not be an accurate proxy for beneficiary experience. Finally, given the cluster of scores on this measure, we recommend that CMS consider retiring the measure from the Star Ratings, as there does not appear to be significant room for improvement absent metric changes. If CMS retains this measure, we request that CMS exclude instances where the PDE costs is only slightly higher than the MPF costs, as well as review the Agency's rounding methodology to ensure that it does not incorrectly produce a different price. Such changes would more accurately reflect Part D Plan performance and would minimize penalizing Part D Plans for those small differences in price for which there may be a reasonable explanation and over which the Part D Plan has no control. More broadly, BCBSA and Plans encourage CMS to provide additional information as to how the Price Accuracy Score and the Claim Percentage Score will be combined. For example, will one score be weighted more than the other? (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.) As part of this effort to provide transparency, BCBSA and Plans request that CMS calculate contracts' scores under both the current and proposed methodologies. BCBSA and Plans request that CMS generally review the MPF Price Accuracy measure to determine whether adjustments should be made to minimize inaccurate price findings due to reasons largely outside of the Part D Sponsor's control. (See also Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.) For example, CMS could shorten the two-week time frame between the price submission and posting to the MPF display, in an effort to recognize that pricing at the point of sale can change daily. Multiple Plans noted that the delay in transmission of the amounts in the price file to the MPF contributes to the number of seemingly inconsistent MPF prices. One Plan noted that its pricing is

Submitter	Response
	updated weekly to reflect updates to the Average Wholesale Price and Maximum Allowable Cost (MAC). This Plan's analysis of its CMS-identified errors revealed that a majority of the errors were caused by this timing difference. Additionally, CMS could consider how to allow for "lower of logic" benefits adjudication systems. Under such systems, the beneficiary pays the lowest of two or more prices (e.g., usual and customary charge, MAC). Not all of these prices are tied to the amounts listed on the price files received by CMS, meaning that the member's price will always differ from the MPF if the "lower of logic" selects such a price. These and other changes are especially important because, in order to achieve a 5 star rating on the MPF Price Accuracy measure, Part D Sponsors must achieve a 100% accurate score. BCBSA and Plans submit that CMS may want to form a working group, including Plan Sponsors, to consider how the MPF Price Accuracy measure can be improved. Recommendations: BCBSA and Plans request that CMS exclude from the Claim Percentage Score those instances in which the price difference is very small. BCBSA and Plans request that CMS provide additional information as to how the Claim Percentage Score and the Price Accuracy Score will be combined to form one MPF Price Accuracy measure. (See Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.) BCBSA and Plans urge CMS to review the MPF Price Accuracy measure to reduce the number of instances in which Part D Sponsors are penalized for inaccurate prices beyond their control. (See Key Recommendation: Use Measures that Accurately Reflect True Plan Performance.)
BlueCross BlueShield of Tennessee	BCSBT requests that CMS provide more information on the specific calculation that will show how the Price Accuracy Score and the Claim Percentage Score will be combined and represented as the MPF Accuracy star measure. BCBST recommends that CMS consider making the MPF Accuracy measure a Display Measure for 2018 due to the significant change in calculation methodology, in order to allow plans an opportunity to understand the implications of the new calculation methodology, as well as the expansion of PDEs

Submitter	Response
	in consideration. Additionally, BCBST suggests that the MPF Pricing Accuracy measure be excluded from the Part D Star Ratings Quality Improvement measure for 2018, as the methodology changes are great enough that there would not be an accurate reflection between years to appropriately assess a plan sponsor's variance or improvement. BCBST also recommends that CMS place this measure on the display page indefinitely due to it being a measure of plan performance and not quality improvement.
Cambia Health Solutions	We believe using PDE-reported Pharmacy Service Type code in conjunction with the MFP Pharmacy cost data to identify retail claims help with consistency in the way claims are identified for inclusion in the measure. Regarding the changes to the methodology by which price accuracy is calculated, we believe that this adds unnecessary complexity to the measure as well as another factor which is outside the sponsor's control. The only available options for sponsors to reach the goal set forth by CMS for the measure is to: 1) Only cover FRF (Proxy) NDC's at all Network Pharmacies which would significantly limit the formulary available to members; and 2) Set prices once at the start of the measurement period and leave them unchanged for nine months until September 30 of the Plan Year which is not responsive to the often daily changes needed to market pricing. The current measure does not accurately depict the reliability of a contract's MPF prices and adding this component does not resolve that measurement deficiency. Our conclusion is that MPF Price accuracy should only be applied to FRF (proxy) NDC's adjudicated at a time set as of MPF data submission to reflect the accuracy and effectiveness of systems and processes over which the sponsor has direct control.
CareSource Management Group	CMS was not specific in the exact changes the agency proposes to make in these areas. Instead, CMS listed broad issue areas it hopes to address in future years, including care coordination, depression and pain management. CMS should put specific measures and changes to the measures out for public comment before these measures become display measures or included in stars. Antipsychotic Use in Persons with Dementia: CareSource supports the provision of new monthly Antipsychotic Use in Persons with Dementia (APD) patient safety reports in 2016, as well as the addition of the APD measure to the 2018 Part D display measure set. The alarming rate of antipsychotic use among older adults with dementia despite the FDA's black box warning that antipsychotics may cause an increased risk of death in this population must be monitored more closely. However, it will be very difficult for Part D plans and PBMs to improve upon this measure without the necessary diagnosis data used to identify patients in the numerator and denominator. While breaking out the measure rates by community-only residents, short-term nursing home residents, and long-term nursing home stay residents for the 2018 display page will aid in surveillance among unique beneficiaries, it will not aid in the

Submitter	Response
	optimal targeting needed to improve quality of care by plans. Like CMS, we do not support the addition of this measure to the Star Ratings at this time, as diagnosis data that is necessary to develop quality improvement plans and calculate the rate as specified by PQA is not yet available to Part D sponsors. MPF Price Accuracy (Part D Star Rating): Based on information in the 2016 Star Ratings Fact sheet, released by CMS, the industry demonstrates overall high performance across the industry, with limited room for improvement and low variability across plans. Therefore, all of the criteria for measure retirement are met and we would recommend CMS consider retirement or movement to the display page for this measure. In lieu of retirement, we respectfully request CMS revisit the measure methodology for MPF: Price File Accuracy Star measure. The majority of plans who were able to achieve 100 operated under very unique health care delivery models or are very small in size which has the potential to reduce variability. Plan Type: The majority of these plans operate under a unique delivery of care model which may allow certain advantages over plans that do not operate under this model. i.e. Kaiser/HealthSpan Plan Size: Lower enrollment plans have a sample size which in some cases reduced their variability on this measure. Additionally, there are noteworthy concerns with the price file submission timeline which should be taken into consideration when determining the thresholds. Files are prepared and submitted by a plan according to the CMS issued submission calendar and guidelines. CMS requires price files to be submitted according to their calendar and does not allow submissions outside of their communicated bi-weekly schedule. CMS will post files 2 weeks after their submission date. The posted files are then displayed on plan finder for a 2 week period. Working within the constraints of this CMS dictated process means that when a beneficiary views drug pricing data on the Medicare.gov Plan finder the data is anywhere between 19 -31 days old. Pricing data for the MPF Display is based on a single reference/proxy NDC and is compared to an expanded list of NDCs on the PDEs. Drug costs vary by NDC; even those of the same strength/dosage form. Since drug prices change daily, this creates inconsistencies between the submitted price and the price on the claim or PDE records. Based on the issues raised with the measure methodology, we respectfully request CMS revisit the thresholds for this measure and adjust the 5 Star thresholds to an accuracy index of 99. This would ensure plans are not penalized because of the measure methodology concerns identified above. In the 2016 Star Ratings, 478 plans received a score on this measure. Of the plans that received a score, only 11 were able to achieve a metric of 100. Based on this data, we do not feel the measure is a fair evaluation of plan performance, as only 2.3% of the entire Medicare plan population (PDP and MAPD) was able to meet the targeted metric. Of the eleven (11) plans achieving a score of 100, seven (7) of the plans were closed systems such as

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	Kaiser and HealthSpan. The remaining four (4) plans were very small and each plan did not contain more than seven thousand beneficiaries. Based on the current methodology, the typical Medicare Part D plan is disadvantaged on this measure which is indicated by the inability of a single PDP plan achieving a score of 100. The PDP industry has demonstrated limited room for improvement, high performance, and low variability among scores; reflected clearly in Table C-2 of the Technical Notes, with a PDP Numeric Average of 99, and a PDP Star Average of 4.7 across the industry. MAPD plans represented an MAPD Numeric Average of 98, and a Star Average of 3.5. Due to the limitations within the measure methodology, CMS could also consider retirement of this measure. In addition to the existing methodology CMS also expressed interest in modifying the methodology to also factor in how often PDE costs exceeded MPF costs. We are supportive of the additional methodology proposal, but feel it needs to be further evaluated by CMS. This enhancement does not address existing measure methodology flaws discussed above, but if finalized, we recommend moving the MPF measure to the Display page.
Centene Corporation	Centene Corporation requests that CMS provide access to their research which showed that the proposed changes lead to little change in the range of contracts' accuracy scores. We suggest that incorporating this measure into a program audit would be the best use of the index rather than including it in star ratings measure set, and recommends potential removal of this measure as the narrowing range in cut points is indicative of an ineffective index of quality. For example; the cut points for MA-PDs score of 99% leads to a 4 Star rating with 100% being a 5 Star. As a result we question the ability of the current measure to discern true differences in performance.
Cigna	We recommend that CMS remove this as a star rating measure because there is no meaningful differentiation between ratings -- plans must achieve perfection to achieve optimal star ratings (100% for 5-Stars, 99% for 4-Stars, etc.). Moreover, there is some lag time that is not being accounted for by CMS. For example, a plan will make a pricing update, and that update can take days to update in CMS' system. This lag can negatively impact a plan's MPF rate. If CMS will keep this as a measure, CMS should provide plans with a monthly report so that plans can address issues as they occur. At this time, CMS provides a report during the Star rating period. We do not support including instances where MPF is higher in the measure score because this does not place a financial burden on the customer. Cigna-HealthSpring also supports increased submission frequency by CMS because this would improve alignment with changes in pricing by the industry.
Commonwealth Care Alliance	CCA believes that this measure should be retired as the range of performance is too tight for meaningful differentiation for the purposes of assigning Star rating.
CVS Health	Based on information in the 2016 Star Ratings Fact sheet, released

Submitter	Response
	by CMS, the industry demonstrates overall high performance across the industry, with limited room for improvement and low variability across plans. Therefore, all of the criteria for measure retirement are met and we would recommend CMS consider retirement or movement to the display page for this measure. In lieu of retirement, we respectfully request CMS revisit the measure methodology for MPF: Price File Accuracy Star measure. The majority of plans who were able to achieve 100 operated under very unique circumstances which allowed them to lock drug prices to achieve the desired metric or have a small sample size which is some cases reduced their variability. Plan Type: The majority of these plans operate under a unique delivery of care model which may allow certain advantages over plans that do not operate under this model. i.e. Kaiser/HealthSpan Plan Size: Lower enrollment plans have a sample size which in some cases reduced their variability on this measure Additionally, there are noteworthy concerns with the price file submission timeline which should be taken into consideration when determining the thresholds. Files are prepared and submitted by a plan according to the CMS issued submission calendar and guidelines. CMS requires price files to be submitted according to their calendar and does not allow submissions outside of their communicated bi-weekly schedule. CMS will post files 2 weeks after their submission date. The posted files are then displayed on plan finder for a 2 week period. Working within the constraints of this CMS dictated process means that when a beneficiary views drug pricing data on the Medicare.gov Plan finder the data is anywhere between 19 -31 days old. Pricing data for the MPF Display is based on a single reference/proxy NDC and is compared to an expanded list of NDCs on the PDEs. Drug costs vary by NDC; even those of the same strength/dosage form. Since drug prices change daily, this creates inconsistencies between the submitted price and the price on the claim or PDE records. Based on the issues raised with the measure methodology, we respectfully request CMS revisit the thresholds for this measure and adjust the 5 Star thresholds to an accuracy index of 99. This would ensure plans are not penalized because of the measure methodology concerns identified above. In the 2016 Star Ratings, 478 plans received a score on this measure. Of the plans that received a score, only 11 were able to achieve a metric of 100. Based on this data, we do not feel the measure is a fair evaluation of plan performance, as only 2.3% of the entire Medicare plan population (PDP and MAPD) was able to meet the targeted metric. Of the eleven (11) plans achieving a score of 100, seven (7) of the plans were closed systems such as Kaiser and HealthSpan. The remaining four (4) plans were very small and each plan did not contain more than seven thousand beneficiaries. Based on the current methodology, the typical Medicare Part D plan is disadvantaged on this measure which is indicated by the inability of a single PDP plan achieving a score of

Submitter	Response
	100. The PDP industry has demonstrated limited room for improvement, high performance, and low variability among scores; reflected clearly in Table C-2 of the Technical Notes, with a PDP Numeric Average of 99, and a PDP Star Average of 4.7 across the industry. MAPD plans represented an MAPD Numeric Average of 98, and a Star Average of 3.5. Due to the limitations within the measure methodology, CMS could also consider retirement of this measure. In addition to the existing methodology CMS also expressed interest in modifying the methodology to also factor in how often PDE costs exceeded MPF costs. We are supportive of the additional methodology proposal, but feel it needs to be further evaluated by CMS. This enhancement does not address existing measure methodology flaws discussed above, but if finalized, we recommend moving the MPF measure to the Display page.
Humana	Humana recommends that due to the measure changes during the data year, MPF Price Accuracy should be a display measure for the 2018 Star Ratings (2016 PDE and MPF data). CMS has stated that if a change is announced during the measurement period that significantly expands the denominator or population covered by the measure, the measure is moved to the Display Page for at least one year. We believe this to be the case in this situation. We also believe, that the purpose of the MPF measure is to incentivize Part D plans to provide accurate pricing information to members and potential members who use the Medicare.gov Plan Finder application to price their drugs. Humana believes that it is a priority that prices displayed on Medicare.gov are accurate. Our incentive to have members and potential members see accurate drug prices goes far beyond any score we receive on this measure. In an ideal world, a customer would be able to see timely and accurate drug pricing information that would reflect exactly what they would pay at a retail pharmacy. However, there are inherent technical limitations that make the pricing displayed on Plan Finder and the price a member receives at the pharmacy counter not possible at this time. For example, plans only submit pricing for the subset of NDCs specified by CMS for display on the Plan Finder application and many NDCs that are not inclusive of this subset adjudicate at pharmacies every single day.
Medica Health Plans	Medica recommends that CMS retire this measure due to the extreme narrow bands demonstrated in the 2016 star ratings. If CMS does not chose to retire the measure, we urge CMS to move the measure to display while determining the new specifications. If CMS chooses to keep the measure for Stars 2017, we urge CMS to consider modifications to account for changes in drug pricing and to use the patient residence code on the PDE claim for determining applicable retail claims used in the MPF comparison. The inclusion of the patient residence code fill further defines retail claims and accounts for the various methods PBM/plan sponsors are using to identify retail HI/LTC claims, resulting in the more accurate results.

Submitter	Response
PCMA	6. MPF Price Accuracy (Part D Star Rating) – CMS is considering updates to this measure for the 2018 Star Ratings and proposes the following: • Change the method by which claims are excluded from the measure to allow claims with 28-34 day supplies, as well as 60-62 and 90-93 day supplies; • Use the PDE-reported Pharmacy Service Type code in conjunction with the MPF Pharmacy Cost data to identify retail claims; and • Change the price accuracy methodology to factor in how often PDE costs exceed MPF costs. ? PCMA previously suggested that the MPF measure be retired because of overall high performance across the industry on this measure which leaves limited room for improvement. The 2016 Star Ratings Fact Sheet confirms that industry performance on the MPF measure remains high with low variability across plans. We believe that all of the criteria for measurement retirement have been met, and we recommend that CMS retire the measure or move it to the display page. In lieu of retirement, PCMA supports the expansion of claims from the current limit of 30 days to include 60 and 90-day supplies but has several concerns with other aspects of what CMS proposes for this measure. The purpose of the MPF measure is to incentivize plans to provide accurate pricing information to members and potential members who use the Medicare.gov Plan Finder application to price their drugs. However, there are inherent limitations that make transparency unrealistic between the pricing displayed on Plan Finder and the price a member receives at the pharmacy counter. The most obvious limitation is that plans only submit pricing for the subset of NDCs specified by CMS for display, and many NDCs not included in this subset are adjudicated daily at pharmacies. In addition, CMS has indicated its desire to decrease misclassification, but the proposed measure changes actually may produce more errors in the data. For example, the risk of sampling variation increases depending on the drugs chosen and the time of year when the metric is measured. PCMA is concerned with the price file submission timeline which should be taken into consideration when determining the thresholds. CMS establishes the schedule for price file submissions and does not allow submissions outside of the bi-weekly schedule. Files are posted two weeks after submission and are displayed on Plan Finder for two weeks. When a beneficiary views drug pricing data on Medicare.gov, the data may be anywhere between 19-31 days old. Average wholesale price (AWP) and maximum allowable cost (MAC) are updated more frequently than every two weeks, which means that every time an update is made, between the bi-weekly cycle of MPF submissions, the price the member pays likely will be less or greater than the MPF value. These factors produce inconsistencies between the submitted price and the price on the claim or PDE record. We believe CMS should revisit the thresholds for this measure and adjust the 5 Star thresholds to an accuracy index of 99. PCMA also is concerned that the proposed modification to factor in how often PDE costs exceed

Submitter	Response
	MPF prices, a so-called "frequency of inaccuracy," applies equal weight to a one cent and a $100 difference between PDE and MPF. We believe that if CMS proceeds with adding a frequency factor, any claims below a predetermined amount (e.g., $1.00) should be excluded from the calculation and deemed de minimus. CMS should focus its efforts on discrepancies with the greatest potential member impact. In light of the significance of the proposed modifications to the MPF measure, PCMA suggests that CMS convene a group of experts, including representatives from plan sponsors and PBMs, to develop realistic and scalable improvements in the measure that will assure the member protections CMS intends to achieve. PCMA Recommendation: PCMA recommends that CMS refrain from expanding the MPF price accuracy measure and including the frequency and magnitude of differences between PDE costs and MPF prices until it has reached out to stakeholders and experts to develop realistic and scalable improvements in the measure. If CMS proceeds as proposed, we urge CMS to exclude small differences between PDE costs and MPF prices as de minimus. Further, we recommend that CMS revisit and adjust the thresholds for this measure.
Peoples Health Network	There were 8 Part D plans that received 5 stars in this measure in CY2014, 6 of which were from the same parent organization. Because this organization is not outsourcing their PBM, their unique position as a fully integrated health care system allows them to make business determinations that are not afforded to most Medicare advantage plans. MPF submissions can only be sent bi-weekly. In order to produce the file, it may take a PBM up to one week to run that data, allowing a gap where the price of the drug could change. Pricing at adjudication can and frequently does change daily based on industry standard Medispan pricing data. Price file submission regulations do not account for the lag time needed to produce the price file.
PrescribeWellness	We support methodology that addressing display of more accurate pricing.
SCAN Health Plan	G. 6 Changes to Existing Star Ratings and Display Measures and Potential Future Changes: MPF Price Accuracy (Part D Star Rating) SCAN Comment: As CMS has proposed changing the methodology of this measure, whereby the calculation will not only include the magnitude of the pricing discrepancy but also the frequency of the pricing discrepancy we propose for this measure to be considered a display measure to give plan sponsors time to understand the results of the calculation and get a better understanding of how to monitor it. We also request for CMS to publish in the Call Letter each year, which drugs or drug classes CMS will use to conduct its monitoring of this measure to be more transparent with plan sponsors. As there are many moving pieces and coordination of different data sources to create drug plan finder files, we propose for CMS to consider changing the methodology of this measure where perhaps files can

Submitter	Response
	be submitted more frequently or pricing updates can be included with the bi-weekly files to help with the fluctuation of pricing differences due to market changes.
SNP Alliance	6. MPF Price Accuracy (Part D Star Rating) In general, we concur with CMS' proposed changes to the MPF Price Accuracy measure for the 2018 Star Ratings. We are hopeful that the inclusion of additional claims will improve the usefulness of this measure. As the measure is currently specified, we are concerned about the very small differences between the cut points, e.g. for MA-PDs a score of 99% leads to a 4 Star rating with 100% being a 5 Star. As a result we question the ability of the current measure to discern true differences in performance. In addition, we recommend that CMS consider establishing a threshold for identifying meaningful differences in price. For example, if the price difference is truly negligible, we question whether CMS should be including these differences in the calculation of the measure. While CMS retains the existing MPF Price Accuracy measure methodology for 2017, we recommend that it mimic its proposed changes on the display page. This would ensure that plans have clear visibility into how CMS' contemplated methodological changes would work, as well as sufficient time to review the impact on performance.
Triple S Advantage, Inc	TSA understands CMS' proposed and would like to request further clarification from CMS in regards to the composite of the Price Accuracy Score and the Claims percentage score to better prepare for the future. In addition, we would like to request from CMS, if possible, to share industry best practices to better align real-time pricing at the point of sale (that can change as often as every day, is updated on a weekly basis and generally increases) with the MPF Price Accuracy Measure. Finally, consider increasing the frequency of MPF submissions to a weekly basis to further ensure fewer discrepancies in this measure.
UCare	UCare does not feel that this measure reflects health plan quality. Unless it can be demonstrated that the proposed changes will eliminate the very small spread between cut-points, CMS should consider eliminating this measure.
UnitedHealthcare	UnitedHealth agrees with CMS' proposal to include retail claims with 28-32, 60-62, or 90-93 days. UnitedHealth also supports CMS' proposal to utilize the Pharmacy Service Type code to determine when a pharmacy is Retail or Long Term Care and include the retail claims in the measurement. UnitedHealth believes this will help with consistency in the way claims are identified for inclusion in the measure. However, UnitedHealth is concerned that this proposed change to the methodology of price accuracy calculation would add unnecessary complexity to the measure well as another factor which is outside the sponsor's control. The only available options for sponsors to reach the goal set forth by CMS are to: 1) Only cover FRF (Proxy) NDCs at all Network Pharmacies which would significantly limit the formulary available to members; and 2) Set

Submitter	Response
	prices once at the start of the measurement period and leave them unchanged for nine months until September 30 of the Plan Year, which is not responsive to the often daily changes needed to market pricing. UnitedHealth also believes that the current measure does not accurately depict the reliability of a contract's MPF prices and that the proposed changes do not resolve that measurement deficiency. UnitedHealth proposes that MPF Price accuracy only be applied to FRF (proxy) NDCs adjudicated at a time set as of MPF data submission, to reflect the accuracy and effectiveness of systems and processes over which the sponsor has direct control.
WellCare	WellCare supports the inclusion of additional claims in this measure. Doing so increases the denominator for the measure and more accurately captures price accuracy.

7. Drug-Drug Interactions (DDI) (Part D Display)

Submitter	Response
Academy of Managed Care Pharmacy (AMCP)	AMCP supports CMS in the thorough evaluation, vetting, and consensus for revisions to DDIs. AMCP encourages CMS to ensure that any changes to the DDI measure take into account the need for flexibility as the use of some medication combinations identified as a DDI may be appropriate in certain patients after evaluating the risks and benefits, similar to how certain patients may benefit from the use of a HRM as discussed in Section B(2). AMCP also encourages CMS to develop a consistent list of DDIs that can be tied to claims systems as each vendor currently utilizes their own unique list of DDIs and there are differences.
BlueCross and BlueShield Association	CMS notes that it expects the PQA to make significant revisions to the Drug-Drug Interactions (DDI) measure to reflect the PQA's efforts to review the drug-drug pairs included in the measure. CMS states that it will monitor any updates, test the updated specifications, and propose changes in the future for the display measure and patient safety reporting. BCBSA and Plans appreciate CMS's transparency on this measure, especially as not all Plans belong to the PQA. We request that CMS provide – in advance – adequate information as to any proposed changes to allow Plans to provide feedback on the modifications before they are implemented. (See Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.) Generally, BCBSA and Plans recommend that CMS carefully review the DDI measure. In Plans' experience, members sometimes switch from one drug to another and therefore have multiple prescriptions that show as overlapping, even though the member has ceased taking that initial medication. Additionally, we believe that Part D Sponsors should not be penalized in the event that a provider

Submitter	Response
	believes that the benefit of taking two particular drugs outweighs the risk of negative interaction. Recommendations: BCBSA and Plans request that CMS provide additional information regarding any proposed changes to the DDI measure. (See also Key Recommendation: Provide Robust Information and Details about Each Measure to Allow Stakeholders to Provide Meaningful Comment.) BCBSA and Plans recommend that CMS review the utility of the DDI measure.
BlueCross BlueShield of Tennessee	BCBST recommends that CMS continue to include this measure as a display measure due to the dynamic nature of drug information updates and potential for outdated measurement data.
Centene Corporation	Centene Corporation requests additional information on the proposed extensive changes to provide feedback. Currently, the DDI measure does not take into account situations in which an individual is prescribed a medication that is then determined to be not effective and is switched to another medication before the first prescription is finished. As a result, it appears that there may be an interaction occurring when, in fact, they've stopped using one medication and begun using another. In order for the measure to be reliable, this situation needs to be taken into account. The measure does not take into account that there is a great deal of variability in drug interactions in terms of timing, severity, and differences in reactions across individuals. The measure does not recognize the ability of physicians to weigh the pros and cons of prescribing particular drugs. In some cases, the benefits of prescribing a particular drug-drug pair may outweigh the negative consequences. Currently, there is no mechanism to refine this measure by excluding individuals for whom the use of these drug combinations is clinically appropriate.
Cigna	We ask that CMS provide more detail about how they would operationalize this measure. Pharmacy data alone would not account for a physician changing medications due to side effects and there are many instances where the clinical benefits outweigh the DDI risks.
Fresenius Health Plans	It should be noted that ESRD patients, on average, experience a higher probability of experiencing drug-drug interactions given the increased number of therapies seen in this population. We will closely monitor the extent of occurrences in our population and opt to comment in later updates to this measure.
Health Care Service Corporation	HCSC has concerns with this measure and we look forward to reviewing the results of the PQA review of the drug-drug pairs

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	included in the DDI measure and CMS' proposed changes to this measure in the future. Specific concerns that we ask CMS to take into consideration include the following. The DDI measure does not account for a great deal of variability in drug interactions in terms of timing, severity, and differences in reactions across individuals. The measure does not recognize that physicians and members may weigh the pros and cons of particular drug-drug pairs and determine that the benefits outweigh the negative consequences. Currently, there is no mechanism to refine this measure by excluding individuals for whom the use of these drug combinations is appropriate. In addition, the DDI measure does not take into account situations in which an individual is prescribed a medication that is then determined not to work out and is switched to another medication before the first prescription is finished. As a result, it appears that there may be an interaction occurring when, in fact, they individual has stopped using one medication and begun using another. In order for the measure to be reliable, this situation should be taken into account. HCSC recommends that CMS work with PQA to address these situations that are currently not accounted for in the DDI measure.
Medica Health Plans	Medica supports an evidence based review of this measure and updates to support the safety of our beneficiaries.
PCMA	7. Drug-Drug Interactions (DDI) (Part D Display) – CMS expects extensive changes from PQA to the measure specifications for this display measure. PCMA Recommendation: PCMA suggests that CMS reach out to stakeholders for input as it monitors updates and tests updated specifications, and take stakeholder input into account before proposing changes to the measure.
PQA	PQA has completed the process to review and revise the specifications for the DDI measure. We look forward to working with CMS to test the updated specifications in 2016.
PrescribeWellness	We support caution in the DDI display so that it accurately addresses significant DDI versus DDI that can not be avoided, but monitored on an ongoing basis to ensure avoidance of ADE and clinical outcomes.
SNP Alliance	7. Drug-Drug Interactions (DDI) (Part D display) We have concerns regarding this measure and look forward to reviewing the results of the PQA's review of the drug-drug pairs included in the DDI measure and CMS' proposed changes to this measure in the future. At this time, however, we would like to express several specific concerns that we ask CMS to take into consideration: --?Currently, the DDI measure does not take into account situations in which an individual is prescribed a medication that is then determined not to work out and is switched to another medication before the first prescription is finished. As a result, it appears that there may be an interaction occurring when, in fact, they've stopped using one medication and begun using another. In order for the measure to be reliable, this situation needs to be taken into account. --The measure does not take into account that there is a great deal of variability in drug

Submitter	Response
	interactions in terms of timing, severity, and differences in reactions across individuals. The measure does not recognize the ability of physicians to weigh the pros and cons of prescribing particular drugs. In some cases, the benefits of prescribing a particular drug-drug pair may outweigh the negative consequences. Currently, there is no mechanism to refine this measure by excluding individuals for whom the use of these drug combinations is appropriate.
Triple S Advantage, Inc	TSA agrees that extensive revisions should be performed on the drug-drug pairs. Many of the identified DDIs are not absolute contraindications. The patient may need to take the pair of drugs, and the only necessary course of action is to monitor the patient for possible adverse effects or dose adjustments.
UCare	Interaction calculations are complex. Technical specifications for this measure would have to be built carefully. For example, Physicians may order a medication change prior to the completion of the current prescription. This may create the false appearance of an individual taking 2 (unique) medications at the same time.
UnitedHealthcare	UnitedHealth recommends that this measure be limited to drug interactions that are absolutely contraindicated. Members often take medications with relative contraindications and if the range of this measure is expanded too far, plans would be encouraged to stop members from taking more than one medication at a time even if clinically appropriate.

8. Center for Medicare and Medicaid Innovation Model Tests (Part C & D)

Submitter	Response
Academy of Managed Care Pharmacy (AMCP)	AMCP commends CMS-CMMI for its efforts to make positive improvements for Medicare beneficiaries through the announcement of the Medicare Advantage Value-Based Insurance Design and Part D Enhanced MTM Model Test. AMCP encourages CMS to closely monitor performance trends of participating plans once the model tests are implemented in January 2017 and to determine if changes are warranted. AMCP encourages CMS to be transparent and flexible as the test models are implemented and as changes to the Star Ratings and display measures change over time and are considered for these test models.
America's Health Insurance Plans	CMS indicates that stakeholders have expressed concern regarding the impact of the Center for Medicare and Medicaid Innovation (CMMI) Model tests on performance in the Star Ratings program between participating and non-participating plans. We have also expressed our concern that organizations not eligible to participate in the MA-VBID and Part D Enhanced MTM model tests will not have access to the same flexibilities and be placed at a disadvantage relative to participating organizations. We urge CMS to engage with MA and Part D plans as well as other stakeholders to determine how the Star Ratings program may be affected by the CMMI model tests and consider possible changes to the methodology to ensure equitable comparison of plan performance.

Submitter	Response
Anthem, Inc	Anthem is focused on ensuring the provision of high-quality plans that improve care delivery, promote wellness and management of chronic conditions through innovation, and achieve meaningful outcomes and cost-savings for our members. To that end, we support CMMI's plans to test a Medicare Advantage Value-Based Insurance Design (MA-VBID) model and a Part D Enhanced MTM model. We believe that both of these model tests have the potential to improve quality and improve costs. However, Anthem is concerned about how CMS will 1) assess the quality of participating plans and 2) compare the quality of participating plans to non-participating plans. To address these concerns, we ask CMS to clarify several issues. First, in regards to the Part D Enhanced MTM model, Anthem requests that CMS alert plans if it anticipates certain Star Ratings measures will be affected by the test. For example, Anthem anticipates that a plan's reduction or elimination of cost sharing for certain covered Part D drugs for a given target population would influence measures related to medication adherence. Second, Anthem believes that any PDP model that combines MTM strategies, risk stratification, differential cost sharing, and financial incentives must take into account the impact of low-SES on the impact of MTM programs and plan performance. Specifically, any application of financial incentives to plan payments must be appropriately adjusted for plans serving high concentrations of low-income subsidy (LIS) members—particularly in the Part D Enhanced MTM model test, which will have an impact on LIS benchmarks overall. Finally, because CMS assigns Star summary ratings at the contract level, we ask CMS to clarify if it assumes that implementing the MA-VBID model in a plan under an existing contract will cause an overall change in that contract's Star Rating.
Blue Cross Blue Shield of Michigan	The Center for Medicare and Medicaid Innovation (CMMI) recently announced two demonstrations that will allow participating plans to test new and innovative flexibilities in the Medicare Advantage and Part D programs. Ultimately, these flexibilities are aimed at improving quality, reducing costs and positively impacting enrollee health. For example, plans participating in the Medicare Advantage Value-Based Insurance Design Model Test can waive cost sharing for members participating in disease management programs. Only plans operating in certain states are given the opportunity to participate in these demonstrations. Because participation is limited based on factors outside of a plan's control, we recommend CMS score plans participating in the demonstrations separately from non-participating plans. This change is necessary in order to level the playing field for plans that are not eligible to participate in the demonstrations.
BlueCross and BlueShield Association	BCBSA and Plans appreciate CMS's attention to the concern that Plan Sponsors participating in the MA Value-Based Insurance Design and the Part D Enhanced MTM model test may be advantaged under the Star Ratings because the contracts will reflect the Plan Sponsors' additional flexibilities to improve the quality of

Submitter	Response
	care for members. We continue to believe that those additional flexibilities create an uneven playing field in terms of Star Ratings measures performance. BCBSA and Plans note that performance on the Star Ratings is intended to drive membership to those contracts with high scores, and beneficiaries can enroll in those contracts with a 5 star rating at any time during the year. As such, ensuring a level playing field is critical to the integrity of the program. BCBSA and Plans encourage CMS to separate those Plan Sponsors which are participating in the model tests from those that are not. For example, CMS could calculate the thresholds for each Star Rating separately, such that the thresholds for participating Plan Sponsors would be different from the thresholds for non-participating Plan Sponsors. This method has the added benefit of testing whether participation in the test models helps Plan Sponsors improve the quality of care for beneficiaries, as reflected by the Star Ratings. Recommendations: BCBSA and Plans encourage CMS to score Plan Sponsors who are participating in the MA Value-Based Insurance Design and the Part D Enhanced MTM model tests separately from those who are not participating, for purposes of the Star Ratings.
BlueCross BlueShield of Tennessee	BCSBT encourages CMS to provide information to plans regarding the impact of this model on the plans participating in the program. BCBST also requests clarification as to whether plans (PBPs) participating in this test will be excluded from the calculation of the national averages and therefore the star ratings cut points associated with the MTM-CMR measure.
Centene Corporation	We are concerned about the issue CMS raises in the Request for Comment and the potential for SNPs, which are ineligible to participate in the MA-VBID model test, to be disadvantaged in the Star Ratings system as a result of improvements in quality among those plans that are participating. We appreciate CMS' attention to this concern and encourage CMS to take action to prevent plans not participating in the model test from being disadvantaged. Allowing SNPs to participate in the demonstration where they operate in states that are eligible for participation would address some of this concern; however, over time SNPs operating in states that are not eligible for participation may still be adversely affected
CVS Health	SilverScript was pleased by the announcement of the Part D Enhanced Medication Therapy Management (MTM) Model Test, and looks forward to the findings that will be learned over the 5 year performance period. We fully support this effort to better align both

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	PDP sponsor and government financial interests, while also incentivizing robust investment and innovation within MTM programs. We are concerned that waiving Part D MTM reporting requirements for participating contracts, which will effectively remove a plan (PBP) from receiving a Comprehensive Medication Review (CMR) completion rate score, could significantly impact the PDP sponsor's performance on this measure. Based on our analysis, exclusion of certain PBPs could lead to PDP sponsors performing much better or much worse on the MTM performance measure, depending on the geographical region the PBP serves. We recommend CMS waive MTM reporting and Stars measurement for Part D sponsors participating in the Enhanced MTM Model test. Using 2014 data, our analysis of CMR completion rate by SilverScript PBPs, with 10 or more members within a PBP, demonstrated within PBP CMR completion rates range from 6.1% - 48.8%. This demonstrates significant differences in CMR completion rate by PBP. Depending on the performance of PBPs that are excluded, a Part D sponsor may be negatively (or positively) impacted by their exclusion. Considering CMS' goal is to not penalize participants or non-participants, our recommendation is to exclude Part D sponsors participating in the Enhanced MTM Model from reporting a Star Rating score on the MTM CMR completion rate measure.
Health Care Service Corporation	CMS states that as the MAVBID and Part D Enhanced MTM "model tests are implemented, we will closely monitor performance trends of participating plans across individual measures and determine if any changes are warranted." We appreciate CMS' attention to this potential inequity between plans that are permitted to participate in the models and those plans that are prohibited from participating. We are concerned that participating plans could experience better process, outcomes, and satisfaction ratings as a result of the activities permitted under the models. We encourage CMS to take action to prevent plans not participating in the model test from being disadvantaged.
Healthfirst	We ask that CMS exclude plans participating in model tests for individual measures from reporting performance for the Star Ratings. These plans are held to different standards and specifications, which may cause differences in performance between participating and non-participating plans. Since cut points are determined by the performance on measures by all eligible plans, it is unfair to include them in same pool as non-participating plans.
Medica Health Plans	Medica is concerned about the favored ability of some MA plans to participate in these tests and to build their work flow processes, infrastructure and data analytics to support improvement as measures move to ratings, versus those plans who are not included up front in the pilots. Medica would like to see more information on this proposal and the impact of removing a subset of plans from specifically defined requirements (flexibility), and how that impacts overall ratings in the entire cohort.

Submitter	Response
Molina Healthcare Inc.	Molina Healthcare is pleased to see CMS moving forward with Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced MTM model tests. We hope that the Agency will consider allowing for the participation of additional health plans in the future.
OutcomesMTM	OutcomesMTM understands the goal of the model test is not to penalize participants or non-participants. Prior to implementing the model test, OutcomesMTM proposes CMS consider modeling the effects the test will have on the cutpoints for the MTM Star Rating for non-participating contracts and consider suspending the MTM Star Rating during the model test years if the effects are anticipated to be unfavorable.
PCMA	8. Center for Medicare and Medicaid Innovation Model Tests – CMS acknowledges concerns that the star ratings of plans participating in the Model Tests may be favorably influenced compared to plans not eligible to participate and affirms its pledge not to penalize participants or non-participants. PCMA is concerned that waiving Part D MTM reporting requirements for participating plans, which would effectively remove them from receiving a CMR Completion Rate score, could significantly impact the star thresholds for this measure. We suggest that CMS take sample size into consideration when evaluating the thresholds for the CMR Completion Rate measure. PCMA Recommendation: PCMA supports CMS efforts to monitor Model Test plans' performance on Star Ratings and to assure that neither participants nor non-participants are penalized. We recommend that CMS take sample size into consideration when evaluating the thresholds for the CMR Completion Rate measure.
Pfizer	Description of the Issue or Question: The CMS Center for Medicare and Medicaid Innovation has announced the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced MTM model tests. Beginning January 1, 2017, in a limited number of states, CMS will give MA only, MA-PD or Part D plans participating in these tests additional flexibilities intended to improve the quality of care and reduce costs in the Medicare Advantage or Part D programs, respectively. CMS notes that stakeholders have expressed the potential for the improvements in quality in these models to favorably influence the Star Ratings of contracts with participating plans, as compared to the performance of those ineligible to participate. CMS further notes that their goal is to not penalize participants or non-participants. As the model tests are implemented, they will monitor performance trends and determine if any changes are warranted. CMS asks for comments on how to address any potential differences in performance between participating and non-participating plans. Suggested Revisions/Comments: Pfizer applauds CMS' efforts to implement innovative model tests, including the Medicare Advantage Value-Based Insurance Design (MA-VBID) and the Part D Enhanced MTM model tests. Pfizer encourages CMS to continue to develop

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	programs to improve patient access to high value care. We encourage CMS to incorporate an open process for ongoing evaluation of both models and allow for stakeholder input on methods of evaluation. Pfizer also encourages CMS to develop measures that incorporate not only the specific targeted conditions within the VBID conditions, but also for comorbidities and overall patient care to ensure holistic care for patients and avoid disparate incentives for appropriate patient care. In addition, Pfizer is open to discussions with CMS to better shape and design the VBID process.
PhRMA	PhRMA appreciates CMS attention to the potential for recently announced Center for Medicare and Medicaid Innovation (CMMI) model tests (i.e., the value-based insurance design and enhanced medication therapy management demonstrations) to improve care in ways that would impact plan performance on the Star Ratings. As noted in our comments on the enhanced MTM demonstration, the Star Ratings measures provide an additional tool for CMS to leverage in its monitoring and evaluation of these models. We encourage CMS to follow an open process for its ongoing evaluation of both models and their impact on quality of care and to continue to seek stakeholder input on methods to address any differences in Star Rating performance between participants and non-participants.
SNP Alliance	8. Center for Medicare and Medicaid Innovation Model Tests We are concerned about the issue CMS raises in the Request for Comment and the potential for SNPs, which are ineligible to participate in the MA-VBID model test, to be disadvantaged in the Star Ratings system as a result of improvements in quality among those plans that are participating. We appreciate CMS' attention to this concern and encourage CMS to take action to prevent plans not participating in the model test from being disadvantaged. Allowing SNPs to participate in the demonstration where they operate in states that are eligible for participation would address some of this concern; however, over time SNPs operating in states that are not eligible for participation may still be adversely affected.
Triple S Advantage, Inc	CMS should consider extending participation of United States territories such as Puerto Rico in such initiatives. Plans in Puerto Rico would then have the opportunity to implement best practices in collaboration with CMS and also CMS would have first-hand understanding of the particularities of the Puerto Rico service area.

H. Measurement and Methodological Enhancements

H. No Subtopics

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Aetna	Setting All Cut-Points Prospectively Aetna enthusiastically supports the Medicare Star Ratings program and has invested significant time and resources in establishing a best-in-class Star Ratings quality measurement and improvement program. As mentioned in previous

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	comment letters, due to the rapid proliferation of value-based contracting between MA plans and providers, Aetna believes that all measure cut-points should be announced prospectively (i.e., prior to the start of the performance measurement period). Because value-based contracting requires investments in people, processes and technology to be successful, setting cut-points prospectively would provide MA plans the ability to integrate the targets into their contractual arrangements with providers. We do not think setting cut-points prospectively will reduce plans' incentives to improve quality; in fact, prospectively updating the cut-points would provide CMS the ability to continuously drive quality improvement. Such a framework would strike the right balance by providing CMS the flexibility to adjust cut-points based on emerging performance, but would also be transparent and help maintain program stability by allowing plans the ability to take steps to achieve stated targets on the front end of the process. We also believe that setting cut-points prospectively would simplify the star ratings system. Cut-Point Stabilization In the 2016 Star Ratings system, CMS made a major methodological change to the manner in which it calculates Star scores through the elimination of long-standing 4-star thresholds. Aetna believes that this should now lead to greater stability in measure-level cut-points. In the last several years, cut-points have fluctuated significantly in many measures, as CMS has made adjustments and modifications to its Star Ratings program. For example, in the last 4 years, the 5-star level for hospital all-cause readmissions has fluctuated from 3% to 9% to 2% to 6% from 2013 to 2016 Star Ratings, respectively. This dramatic fluctuation in cut-points creates confusion for consumers, plans, providers, and other stakeholder evaluating high quality performance in the Star Ratings program. Now that CMS has moved to its new system for calculating Star Ratings, we believe that CMS should move to stabilize cut-points and create cut-point "ceilings", whereby cut-points will not increase by more than 2% in any given year. This will strike a proper balance, whereby plans that invest in quality improvement programs will be rewarded, while CMS can increase cut-points incrementally to continue to "raise the bar". This will also create much needed stability to the Stars program, which has seen significant changes in the last few years. Advanced Illness Measure Aetna continues to promote the concept that measures should be developed around advanced illness engagement and incorporated into the Star Ratings program. CMS includes numerous measures around preventing screenings and outcome-based measures in the current Stars system. However, measures around advanced illness engagement and support is notably absent – and we believe should be included as a quality measure for Medicare members. Aetna will continue to work with quality sponsoring organizations, such as NQF, on the development and refinement of such measures. Additional comments on Medication Therapy

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	Management (MTM) measure: We recommend CMS remove members in Long Term Care (LTC) from the MTM measure. This has been a huge challenge to complete comprehensive medication reviews (CMRs) for LTC residence. Currently LTC facilities are set up where consultant pharmacists are providing medication review as standard practice. Having health plans reaching out to LTC patients creates disruption to LTC facility work flow while duplicating the service already provided to these beneficiaries. Benchmark Cap The Affordable Care Act benchmark cap undermines the shift towards paying for quality that Congress enacted in the same package of Medicare changes. In some areas of the country, the cap reduces or completely eliminates the amount of the benchmark that would be attributable to the quality incentive payment – thus effectively eliminating the incentive to achieve a star rating of 4 Stars and above. The treatment of MA quality incentive payments is also in stark contrast to other quality programs in Medicare. In other Medicare programs, if a provider meets the required metrics for a quality payment, they receive that payment irrespective of other payment or formula reductions. Recommendation We recommend CMS use its authority to eliminate or minimize the impacts associated with the benchmark cap in order to sustain the movement towards recognizing quality care, and to help beneficiaries maintain their benefits and keep their MA plans. If the benchmark cap is left in place, removing the quality incentive payments from the calculation of the cap would solve a large part of the problem.
America's Health Insurance Plans	In order to foster stability and transparency in the Star Ratings program, we continue to believe that plans should have as much information as possible prior to the beginning of the measurement period such as changes to Star Ratings measurement methodology and cut point trends. This would enable plans to have an opportunity to gain experience with methodological changes, evaluate the cut point trends, and work with their network providers to integrate performance targets into their value-based contracts and establish longer term quality improvement benchmarks. CMS should also limit year-to-year cut point changes to a range based on industry performance trends to minimize wide fluctuations. In addition, as noted above, CMS should provide at least two years for plans to gain experience with capturing and reporting data for new measures and ensure that validation has been completed prior to incorporating new measures into the Star Ratings program. Policies that support stability and transparency in the Star Ratings program are critical to permitting MA and Part D plans to design and pursue activities to meet CMS priorities and achieve and maintain high star ratings. Moreover, MA plans that focus on serving low-income beneficiaries face observed barriers that impact their performance under the Star Ratings which makes it particularly important that the agency adopt these policies.
Anthem, Inc	In addition to the recommendations and concerns cited above,

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	Anthem requests that CMS consider the below overarching recommendations as it works to improve the Star Ratings program. Implement changes to the Stars measures and methodologies prospectively; finalize measures and their methodology well in advance of start of the measurement period. Quality improvement takes planning, time, and investment. Plans allocate resources in advance for such quality improvement efforts, and past guidance—including explanations of methodological changes included in sub-regulatory guidance and in the annual Call Letter—has not provided enough detail on the specific measures that will be added or retired or how the methodology will be changed. Frequent retrospective recalibration of the program and changing of goals creates a challenging system that does not appropriately measure true plan quality. The Star Ratings system should accurately reflect plan quality and be used as an effective and accurate tool for beneficiaries making enrollment decisions. Retrospective policies result in inaccurate information being provided to beneficiaries and unjustifiably lower payments to plans. This limits beneficiary transparency, hindering beneficiaries' ability to choose from a variety of quality plan choices. Accordingly, Anthem strongly recommends CMS apply all modifications on a prospective basis and finalize measures and their methodology prior to the start of the measurement period in order to give plans adequate notice. This transparency is critical for plans to meet the goal for performance that CMS expects and to ensure beneficiaries are able to rely upon the Star Ratings as a true measure of quality when selecting a plan. Implement more formal rulemaking, expand dialogue with plans, and provide information as soon as possible. Anthem reiterates its request that CMS utilize annual and formal notice and comment rulemaking to propose changes to the Star Ratings. In particular, Anthem continues to encourage CMS to publish proposed and final changes to the Star Ratings methodology in the Federal Register well in advance of the measurement period, and to afford plans adequate opportunity—at least 60 days—to comment on the proposed changes. We believe the Agency has a duty to engage in more frequent and transparent conversations with stakeholders regarding potential changes to the Star Ratings system. In order to meet CMS' expectations for new or modified quality measures, plans must be able to prepare and execute initiatives to improve their performance on those measures. More specifically, Anthem does not believe that the 2017 Call Letter is the appropriate vehicle to announce 2018 measures. Since the 2018 Star Ratings reflect the 2016 performance year, announcing 2018 measures in the 2017 Call Letter would force plans to begin 2017 with uncertainty. We ask that CMS instead release its proposed changes for 2018 measures and methodologies at an earlier time. Without timely and sufficient transparency, plans end up unjustly penalized, resulting in investments that ultimately are not recognized by CMS. For example,

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	we incorporated into our bid the cost of programs we developed to impact scores for measures we expected to be included in the Star Ratings—including the HRM measure. This includes developing new programs with provider incentives and working closely with contracted networks to ensure their optimal performance. We ask that CMS not only take into account the burden on plans but also provider networks that results from the Agency announcing 2018 measures in the 2017 Call Letter. Anthem also requests that CMS release updated plan Star Ratings no later than August 15 of each year, in order to allow plans to include the current year ratings in the enrollment process. More than 50 percent of all enrollment materials for the entire year are printed in September, and delivered in October to selling agents. For Anthem alone, this was approximately 630,000 kits. This means that a significant portion of Annual Election Period (AEP) enrollees are making purchasing decisions with last year's plan Star Ratings bound into our enrollment materials. We urge CMS to consider the consequential effect on beneficiaries' ability to make fully informed decisions. Increase focus on outcomes measures. We continue to believe that the Star Ratings system should include more outcomes measures that focus on improvements in beneficiaries' health. In order to avoid restrictions on how members access services and disincentives for health plans to implement innovative approaches to disease and care management these should truly be measures of outcomes, rather than measures of process. We encourage CMS to select outcomes measures with more direct linkage to the actions and influence of a plan rather than those that have a broad focus and are influenced by an infinite number of external variables outside the immediate control of the plan. In particular, we suggest that CMS attribute greater weight to data-driven measures developed based on rigorous scientific and evidence-based information than to measures that are constructed from enrollee surveys, which are subjective responses, subject to recall, from beneficiaries. Ensuring that the Star Ratings truly measure plan value and performance will, in turn, make the plan ratings a more useful and meaningful tool for beneficiaries to employ when selecting a MA or Part D plan. Consider a viable alternative to the predetermined 4-Star thresholds. Anthem remains strongly opposed to CMS' removal of thresholds as plans value the stability that these thresholds provide and use them as benchmarks to track achievement. As we stated in our comment letters in response to CMS' November 2014 Request for Comments and February 2015 draft Call Letter, Anthem finds the thresholds immensely helpful in tracking our own improvement, including when we set quality expectations and performance targets jointly with providers. Without the predetermined thresholds, plans are left uncertain as to the goals that CMS is setting and expecting them to achieve. The elimination of the 4-Star thresholds detrimentally impact plans' collaboration efforts with provider networks. To that end, we encourage CMS to

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	revisit the use of thresholds in certain instances—for example, with newer measures or measures where plans work with providers to achieve meaningful improvements. Another potential alternative would include obtaining prospective cut-points as early as possible.
BIO	BIO asks CMS to explore the addition of Star Ratings measures specific to two therapeutic areas relevant to the Medicare population: psoriasis and rheumatoid arthritis (RA). First, BIO suggests the development of a plan-level measure to address treatment of psoriasis. In the 2016 Medicare Physician Fee Schedule Final Rule, CMS adopted the measure "Psoriasis: Clinical Response to Oral Systemic or Biologic Medications" within the Physician Quality Reporting System.[1] In doing so, CMS noted that the measure represents a National Quality Strategy domain gap in that it addresses person and caregiver centered experience and outcomes. Development of a plan-level measure for the Star Ratings will help to align incentives across CMS' quality reporting programs and improve care for this common chronic condition. Second, BIO recommends that CMS consider incorporating more granular and outcomes-based measures related to the treatment of RA in the Star Ratings program. Despite the availability of numerous treatment options for Rheumatoid Arthritis (RA), there continues to be a large number of patients who are inadequate responders. Some of the barriers to treatment escalation for patients and physicians result from concerns about injection experience, side effects, out-of-pocket cost requirements, and other patient access issues.[2][3] As a result, many patients are not achieving remission or necessary treatment escalation goals at an appropriate time.[4] Only about one-third of patients achieve clinical remission of RA and up to 40 percent of patients still experience moderate or high disease activity after one year of receiving biologics. Taken together, up to two-thirds of patients with RA are insufficiently controlled on their current therapy.[5][6] If patients fail to achieve treatment goals, it may contribute to irreversible disease progression. Inadequate response to RA treatment can also lead to increased healthcare resource utilization and costs. RA is a chronic disease with a prevalence that increases with age, and as patients accrue dysfunction and damage over time, their level of disability also increases. The economic burden of inadequately treated RA can include increased healthcare spending on patient care as well as other indirect costs resulting from such disability. Higher costs arising from the complications of RA vary significantly depending on the patient's level of disease activity. Moderate or high disease activity can lead to structural damage, disability, increased risk of cardiovascular events, and increased healthcare resource utilization, including higher rates of hospitalizations, joint surgery, and durable medical equipment (DME) utilization.[7][8] Given these risks, we remain concerned that existing quality measures for RA do not sufficiently reflect clinically meaningful characteristics of the disease. To achieve this goal, BIO

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	asks CMS to incorporate Star Ratings measures that enable health plans and providers to classify RA patients according to their level of disease activity, and assess whether they have been initiated on an appropriate treatment as indicated by their disease activity. A 2011 study by Curtis et al. demonstrated a validated algorithm that relies on prescription claims data to identify an RA patient's level of disease activity (i.e, low or high).[9] Working with stakeholders to adapt this approach, future quality measures could be significantly more granular by taking patients' disease activity into consideration and setting up high-risk RA patients for the best possible outcomes. Additionally, to the extent possible, we encourage CMS to shift to more outcomes-focused Star Ratings measures for RA that are aligned with current clinical guidelines. A focus on outcomes-based measures can help advance the current standard of care in ways that can improve patient health and reduce costs associated with ongoing complications associated with uncontrolled RA. Endnotes: [1] 80 Fed. Reg. 70,886 (November 16, 2015). [2] Wolfe F., and K. Michaud. 2007. Resistance of rheumatoid arthritis patients to changing therapy: discordance between disease activity and patients' treatment choices. Arthritis & Rheumatology 56(7):2135-2142. [3] Solomon D.H., A. Bitton, J. N. Katz, H. Radner, E. Brown, and L. Frarnkel. 2014. Treat to target in rheumatoid arthritis: fact, fiction, or hypothesis? Arthritis & Rheumatology 66(4):775-782. [4] Harrold L. R., J. T. Harrington, J. R. Curtis, et. al. 2012. Prescribing Practices in a US cohort of Rheumatoid Arthritis Patients Before and After Publication of the ACR Treatment Recommendations. Arthritis & Rheumatology 64(3):630-638. [5] Harrold L., G. W. Reed, N. Boytsov, et. al. 2015. Combination therapy, switching and persistence patterns by longitudinal disease activity strata in patients with rheumatoid arthritis [abstract]. Arthritis & Rheumatology 67 (suppl 10). [6]Shahouri S.H., K. Michaud, T. R. Mikulus, et. al. 2011. Remission of rheumatoid arthritis in clinical practice: application of the American College of Rheumatology/ European League Against Rheumatism 2011 remission criteria. Arthritis & Rheumatology 63(11):3204-3215. [7] Stephens S., M. F. Botteman, M. A. Cifaldi, et. al. 2015. Modelling the cost-effectiveness of combination therapy for early, rapidly progressing rheumatoid arthritis by simulating the reversible and irreversible effects of the disease. BMJ Open 5(6):e006560. [8] Solomon D.H., G. W. Reed, et. al. 2015. Disease activity in rheumatoid arthritis and the risk of cardiovascular events. Arthritis & Rheumatology 67(6):1449-1455. [9] Curtis J.R., J. W. Baddley, et. al. 2011. Derivation and preliminary validation of an administrative claims-based algorithm for the effectiveness of medications for rheumatoid arthritis. Arthritis Research & Therapy 13(5):R155.
Blue Cross Blue Shield of Michigan	In addition to the specific feedback CMS is asking for in its Request for Comments, BCBSM would like to comment on two additional issues related to the Star Ratings: -BCBSM does not believe the

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	Improving or Maintaining Physical Health and Improving or Maintaining Mental Health measures should be weighted a 3. Instead, we recommend the measures be weighted a 1 for two reasons. The first reason is related to reliability of the measure results. For instance, the measures are based on small sample sizes which could lead to less dependable results. Also, we have concerns that the sampling stratification is inadequate to ensure comparability between plans. The second reason we believe the measures should be weighted a 1 is because the measures are not under a plan's direct control. Improvement in these measures is highly dependent upon the relationship between the primary care provider and the patient, and is evaluated using the Health Outcomes Survey (HOS) as a data source. Other measures based on HOS data are only weighted a 1. -In order to help plans improve in the Part D measures, BCBSM recommends CMS allow plans to implement rewards and incentives programs targeted at the Part D measures. Research suggests that incentives can have a big impact on modifying member behavior to improve outcomes like medication adherence. For example, a meta-analysis of 15 randomized studies and 6 non-randomized studies published in 2012 found that reinforcement interventions significantly improved medication adherence. The same meta-analysis also found that interventions that were longer in duration, included an average reinforcement of $50 or more per week and reinforced patients at least weekly had the biggest impact. (American Journal of Medicine, Vol. 125, Issue 9, p 888-896, "Financial Reinforcers for Improving Medication Adherence: Findings from a Meta-analysis")
BlueCross and BlueShield Association	BCBSA and Plans appreciate CMS's commitment to continuing to improve the Star Ratings by identifying new measures and methodological enhancements. As CMS makes such changes, BCBSA and Plans encourage the Agency to use notice and comment rulemaking, which provides commenters with 60 days to submit feedback. (See also Key Recommendation: Use the Formal Notice and Comment Rulemaking Process to Announce and Implement Changes to the Star Ratings.) We also encourage CMS to provide sufficient time (e.g., two years) for Plan Sponsors to adjust to the addition or removal of measures from the Star Ratings, so that Plan Sponsors can appropriately adjust to changes before the measurement period begins. Additionally, BCBSA and Plans recommend that CMS consider the feasibility of alternate levels of evaluation for Star Ratings for MA contracts that are linked to numerous individual MA plans offered in different states (e.g., one contract with plan benefit packages in California and Florida). For example, could the Star Ratings measures for these contracts be evaluated at the state level such

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	that one contract would have two separate ratings (e.g., one for the California plan benefit packages and one for the Florida plan benefit packages)? BCBSA and Plans ask CMS to evaluate whether such an approach is administratively manageable and would provide more meaningful information to beneficiaries regarding the quality of the care provided in their geographic area. Finally, BCBSA and Plans request that CMS consider whether the Agency can provide new Star Ratings scores and data earlier in the year. As one Plan noted, most of its enrollment materials for the year are printed in September, for delivery to agents in October. Plan Sponsors would be able to better inform beneficiaries of their most recent Star Ratings scores if CMS could provide this updated information earlier. Recommendations: BCBSA and Plans recommend that CMS make changes to the Star Ratings using formal notice and comment rulemaking. (See also Key Recommendation: Use the Formal Notice and Comment Rulemaking Process to Announce and Implement Changes to the Star Ratings.) BCBSA and Plans recommend that CMS consider alternate levels at which to apply the Star Ratings measures for those contracts that offer MA plans in different states. Finally, BCBSA and Plans request that CMS consider whether the Agency could provide Star Ratings scores earlier each year.
BlueCross BlueShield of SC	Encourage the addition of four star thresholds back to the measurements. Plans often times do not have a way to gauge where they are at during the year on all measures. The Acumen reports does provide an average so a plan can see if they are above or below. If predetermined four star thresholds are not an option then an addition to the Acumen reports to show the highest and lowest value throughout the industry during the reporting time. This would then provide plans with a contract average, high and low. For example the 95% for 5 stars on diabetes would have been helpful for plans to know during the year. This way plans could strategically know where to put resources. In certain areas of the country achieving 95% adherence on diabetes measure is not possible. These plans could then set for being above average to hopefully achieve a four star rating while focusing on another measure that could possibly move and make a bigger difference in the overall rating. I just think that plans are better able and more willing to know

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	where to allocate resources if we have a better estimate of where the cut-points will be during the year.
BlueCross BlueShield of Tennessee	BCBST commends CMS on its commitment to continuing to improve the Part C and D Star Ratings. BCBST strongly encourages CMS to involve plans in the development of operational measures, more specifically, the Call Center Foreign Language Line and TTY Availability measure. BCBST is concerned that the methodology used by CMS' contractor may have been flawed. For instance, CMS' contractor used an auto-dialer when conducting the secret shopper calls without regard to plans using the latest anti-spam/hacking technology to prevent robo-calls. Also, BCBST is concerned that the CMS' contractor did not use a statistically valid sample when completing the calls and applying the results to all contracts within the plan.
CareSource Management Group	Transition from ICD-9 to ICD-10: CMS's proposal makes sense. We support CMS's proposal to continue watching PQA and NCQA as they assess impact during the transition. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D): We appreciate CMS's provision of detailed files on HPMS in order for plans to review and confirm their Medication Therapy Management (MTM) data. We also support the movement away from MTM process measures and look forward to inclusion of outcomes-based MTM measures in the Star Ratings Program in the future. In the interim, we recommend CMS evaluate changes to the MTM Comprehensive Medication Review Completion Rate (CMR) measure methodology. We are also concerned that misaligned incentives that reward volume could result in lower quality of CMRs being performed in order to achieve the rates desired. Similar to other process measures in the Star Ratings Program, we request CMS consider weighting this measure by enrollment prior to benchmarking plans against one another. The thresholds provided by CMS in the Second Plan Preview indicate significant shifts in performance as compared to prior years. Previous data would have been significantly skewed by outliers in the cluster analysis used to determine the Star thresholds. Historical industry data indicates that a large majority of the industry achieved a 30% or less CMR completion rate. 2014 Star Ratings: 382/452 MAPD contracts (who received a score on this measure) or 85% achieved a MTM CMR completion rate of 30% or less. 2015 Star Ratings: 374/470 MAPD contracts (who received a score on this measure) or • 80% achieved a MTM CMR completion rate of 30% or less. • 2016 Star Ratings: MAPD contracts achieving a CMR completion rate of 30% would receive a 2 Star Rating. Based on this information, we recommend CMS evaluate changes to the measure methodology to more fairly evaluate plan performance on the MTM CMR completion rate measure. We support the replacement of this measure with outcomes-based MTM metrics, such as the two metrics that PQA is currently developing, "Patient Satisfaction

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	Survey following Comprehensive Medication Review" and "MTM-Part D: Specific Drug Therapy Problem (DTP) Resolution." Outcomes measures such as these are better aligned with the quality of care provided to beneficiaries through an MTM interaction. Additional Comment: Complaints: We recommend CMS evaluate modifications to the exclusion criteria on the Complaints Star measure. We specifically recommend CMS evaluate the following categories for exclusion: CMS/SSA delays of premium withhold election changes. o These occur when CMS/SSA doesn't process timely or reconciles up to several years later. Marketing Misrepresentation caused by 1-800 Medicare representatives. o Marketing Misrepresentation normally count against the Plan. However for cases were the 1-800 Med rep provides false information is not the fault of the plan. • CMS/SSA system discrepancies. o MARx is updated; however the Next Generation Desktop (another CMS system) is not. o Over-lay issues with the change in HICN Accumen: Acumen reporting provides valuable tracking and feedback for plans on a monthly basis. In many cases this reporting is cross referenced against internal reporting to validate metrics, which provides plans with actionable data to drive quality improvement. We have identified multiple enhancements that would allow for more timely quality monitoring, and provide health plans with additional resources to drive Drug Plan Customer Service, Member Complaints and Changes in the Drug Plan's Performance, and Member Experience. We respectfully request CMS consider supplying plans with quarterly metrics for operational star measures and also include these measures within the monthly Acumen reporting along with the Drug Safety and Accuracy of Drug Pricing data. This additional reporting will exhibit greater transparency of performance and support CMS's efforts to ensure Medicare beneficiaries have the information necessary to make informed enrollment decisions by comparing available health and prescription drug plans. The addition of an industry metric range would be helpful in determining potential outliers, which may skew the thresholds on a particular quality measure. If CMS were to provide a column with an industry range for each measure, it would allow health plans to associate a level of risk with their projections for performance. Many health plans project internal thresholds for future measurement periods and set targets for quality performance. The industry metric range would allow plans to associate a level of risk with their projected performance and drive improvements to provide higher levels of quality to its beneficiaries. We hope that the Star ratings program will consider and address our comments in its continued collaborative effort to improve and refine the STARs system. Thresholds: The release of the 2016 Star Ratings highlighted volatility in industry performance. Many measures displaying a significant increase or decrease in the ability for health plans to achieve 5 Stars. This volatility appears to be counter to the Stars program goal of driving continuous improvement in the Quality

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	of Care and general health status of Medicare beneficiaries. There were significant movements in the 5 Star PDP and MAPD thresholds on the following measures: Appeals Auto-Forward, Appeals Upheld, Complaints, and Medication Adherence for Diabetes and Medication Therapy Management Comprehensive Medication Reviews. In addition, the MAPD thresholds also demonstrated variability on Appeals Auto-Forward, Complaints and Medication Therapy Management Comprehensive Medication Reviews. We've illustrated the noteworthy 5 Star PDP and MAPD threshold changes below: PDP 2015 Stars 2016 Stars Appeals Auto-Forward <=0.1 <=5.3 Appeals Upheld >=78% >=91% Complaints <=0.08 <=0.01 Medication Adherence for Diabetes >=85% >=95% MAPD 2015 Stars 2016 Stars Appeals Auto-Forward <=0.7 <=5.0 Complaints <=0.17 <=0.08 In each case, the industry data illustrates outliers having a dramatic impact on published thresholds, resulting in unrealistic 5 Star benchmarks relating to quality within the industry. This increased impact of outliers may be a result of the removal of the predetermined cut points. Without predetermined cut points, plans no longer had the ability to set targets based on information provided by CMS and variation in performance increased. Additionally, while this is the second year CMS has used Ward's minimum variance method to create industry clusters, outliers had an increased impact on published thresholds. In the 2015 Star Ratings, the predetermined thresholds provided a framework for industry performance, which mitigated the impact of outliers. CareSource requests CMS to consider an alternative approach to setting thresholds. For example, if thresholds were set by CMS every three years, it would allow plans to drive continuous improvement by setting annual targets; thereby focusing their resources to innovative and effective ways to provide higher quality to beneficiaries. This approach would ensure thresholds remain stable or steadily improve year-over-year which would eliminate situations where the 5 Star threshold decreases from one year to next as seen in the MAPD 2016 5 Star thresholds for RAS Antagonists and Statin Adherence. Consistent improvement over a multi-year period could lead to higher quality in the marketplace compared to volatility in year to year improvement. Changes to Existing Star Ratings and Display Measures and Potential Future Changes: CMS is considering updates to the Medicare Plan Finder Price Accuracy measure, including how current methodology is limited to 30-day claims filled at pharmacies reported by sponsors as retail only or retail and limited access only. If CMS pursues this, then the quality measure will differ from how pricing information is displayed on Medicare Plan Finder. As such, we request that CMS change plan finder submissions to allow plans to submit pricing data for 30 days. For any changes CMS is considering making to display measures, CAHPs, and CMMI, we request that CMS identify the specific modifications to be made and give plans ample time to review the changes and prepare for them.

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	For example, if the Medicare Plan Finder Price Accuracy measure were to be changed mid-2016, issuers would have insufficient time to account for those changes, and 2018 Star Ratings would be adversely impacted. If CMS is unable to give plans sufficient time to prepare, then CMS should hold off on making changes to measures for an additional year or more.
CVS Health	Call Center Additional Comment: TTY/Foreign Language Call Center Monitoring SilverScript recommends CMS revise the methodology used to determine the testing sample size for each language tested. More specifically, we recommend CMS test languages proportional to the prevalence of each language in the 65+ U.S. populations. Using U.S. Census Bureau data from 2014, we recommend CMS test each language for each plan according to the prevalence rates below: (Supporting documentation submitted via email) • Based on the U.S. Census Bureau's American Community Survey data from 2014, there are approximately 3.2 million people age 65 and older who speak Spanish at home in the United States. There are 2.8 million more Spanish speakers age 65 and over than those who speak Tagalog, and over 3 million more than those who speak Vietnamese. Based on this information, we recommend CMS test languages according to the rate they are spoken within the U.S. population. The current method of testing minority languages at the same rate as Spanish and other more common languages does not provide an accurate reflection of a plan's ability to provide effective communication for our Limited English Proficient prospective and current members. Because the number of "secret shopper" calls for minority languages is disproportionate to the Medicare population, it creates an artificial surge in demand. • Based on the SilverScript call results last year, while Spanish is the most common language among the U.S. population, it was the language tested least by CMS. We would recommend the test calls align with the rate each language is spoken in the U.S. population. (Supporting documentation submitted via email) • Finally, we recommend CMS allow an extra 60 seconds for the interpreter to begin addressing questions related to Medicare Part D. We've found from our test calls that there is a distinction between connecting to an interpreter and answering questions related to Medicare. We believe CMS should have a 7 minute timer to connect to the interpreter and then allow 60 seconds for the question to be asked and addressed. Based on review of our prior call results we also request CMS introduce a rigorous Quality Assurance and Audit process over the test call process. We have experienced several calls which were documented as failures; however, upon retrospective review, were determined to be successful calls.

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	Appeals Upheld SilverScript has dedicated significant time and resources into quality assurance, quality improvement, and performance monitoring for the Appeals Upheld measure. In 2014, we launched extensive monitoring in order to review each overturn and thoroughly understand the root cause behind each overturn. From this data, we were able to immediately execute improvement opportunities, such as revisions to the coverage determination process, changes to the utilization management edits, and modifications to clinical criteria. We also initiated dialogue with Maximus Federal Services—the Part D Independent Review Entity (IRE)—to request reopening of cases where the IRE decision is incorrect, according to Medicare regulations. Through our rigorous and ongoing review of IRE decisions, we have identified a category of overturns that is outside our control for improvement. When the IRE obtains new or different information than the plan received, it is making a decision based upon different underlying facts. The plan cannot be held accountable for making the same decision as the IRE when essential information on which to base the decision has either been previously withheld, or has come to pass in time. While Maximus should continue to track new or different information so that clinical quality remains high, we recommend that these cases be excluded from the measure. Complaints We recommend CMS evaluate modifications to the exclusion criteria on the Complaints Star measure. We specifically recommend CMS evaluate the following categories for exclusion: • CMS/SSA delays of premium withhold election changes. o These occur when CMS/SSA doesn't process timely or reconciles up to several years later. • Marketing Misrepresentation caused by 1-800 Medicare representatives. o Marketing Misrepresentation normally count against the Plan. However, for cases were the 1-800 Med rep provides false information is not the fault of the plan. • CMS/SSA system discrepancies. o MARx is updated; however the Next Generation Desktop (another CMS system) is not. o Over-lay issues with the change in HICN Beneficiary Access and Performance Problems We respectfully request CMS revisit the measure methodology for Beneficiary Access and Performance Problems. Based on our analysis, larger plans tend to be disadvantaged on this measure as compared to smaller plans. In the 2016 Star Ratings there were 482 plans that received a metric score for this measure. Utilizing contracts with enrollment greater than and less than 50,000 lives (based on October 2015 Enrollment) we can determine that 378 plans with less than 50,000 lives received a metric score on this measure, while only 104 plans had enrollment greater than 50,000

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	lives. Of the plans with less than 50,000 lives, 219 out of 378 plans receiving a score achieved a metric of 100, which is approximately 85% of the total plans achieving 100. This total represents approximately 58% of the total contracts receiving a score with less than 50,000 lives. Of the plans with greater than 50,000 lives, only 40 out of 104 receiving a score achieved a metric of 100, which is approximately 15% of the total plans achieving 100. This total represents approximately 38% of the total contracts receiving a score with greater than 50,000 lives. This clearly demonstrates the disadvantage larger plans experience as there is a 20% reduction in plans ability to achieve a metric score of 100 when enrolling greater than 50,000 lives. Each year, Medicare checks each plan to see if there are problems with the plan. For example, Medicare checks whether: Members are having problems getting services, and Plans are following all of Medicare's rules. This measure is not currently weighted based on enrollment and methodology and is only based on Civil Monetary Penalties (CMP), and Compliance Activity Module (CAM) data (includes: notices of non-compliance, warning letters with or without a business plan, and ad-hoc corrective action plans (CAP) and CAP severity). The metric score is calculated based on a formula of the above listed notifications and their severity. It is not based on compliance notifications per 10,000 beneficiaries or a similar calculation. This increases the likelihood of larger plans receiving compliance notifications due to a higher frequency of interactions and additional opportunities for beneficiary impact. We hope that the STAR ratings program will consider and address our comments in its continued collaborative effort to improve and refine the STARs system. Acumen Acumen reporting provides valuable tracking and feedback for plans on a monthly basis. In many cases this reporting is cross referenced against internal reporting to validate metrics, which provides plans with actionable data to drive quality improvement. We have identified multiple enhancements that would allow for more timely quality monitoring, and provide health plans with additional resources to drive Drug Plan Customer Service, Member Complaints and Changes in the Drug Plan's Performance, and Member Experience. We respectfully request CMS consider supplying plans with quarterly metrics for operational star measures and also include these measures within the monthly Acumen reporting along with the Drug Safety and Accuracy of Drug Pricing data. This additional reporting will exhibit greater transparency of performance and support CMS's efforts to ensure Medicare beneficiaries have the information necessary to make informed enrollment decisions by comparing available health and prescription drug plans. The addition of an

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	industry metric range would be helpful in determining potential outliers, which may skew the thresholds on a particular quality measure. If CMS were to provide a column with an industry range for each measure, it would allow health plans to associate a level of risk with their projections for performance. Many health plans project internal thresholds for future measurement periods and set targets for quality performance. The industry metric range would allow plans to associate a level of risk with their projected performance and drive improvements to provide higher levels of quality to its beneficiaries. We hope that the Star ratings program will consider and address our comments in its continued collaborative effort to improve and refine the STARs system. Thresholds The release of the 2016 Star Ratings highlighted volatility in industry performance. Many measures displaying a significant increase or decrease in the ability for health plans to achieve 5 Stars. This volatility appears to be counter to the Stars program goal of driving continuous improvement in the Quality of Care and general health status of Medicare beneficiaries. There were significant movements in the 5 Star PDP and MAPD thresholds on the following measures: Appeals Auto-Forward, Complaints, and Medication Adherence for Diabetes and Medication Therapy Management Comprehensive Medication Reviews. In addition, the MAPD thresholds also demonstrated variability on Appeals Auto-Forward and Complaints We've illustrated the noteworthy 5 Star PDP and MAPD threshold changes below: (Supporting documentation submitted via email.) In each case, the industry data illustrates outliers having a dramatic impact on published thresholds, resulting in unrealistic 5 Star benchmarks relating to quality within the industry. This increased impact of outliers may be a result of the removal of the predetermined cut points. Without predetermined cut points, plans no longer had the ability to set targets based on information provided by CMS and variation in performance increased. Additionally, this is the second year CMS has used Ward's minimum variance method to create industry clusters. A known concern of the Ward's method is the impact of outliers in determining clusters. In the 2015 Star Ratings, the predetermined thresholds provided a framework for industry performance, which mitigated the impact of outliers. The change in statistical analysis used to determine the thresholds has increased the significance of outliers on the Star thresholds. When CMS alters the methodology of the Star Ratings program, we request CMS provide advance notice and simulated data demonstrated the potential impact of the changes. SilverScript asks CMS to consider an alternative approach to setting thresholds. For example, if thresholds were set by CMS every three years, it would

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	allow plans to drive continuous improvement by setting annual targets towards achieving the three year target; thereby focusing their resources on innovative and effective ways to provide higher quality to beneficiaries. This approach would ensure thresholds remain stable or steadily improve year-over-year which would eliminate situations where the 5 Star threshold decreases from one year to next as seen in the MAPD 2016 5 Star thresholds for RAS Antagonists and Statin Adherence. Consistent improvement over a multi-year period could lead to higher quality in the marketplace compared to volatility in year to year improvement. We hope that the Star ratings program will consider and address our comments in its continued collaborative effort to improve and refine the Star system.
Eli Lilly	1. Measure Concepts - Rheumatoid Arthritis: Lilly agrees with comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO) that a large number patients suffering from Rheumatoid Arthritis (RA) today are inadequate responders, despite the availability of numerous treatment options. Some of the barriers to treatment escalation for patients and physicians result from concerns about injection experience, side effects, out-of-pocket cost requirements, and other patient access issues. As a result, many patients are not achieving remission or necessary treatment escalation goals at an appropriate time. Only about one-third of patients achieve clinical remission of RA and up to 40 percent of patients still experience moderate or high disease activity after one year of receiving biologics. Taken together, up to two-thirds of patients with RA are insufficiently controlled on their current therapy. Not achieving treatment goals may result in irreversible disease progression. Inadequate response to RA treatment can also lead to increased healthcare resource utilization and costs. RA is a chronic disease with a prevalence that increases with age, and as patients accrue dysfunction and damage over time, their level of disability also increases. The economic burden of inadequately treated RA can include increased healthcare spending on patient care as well as other indirect costs resulting from such disability. Higher costs arising from the complications of RA vary significantly depending on the patient's level of disease activity. Moderate or high disease activity can lead to structural damage, disability, increased risk of cardiovascular events, and increased healthcare resource utilization, such as higher rates of hospitalizations, joint surgery, and durable medical equipment (DME) utilization. Given these risks, Lilly is concerned that existing quality measures for RA do not sufficiently reflect clinically meaningful characteristics of the disease. Lilly therefore requests that CMS shift to more outcomes-focused RA measures aligned to current clinical guidelines. This approach can help advance the current standard of care in ways that would meaningfully improve patient health and reduce costs associated with ongoing complications associated with uncontrolled RA. One

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	way to achieve these goals is to incorporate Star Ratings measures that enable health plans and providers to classify RA patients according to their level of disease activity, and assess whether they have been initiated on an appropriate treatment (e.g. bDMARD or JAKi), as indicated by such disease activity . Curtis et al. (2011) have demonstrated a validated algorithm that relies on prescription claims data to identify an RA patient's level of disease activity (i.e, low or high). Using a similar approach, future quality measures can and should be more granular, by taking patients' disease activity into consideration and setting up high-risk RA patients for the best possible outcomes. To the extent possible, Lilly encourages CMS to shift to more outcomes-focused Star Ratings measures for RA that are aligned with current clinical guidelines and better reflect the nature of treatment. An outcomes-focused approach would help advance the current standard of care in ways that can improve patient health and reduce the costs associated with ongoing complications of uncontrolled RA. Additional Comment: 2. Measure Concepts - Psoriasis: Lilly also urges the Agency to develop a plan-level measure to address the treatment of psoriasis. In the 2016 Medicare Physician Fee Schedule Final Rule, CMS adopted the measure "Psoriasis: Clinical Response to Oral Systemic or Biologic Medications" within the Physician Quality Reporting System. In doing so, CMS noted that the measure represents a National Quality Strategy domain gap in that it addresses person and caregiver centered experience and outcomes. Lilly also agrees with the Agency's comments that this measure effectively targets an underrepresented clinical category within the quality measure set, and we believe that similar benefits would be achieved by adding comparable measure language to the Medicare Star Ratings Program. Additionally, the development of a plan-level measure for the Star Ratings would be consistent with the Department of Health & Human Services' goal of aligning measures across quality reporting programs wherever possible, while also improving care for this common chronic condition.
Fresenius Health Plans	Thank you for the opportunity to comment on the impact of disability and specifically ESRD on Star Ratings. As an MA organization focused exclusively on caring for ESRD beneficiaries through C-SNPs, we are concerned that the current star rating methodology is not a true reflection of the performance and experience of our patients. We recommend that CMS considers excluding ESRD beneficiaries from the star measure calculations or alternatively creating ERSD-specific measurements to put in place of star rating for ESRD C-SNPs. Further, we welcome the opportunity to dialogue around ESRD-specific measures and rating methodology. As ESRD SNPs require a unique model of care because of the special needs of these beneficiaries, the applicable measurements should also reflect the special needs of these beneficiaries (which includes where and how services are provided). While the ultimate star rating

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	applies to the entire contract, sponsors with beneficiaries who are not special needs are able to absorb the impact of the special needs beneficiaries, while C-SNP contracts are not. It is unfair and not meaningful to compare the top 1-2% sickest population to the entire Medicare population.
GlaxoSmithKline	Development of Quality Measures to Increase Adult Immunizations: GlaxoSmithKline (GSK) encourages CMS to support the development of quality measures for all Advisory Committee for Immunization Practice (ACIP) recommended adult immunizations and to include those measures into Medicare quality reporting programs. GSK notes that despite the ACIP recommendations and Healthy People 2020 targets, adult immunization rates remain low(1). Quality measures have the potential to increase immunization rates(2). Adult immunization quality measures currently only focus on influenza, pneumococcal and hepatitis B immunization. The National Quality Forum (NQF) has also published a report, "Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations," that defines the gaps in adult immunization quality measurement and recommends priorities for measure development. NQF completed a two-phase project focused on identifying, endorsing, and updating population health measures, including maintaining and expanding previous efforts in measuring clinical prevention and immunization. NQF endorsed several variations of flu and pneumonia adult immunization measures at that time. Additionally, the National Quality Forum (NQF) released a report in August 2014 that documents the gaps in adult immunization measures and prioritizes the development of several measures including composite measures that incorporate immunization with other preventive care services(3). HHS has demonstrated its commitment to population health management recently through announcement of the "Better Care, Smarter Spending, Healthier People" initiative, in which HHS reaffirmed its dedication to using incentives for higher-value care, thereby fostering greater integration and coordination of care and attention to population health(4). The HHS National Quality Strategy and National Prevention Strategy also states that preventive care services must continue to be a priority if efforts to increase the population's overall health and reduce the number of preventable, premature deaths are to be achieved(5). GSK encourages CMS to support the development of quality measures and inclusion of adult immunization measures to the Star ratings program for Part C and D plans (1) MMWR, February 7, 2014/ 63(05); 95-10 (2) Performance Measures, Vaccinations, and Pneumonia Rates Among High-Risk Patients in Veterans Administration Health Care. American Journal of Public Health. December, 2007; 97(12): 2167-2172 (3) National Quality Forum. Priority Setting for Healthcare Performance Measurement: Addressing Performance Measure Gaps for Adult Immunizations. August 15, 2014.

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	http://www.qualityforum.org/Publications/2014/08/Priority_Setting_for_Healthcare_Performance_Measurement__Addressing_Performance_Measure_Gaps_for_Adult_Immunizations.aspx (accessed February 16, 2015). (4) "Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value," CMS News Release, Monday, January 26, 2015. http://www.hhs.gov/news/press/2015pres/01/20150126a.html (5) Endorsement Summary: Population Health: Prevention Measures, NQF, May 2012. http://www.qualityforum.org/News_And_Resources/Endorsement_Summaries/Endorsement_Summaries.aspx (accessed February 22, 2015).
Health Care Service Corporation	As the Medicare managed care program has developed over time, MAOs have adopted different strategies in developing HMO contracts, which is the level at which CMS measures Star Ratings. Some sponsors have established single state or local entities or have formed a separate legal entity in each state and obtained a separate Medicare contract for each State. The evolution of value-based care and the intense activity throughout organizations and across all lines of business to achieve the Secretary's goals with respect to paying for value are creating different synergies between MAOs and providers that necessitate contract alignment to be most effective in driving improved Star Rating performance. Permitting MAOs to align by state would enable more meaningful physician incentive programs to promote quality and efficient use of health services. This option would improve quality because providers could more directly link their performance to their Star Ratings, and associated quality bonus and other performance-based incentives. In addition, Star Ratings associated with each contract would better reflect Medicare beneficiaries' experiences in their respective geographic areas. HCSC recommends that CMS permit plans to align contracts by state to provide transparency and more accurate information for beneficiaries in Star Ratings; enable MAOs to more effectively hold providers accountable for performance to achieve triple aim results; and promote value-based care.
Health Partners Plans, Inc.	"With the proposal of the Categorical Adjustment Index and Indirect Standardization adjustments to the Stars program, Health Partners Medicare would like be able to access CMS Simulated Plan Specific Data for each of these two approaches. This will enable plans to accurately assess the impact to the Stars scoring and to scope the work needed to verify these scores during the Plan Preview periods."
Healthfirst	Complaints about the Health Plan (Part C/D) Throughout the year, Healthfirst has received a number complaints through CTM that can be classified as either simple questions (i.e., not a complaint), issues that don't match the level of importance assigned to them, CMS policy issues, or issues related to a state Medicaid beneficiary who is not in receipt of Medicare. While working through these complaints,

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	we have been able to document the fact that these are not issues germane to Medicare, or to our plan. Our Regional Office representatives have been able to evaluate our documentation and in some cases we have successfully reclassified issue levels or changed an issue from a “plan issue” to a “CMS issue.” We are still evaluating the total impact to our CTM complaints, but it appears we have received more than 14 of such issues in 2015 so far, averaging at least one per month. This represents a significant volume of the total complaints, and in our view, also stands out as a training concern for the individuals who staff the 1-800-MEDICARE phone lines. We ask that CMS address this issue and provide additional training for individuals who staff the 1-800-MEDICARE phone line so that plans only receive “true” complaints through CTM, as non-complaints that come through CTM adversely impact a plan’s star rating unfairly. Cut Point Methodology Large incremental increases in measure cut points year-over-year remains problematic. To support health plans in their quality improvement activities, we request that CMS place a cap on cut point increases (i.e. no more than 5% over previous year), minimizing the volatility of the Star Ratings program.
HealthPartners	HealthPartners strongly recommends that CMS discontinue the use of the HOS measures in the Star Ratings because the information obtained from the surveys is not actionable. As an alternative, if CMS is not ready to remove all HOS measures from the Star Ratings, we recommend that the weight be reduced for measures C04-Improving or Maintaining Physical Health and C05 - Improving or Maintaining Mental Health because they are not true outcomes measures. The questions related to these measures are based on members' experiences and thus should be categorized as experience measures. Members may be receiving appropriate health care services, however their responses regarding their physical health or mental status may have worsened year over year due to normal aging or other factors unrelated to health care. In addition, self-report survey responses are subjective and often biased by the beneficiaries' feelings at the time they fill out the survey. For example, if a member doesn't feel well at the time s/he fills out the survey, the response tends to be more negative. If the person feels good at the time, then the response tends to be more positive.
Humana	Humana respectfully requests that the following types of complaints be added to the current Complaints Tracking Module (CTM) Exclusion List: - Billing related CTMs regarding refund requests where no refund is due from Humana - CTMs related to SSA delays and issues - CTMs related to Late Enrollment Penalty (LEP) assessments - Disenrollment related CTMs when no prior request was received by the plan - OEC (Online Enrollment Center) Related Issues (CTMs because the mbr had issues with their OEC experience) We believe that these complaints are outside of the

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	plans control and cannot be clearly attributed to the plan, and therefore should be not be calculated against the Complaints about the Health Plan and Complaints about the Drug Plan Star measures. Humana respectfully requests that CMS consider excluding members with dementia or Alzheimer's from survey measures until such time as methodologies can be implemented to ensure the quality of data collected from this subset of members. Humana requests additional transparency in the CAHPS survey administration process and results. Larger plans cross multiple geographies and leverage numerous health systems to support beneficiary healthcare. In order to develop effective quality improvement interventions, health plans need to have more specific data to conduct root cause analysis. Humana requests that member level information is published in a secure format to healthplans, along with results.
Kaiser Permanente	Plan All-Cause Readmission Measure Kaiser Permanente recognizes and agrees with the importance of reducing avoidable readmissions. However, as we described in our comments last year, we have significant concerns about the statistical reliability of the Plan All-Cause Readmission measure. Based on our own national performance analysis and conversations hosted by several industry groups, we believe many other plan sponsors may have the same concerns. The examination of national performance results on this measure over the past three to four years suggests that contracts with comparatively small enrollment fluctuate between the lower and higher ends of the 5-star ratings, and contracts with comparatively large enrollments tend to stay in the middle of the ratings. This pattern is consistent with statistical unreliability and persisted this past year after the removal of the pre-determined four star threshold. We are currently working with the most recently published (October 2015) performance results to confirm these trends. We expect to be able to share our findings with CMS by the time the draft Call Letter is released.
Medica Health Plans	1. Medica would like CMS to consider achievement levels along with grading on the curve for some measures or receiving the improvement measures above a 3 star rating. It takes a considerable effort to achieve excellent results year after year. 2. Medica has concerns about the impact of introducing many new measures at once to the ratings in a given year, and being able to meet the continuous improvement goals for beneficiaries on all measures. 3. Medica continues to have concerns about some of the rigor around screening requirements for the frail elderly; CMS should address how Palliative Care Programs integrate with star ratings as the population continues to have an increased life expectancy. Our oldest beneficiaries are often not interested in life prolonging procedures that would result from screenings, and would prefer a more holistic look at their health and overall wellbeing. We believe some beneficiaries could benefit greatly from a Palliative Care

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	Consultation and related supportive service in many cases. 4. Medica would like to see the Advance Directive Measure from the HEDIS data set included in star ratings.
Novo Nordisk	(NOTE: should be under "Impact of socio-economic and disability status", but drop-down would not allow input) Novo Nordisk appreciates CMS' efforts to ensure that performance on measures within the Star Ratings truly reflects the quality of care, and is not impacted by factors outside the control of participating plans. Novo Nordisk agrees with CMS' assertion that any adjustment applied to Star Ratings measures to account for socio-economic status and disability must be firmly grounded in evidence that adjustment factors, in fact, have an impact on the overall Star Ratings for individual plans. Going forward, Novo Nordisk urges CMS to also consider any unintended consequences of the adjustment approaches it is considering (specifically, a categorical adjustment index or indirect standardization). It is imperative that efforts to "level the playing field" for plans is balanced against any negative impact that adjustments may have on patient care. CMS should also explore approaches to aid plans in improving care for low income subsidy (LIS), dual eligible, and disabled members, particularly for those measures found to be impacted by a high prevalence of members in these categories. For example, if blood sugar control is found to be negatively impacted by LIS status of diabetes patients, CMS should consider novel approaches to support plans in better reaching LIS members to enhance treatment adherence and subsequently improve their long-term outcomes.
PCMA	CMS solicits comments and input on issues not described in earlier sections. PCMA identified several issues for consideration which appear below. 1. Exclusion of Dementia and Alzheimer's Diagnoses – PCMA suggests that CMS exclude members with the diagnosis of dementia and Alzheimer's from the CAHPS Surveys. We are concerned that members with these diagnoses may not have the mental status to define the differences in experiences and timeframes measured in the surveys because their perceptions of physical and mental health status can vary based on the transient expression of their disease (e.g., this year versus last year's flu shot, "within the last six months). 2. TTY/Foreign Language Call Center Monitoring – PCMA recommends that CMS revise the methodology used to determine the testing sample size for each language tested, and specifically that CMS should test languages in proportion to the prevalence of each language in the 65+ U.S. population based on Census Bureau data. 3. Complaints – PCMA recommends that CMS evaluate modifications to the exclusion criteria on the Complaints Star Rating measure, and specifically in the following categories: • CMS/SSA delays of premium withhold election changes; • Marketing Misrepresentation caused by 1-800- Medicare representatives; and • CMS/SSA system discrepancies 4. Beneficiary Access and Performance Problems – PCMA requests CMS to revisit the

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	measure methodology for Beneficiary Access and Performance Problems. This measure is not weighted based on enrollment and is based only on Civil Monetary Penalties and Compliance Activity Module data. It is not based on compliance notifications per 10,000 beneficiaries or a similar calculation. We believe these factors increase the likelihood of larger plans receiving compliance notifications due to a higher frequency of interactions. 5. Acumen – PCMA suggests that CMS consider supplying plans with quarterly metrics for operational Star measures and include those measures in the monthly Acumen reporting, along with the Drug Safety and Accuracy of Drug Pricing data. This additional reporting would provide greater transparency for performance and support CMS efforts to ensure Medicare beneficiaries have the information necessary to make informed enrollment decisions. 6. Thresholds – The release of the 2016 Star Ratings highlighted volatility in industry performance. Many measures display a significant increase or decrease in the ability of plans to achieve 5 Stars. There were significant movements in the 5 Star PDP thresholds for the following measures: Appeals Auto-Forward, Appeals Upheld, Complaints, and Medication Adherence for Diabetes. PCMA members report that industry data illustrate that outliers have a dramatic impact on published thresholds, resulting in unrealistic 5 Star benchmarks relating to quality within the industry. This increased impact of outliers may be a result of the removal of the pre-determined cut points. In the 2015 Star Ratings, the predetermined thresholds provided a framework for industry performance which may have mitigated the impact of outliers. PCMA requests that CMS consider an alternative approach for setting thresholds. If thresholds were set by CMS every three years, plans could drive continuous improvement by setting annual targets and focusing resources on innovative ways to provide higher quality to beneficiaries. Such an approach would ensure thresholds remain stable or steadily improve from one year to the next. Consistent improvement over a multi-year period could lead to higher quality and would be preferable to the current levels of volatility.
Peoples Health Network	We respectfully recommend the following with regards to the HEDIS measures: Eliminating inpatient claims for measure denominator identification for the Comprehensive Diabetes Care measure due to inaccurate diagnosis from the inpatient setting and no subsequent outpatient coding; • Addition of oral corticosteroids as DMARD therapy for the ART measure for members who will no longer benefit from or have therapeutic contraindications to DMARD therapy; and • Removal of the diagnosis requirement for the Controlling BP measure. This requirement rarely results in members being excluded from the measure. This will expedite the chart review process. Additional Comment: We respectfully recommend the following with regards to Medication Adherence: • Allow members whose meds have been discontinued to be excluded from the denominator for the

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	measure. • Allow VA claims for medications to be included to document adherence for the measure. • Exclude the first fill and restart the "clock" if there is greater than or equal to 6 months between the first fill and the second fill.
Pfizer	Pfizer encourages CMS to consider measures related to psoriasis for inclusion in the Star Ratings program in future years. Psoriasis is a therapeutic area extremely relevant to the Medicare population and one that currently represents an unmet need in the Star Ratings program. Pfizer suggests CMS consider the development of a plan-level measure assessing clinical outcomes associated with psoriasis treatment to address this gap, and to help meet priorities and objectives of National Quality Strategy by improving care for this therapeutic area. In addition to psoriasis, Pfizer encourages CMS to consider incorporating measures related to rheumatoid arthritis (RA). Pfizer agrees with BIO's recommendation that CMS consider incorporating more granular and outcomes-based measures related to the treatment of RA in the Star Ratings program. Gaps in treatment exist despite the availability of various treatment options for RA. Only about one-third of patients achieve clinical remission of RA and up to 40 percent of patients still experience moderate or high disease activity after one year of receiving biologics. Failure to achieve treatment goals contributes to irreversible disease progressing as well as increased utilization of healthcare resources and higher spending. Higher costs arising from the complications of RA vary significantly depending on the patient's level of disease activity. Moderate or high disease activity can lead to structural damage, disability, increased risk of cardiovascular events, and increased healthcare resource utilization, including higher rates of hospitalizations, joint surgery, and durable medical equipment (DME) utilization. Pfizer believes that the existing quality measures for RA do not adequately address meaningful characteristics of the disease. Therefore, Pfizer agrees with BIO's recommendation of incorporating into the Star Ratings measures that enable health plans and providers to classify RA patients according to their level of disease activity and assess whether they have been initiated on an appropriate treatment as indicated by their disease activity as well as shifting to more outcomes-focused Star Ratings measures for RA that are aligned with current clinical guidelines. These two recommendations can improve the health of the population and reduce costs associated with mismanaged or uncontrolled RA. Harrold L, Reed GW, Boytsov N, et al. combination therapy, switching and persistence patterns by longitudinal disease activity strata in patients with rheumatoid arthritis [abstract]. Arthritis Rheumatol. 2015; 67 (suppl 10). Shahouri SH, Michaud K, Mikulus TR, et al. Remission of rheumatoid arthritis in clinical practice: application of the American College of Rheumatology/ European League Against Rheumatism 2011 remission criteria. Arthritis Rheum. 2011;63(11):3204-3215.

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PhRMA	CMS is seeking input on improving Part C and D Star Ratings by identifying new measures. As CMS makes changes to maintain and improve the Star Ratings, we encourage you to do so with an eye towards achieving a comprehensive measure set to assess and report on plan quality. Comprehensive measure sets include a mix of measure types, i.e., outcomes and processes; disease-specific and cross-cutting; and clinical and patient-reported data sources, to ensure that measure sets provide a complete picture of the quality of patient care. Measuring the outcomes of care delivered by health plans is particularly essential to ensure that plans deliver high quality care to patients and do not restrict patient access to essential treatments as plans seek to manage the cost of care. Inclusion of additional outcome measures addressing a broader range of conditions would strengthen the program and help assure that it achieves its goals. In particular, gaps in currently available measures related to cancer treatment and symptom management, pain management, mental illness, dementia/cognitive impairment, and multiple co-morbidities hamper the ability of the program to appropriately measure quality of care for these conditions. Both patient-reported outcomes and clinical outcomes are important, and PhRMA supports CMS seeking ways to incorporate these types of measures, such as the proposed depression measure, in future Star Ratings. We encourage CMS to give particular attention to patient-centered measures, e.g., those that reflect patients' priorities for measuring and reporting on quality of care. In seeking measures in these areas, CMS should look to measures that have been developed, tested, validated, and endorsed by a multi-stakeholder consensus based organization. Additional Comments: PhRMA suggests development of a plan-level measure to address treatment of psoriasis. In the 2016 Medicare Physician Fee Schedule Final Rule, CMS adopted the measure "Psoriasis: Clinical Response to Oral Systemic or Biologic Medications" within the Physician Quality Reporting System. In doing so, CMS noted that the measure represents a National Quality Strategy domain gap in that it addresses person and caregiver centered experience and outcomes. Development of a plan-level measure for the Star Ratings will help to align incentives across CMS' quality reporting programs and improve care for this common chronic condition.Additional Comments: PhRMA suggests development of additional measures to address treatment of rheumatoid arthritis (RA). RA is a chronic disease with a prevalence that increases with age, and as patients accrue dysfunction and damage over time, their level of disability also increases. Despite the availability of numerous treatment options for Rheumatoid Arthritis (RA), there continues to be a large number of patients who are not achieving remission or necessary treatment goals. A shift to more granular, outcomes-focused measures that are aligned to current clinical guidelines can help advance the current standard of care in ways that would meaningfully improve patient

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	health and reduce costs associated with ongoing complications from uncontrolled RA. For example, future measures could enable health plans and providers to classify RA patients according to their level of disease activity and assess whether they have been initiated on an appropriate treatment as indicated by their disease activity, thus positioning RA patients for the best possible outcomes.
Silverlink Communications	Silverlink Communications thanks CMS for the opportunity to comment on the star rating system. We recognize CMS's commitment to transparency and collaboration. Silverlink is the proven leader in engagement management technology for healthcare organizations. We have executed over 192 million communications to Medicare beneficiaries in all 50 states. Our solutions enable health plans and other key stakeholders to engage and support their members in smarter and more effective ways. We deliver better control, coordination and effectiveness in member communications to promote healthy and loyal behaviors. With our unique vantage point as a multi-channel healthcare communications vendor, Silverlink has insights into the total breadth of communications that are directed at today's Medicare Advantage beneficiaries. Based on more than 13 years of experience, we know that overwhelming individuals with healthcare messages can cause them to disengage. CMS is suggesting to increase the overall number of weighted measures in the Star rating system and Silverlink is concerned that by adding more measures, and redundant measures, the Star Rating system will become a less effective performance improvement tool. An uncoordinated approach to measurement where multiple organizations are responsible for the same activity causes fragmentation and creates confusion for the beneficiaries and providers. This leads to wasteful outreach, and, ultimately, to beneficiaries ignoring communications due to the sheer volume of information directed at them. Silverlink encourages CMS to include a measure of beneficiary engagement in the Star Rating system. According to the Institute of Medicine, "Individuals who are engaged are ready to manage their own health and health care, with the knowledge, skills, and tools needed to maximize their individual and family well-being." There are several standard tools used by healthcare organizations to measure engagement and it is a key indicator of success in any population health management program. Organizations have found that engagement is correlated to outcomes such as spending, hospital admissions, ER visits and medication adherence.
SNP Alliance	H. Measurement and Methodological Enhancements We have several comments in this section: ?--We request that all measure modifications be made on a prospective basis and that measures and their specification be finalized prior to the start of the measurement period in order to give plans adequate notice and opportunity to impact their scores. This transparency and notice is critical to plans' effort to meet CMS' performance goals. ? --We

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	request that CMS increase its focus on outcome measures to the greatest extent possible. --?We request that CMS, with input from plans, review the current timeframes for the release of Stars, CAHPS, and HOS data to identify opportunities for earlier release of this information so that plans have access, to the greatest extent possible, to the most recent data available for marketing and planning for the upcoming year. --?The SNP Alliance is concerned that contract-level Star ratings for contracts that include plans of different types, e.g. general MA and/or one or more SNP types, and in multiple states may not provide consumers a true picture of the performance of the individual plans in which they are enrolled. Until SES issues are addressed, however, being evaluated at the plan level, if they focus exclusively or disproportionately on duals, harms plans. In the interest of addressing issues of fair competition on Star ratings, we request that CMS explore options that more fully account for differences at the state and plan levels in ways that are respectful of broader contracting interests.
UnitedHealthcare	General Comment on Star Ratings System: UnitedHealth strongly supports the aims of the National Quality Strategy: to improve overall healthcare quality, improve the health of the US Population via proven interventions, and reduce the cost of quality healthcare. UnitedHealth respectfully requests that CMS consider moving towards a more standardized approach for providers and payers that allows providers and Medicare Advantage Organizations to focus on the same quality measures to drive consistency in quality of care. The RAND Corporation recently estimated that more than 580 health-related organizations now disseminate quality measures, including many CMS measures. CMS itself publishes at least 25 quality programs and over 800 unique quality measures. According to the April 2015 report of the Institute of Medicine on the core metrics of health care progress, the ??imperfect, too numerous, and uncoordinated' measures in use today have led to burdensome data collection, unclear prioritization of measures with the most potential to improve health and an inability to compare performance across systems, states and individuals." As a solution to these problems, the Institute of Medicine proposes a standardized approach to health improvement measurement and recommends 15 core categories of metrics in the hopes that greater standardization can improve efficiency and also have a more significant impact on health outcomes at a lower cost. See Institute of Medicine (IOM) Committee On Core Metrics For Better Health At Lower Cost, "Vital Signs, Core Metrics For Health Care Progress", 2015. United supports this goal and recommends that industry and CMS develop meaningful and standard measures together. Additional Comment: Retroactivity of Measures and Thresholds: UnitedHealth appreciates the improvements CMS has made in recent years to provide advance notice of changes to measures and methodology. CMS has adopted a framework for determining how to respond to specification changes

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	to measures used for the 2017 Star Ratings, but has also been identifying changes for 2018 and beyond. These indications on direction for measures are of great use to plans in quality improvement planning, working with providers, etc. However, implementing new thresholds and methodology in plan years already underway imposes impermissible retroactive requirements on plans. UnitedHealth notes that retroactive requirements are impermissible when, without Congressional authorization for doing so, the requirements substantively change prior agency practice and consequences for events completed before the adoption of the requirements. See Nat'l Mining Ass'n v. Dep't of Labor, 292 F.3d 849, 860 (D.C. Cir. 2002) and Northeast Hospital Corporation, v. Kathleen Sebelius, 657 F.3d 1, 13-14 (D.C. Cir. 2011), citing Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988). We further note that 42 CFR § 422.521 requires that CMS not implement, other than at the beginning of a calendar year, requirements that impose new significant costs or burdens on MA plans. Under the existing process, the 2017 Star Rating methodology will be finalized in April 2016, four months after the measurement period has ended for most measures and during the measurement period for CAHPS and Foreign Language, giving plans no way to influence the measure. The delay in finalizing the methodology can change the consequences for interventions implemented before the adoption of the requirements, and leaves plans with no opportunity to take action as the critical intervention period for the measurement has passed. The delay also imposes significant costs and burdens, as organizations that make investments on Star Rating-related activities only to find those investments to be misplaced after receiving the final methodology and measures. UnitedHealth experiences firsthand the challenges of finalizing Star Rating measures retroactively. Retroactive changes also have downstream impacts, by creating stress for providers and requiring them to adapt their practice to meet new standards with little or no advance notice. Additionally, as Star ratings become ever more consequential to plans' (and ultimately providers') success, UnitedHealth is concerned that the current process of retroactively setting requirements will undermine the perceived credibility of the Star rating system. This could invite criticism, debate, or other challenges that would make the system even more unpredictable. Along with UnitedHealth's general recommendation to avoid retroactive implementation of measures and methodology, UnitedHealth offers a few specific recommendations: 1. Consider implementing a standard of two years on the display page for new measures before inclusion in Star ratings, to avoid finalizing measures after the performance year has started. 2. Alternatively, CMS could adopt a policy of finalizing Star Rating measures only while plans still have the opportunity to impact their results (e.g., finalize 2018 Star Rating methodology no later than April 2016). 3. Consider setting thresholds one year earlier than

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	is the current practice. CMS could, for example, set known thresholds derived from rates used in 2016 Star ratings, making adjustments for measure specification changes where necessary, to set thresholds for 2017 Star ratings. Additional Comment: The Rulemaking Process: UnitedHealth urges CMS make changes regarding the star rating program through rulemaking. While the program has been used since 2008, it has not been subject to the rigors of the notice and comment process that the Administrative Procedures Act (APA) requires. Since 2008 the stars program evolved from a consumer information program to a payment system for Medicare Advantage and Part D plans. Instead of issuing a rule, CMS has issued annual proposals and calls for comments. These key provisions that establish plan payments—bonuses and rebates--should be put through the ruling making process. CMS' use of the star rating system in this manner amounts to promulgation of "substantive" or "legislative" rules and brings it squarely within the Administrative Procedure Act's Federal Register notice and comment requirements, 5 U.S.C § 553. After all, these provisions are part of "…an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy … and includes the approval or prescription for the future of rates, … prices, … or allowances therefor or of … accounting, or practices bearing on any of the foregoing". 5 U.S.C. 551(4). The stars program and associated payment implications set forth in the proposed changes meet this definition because "in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties [and] the agency has explicitly invoked its general legislative authority." American Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1110 (D.C. Cir. 1993) (setting forth two independent defining characteristics of rules). CMS would not have the authority to amend or suspend payment to plans or the authority to decrease or withhold stars' bonuses/rebates to the plans based on the proposed changes, but for the memo it has issued with the specifics of the program setting forth these changes. Plans would not qualify for the bonus based on the proposed changes or be able to provide star rating information reflecting the changes to consumers if they did not report their star data, and the changes to the star rating system will be used to eliminate low-performing plans. The changes therefore have a binding effect on the plans, and the government uses it to measure and pay plans. Also, CMS has invoked only a general authority as the basis for stars program and associated payment in referring to the "National Quality Strategy" and in that, the Affordable Care Act as the basis for the Star Ratings strategy. Finally, the Medicare rulemaking provisions, 42 U.S.C. § 1395hh, require Federal Register notice-and-comment rulemaking for every "rule, requirement, or other statement of policy … that establishes or changes a

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	substantive legal standard governing the … payment for services, or the eligibility of … entities, or organizations to furnish or receive services ….” Given these points and the impact to the Medicare Advantage program and rates paid to MA plans, the star rating system should undergo rulemaking procedures to afford the public the protections and opportunity for meaningful comment intended by Congress because that leads to better and more informed agency decisions and policy outcomes. Additional Comment: Fraud, Waste, and Abuse in Star Ratings: UnitedHealth believes there are opportunities within the Stars program to achieve considerable improvement in our identification and recovery efforts resulting from fraud, waste, and abuse (FWA): • Maximus Appeal Overturns/Stars Protection: If a recovery effort is appealed, Maximus may overturn a denied claim, even though it is fraudulent, because the medical records appear accurate and complete. This creates a tension between attempting to pursue FWA recoveries and maintaining a low appeal overturn percentage, which negatively impact Star ratings. UnitedHealth asks that CMS either: (1) issue an RFP an retain an appropriate contractor to perform reviews of non-par provider FWA related appeals; (2) expand the MAXIMUS scope of work to include the appropriate skill sets and processes to address FWA cases as a whole; or (3) allow FWA related appeals to go directly to the ALJ like in FFS Medicare. CTMs/Stars Protection: Providers know that complaints to Medicare, or CTMs, count against plans. Therefore, providers complain to CMS to encourage plans to forego recovery efforts. If a plan has good cause to open an SIU investigation into a provider, the CTMs against the plan from the providers or members associated with the case should not count against the plan. This is a tactic used by providers to discourage plans from aggressively seeking recoveries owed to the plan. UnitedHealth recommends that CMS add payment integrity exclusion criteria to Star Rating Measure C30, Complaints to Medicare. Additional Comment: Bias Against Open-Access Plans: The premise of Stars is that all MAO plans are measured equally and that any inconsistencies in the measurement are applied across all plans therefore eliminating bias or error. However, for the C35 appeals fairness measure, there is significant bias between plans that should be quantified by CMS. On a relative basis, open-access plans have a higher probability of appeals going to the IRE as a percentage of denied claims as compared to other plans with a more robust network. UnitedHealth asks that CMS refine measure C35 to include the percentage of payments to non-par providers as a % of total payments made by the plan, in addition to the total number of denials made as a result of payment integrity efforts. Additional Comment: Quality Bonus Payments for Low Enrollment Plans: UnitedHealth requests clarification on the calculation of the Quality Bonus Payment ("QBP") for low enrollment plans. Section 1853(o)(3)(A)(ii) of the Social Security Act requires that low enrollment plans “not able to have a quality rating”

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	due to insufficient data be treated as qualifying plans entitled to an increase in payment under section 1853(o), but does not address the amount of this required increase. The 2016 Advance Notice states that "new MA plans and low enrollment MA plans should receive the same treatment for the purpose of establishing the amount of quality bonus payments." The Advance Notice provides that new MA contracts receive a 3.5% QBP, or, if the parent organization had an MA contract with CMS in the previous 3 years, the new contract will receive the enrollment weighted average of the Star Ratings earned by the parent organization's existing contracts. The Advance Notice states that a low enrollment MA plan will receive a 3.5% quality bonus payment, as with truly "new" MA contracts, but does not address the case where a low enrollment MA contract's parent organization has existing MA contracts. Because low enrollment MA plans are to be treated the same as new plans for the purpose of the QBP, then low enrollment contracts should receive the enrollment weighted average of the Star Ratings earned by the parent organization's existing MA contracts. This method would tie the QBP to the plan's quality using the most accurate available information, its parent organization's performance. Mandating Measure Data on Claims Forms: UnitedHealth respectfully requests that CMS allow plans to condition non-contracting provider reimbursement on submission of required Star Ratings measure data on claim forms as part of the service rendered, or alternatively, require supplemental data forms to be submitted administratively. Providers and Medicare Advantage plans face ever increasing reporting demands and rising data capture costs and have limited ability to capture certain clinical information necessary for Star measures. Star Ratings measures should not be indicators of a plan's ability to capture data but rather be a true measure of successful clinical quality. By requiring that providers submit this information, CMS could ensure more complete and accurate data and minimize the costs of capturing that data for both providers and Medicare Advantage plans. Additional Comment: Reward Factor Thresholds: UnitedHealth has a few comments and questions related to the mean portion of the reward factor. First, UnitedHealth requests that CMS clarify why the 85th percentile is used to define the cutoff for high mean and the 65th percentile to define the cutoff for low mean. These percentile levels cause only 4+ star contracts to receive a reward factor which widens the gap with those below 4. United respectfully recommends that reward factor thresholds be based on raw score cutoffs, which are more meaningful than the selected 65th/85th percentiles. We propose defining relatively high as 50% of the way from the 3.5 rounding threshold (3.25) to the 4.0 rounding threshold (3.75), which would produce a maximum threshold cap of 3.500. We believe 3.500 is a reasonable threshold, consistent with the CMS-defined relatively high threshold in previous years' calculations when based on percentiles alone. Similar caps could be set for the high mean

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	threshold as a value half-way between the 4.0 rounding (3.75) and the 4.5 rounding (4.25), which would produce a threshold of 4.000.Additional Comment: Quality Improvement Measures - Unattainable Statistically Significant Improvement: UnitedHealth has found that for some contracts, it is impossible to obtain statistically significant improvement for a measure because it would require increasing to a rate that is beyond the maximum possible value. For example, a contract may increase their data value from 95% to 100%, but that increase would not be statistically significant (they would need to obtain a rate of 101%, which is impossible). The opposite currently holds true as well; a contract that declines from the prior year and is currently at the minimum possible value would receive statistically significant decline. UnitedHealth proposes that if a contract improves from the prior year and is currently at the maximum possible value, then they should be rewarded with statistically significant improvement for that measure, and a contract with the minimum possible value declines from the previous year, it should receive statistically significant decline. This change would fairly reward contracts that are high performing and penalize those that are low performing. We understand that there is already a “hold harmless” provision in place, but believe that this proposal would address the issue more directly. The current hold harmless provision changes a measure from significant decline to no significant change if the contract has 5 Stars both years. This provision makes sure that contracts are not penalized for remaining at high performing levels. Our proposal would change a measure from "no significant change" to "significant improvement" if it increased to the maximum attainable value but did not achieve a significant improvement. This ensures that contracts are not penalized for getting a perfect score. Additional Comment: Appeals Measures: UnitedHealth respectfully requests that CMS address the fact that the design of the appeals measures penalizes those plans with no beneficiary appeals; i.e. a plan with zero appeals gets no Star Rating. While receiving no Star rating is technically neutral, this can negatively impact those plans with small enrollment that are at risk of not receiving an overall Star rating. As a plan with no appeals is offering higher quality to members, UnitedHealth recommends an alternative specification for those plans with low or no appeals. For example, the measure could specify that if the denominator is less than X, the plan automatically receives a Star rating of 5, as the low number of appeals itself indicates high quality. Additional Comment: Call Center – Foreign Language Interpreter and TTY Availability: During plan preview period for Star year 2016 data, UnitedHealth found that the Foreign Language Interpreter and TTY Availability measures were calculated differently than outlined in the Technical Notes. Per the Technical Notes, "the Customer Service Contact for Prospective Members phone number associated with each contract was monitored." However, during Plan Preview

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	correspondence, CMS indicated that the measure is not associated with the Prospective Members phone number but instead a number with the same hours of operation; calls are randomly made based on group of contracts with the same call center indicator and hours of operation. Can CMS explain this discrepancy, or update the Technical Notes to accurately describe the methodology used for the measure? Additional Comment: Patient Safety Adherence Measures: The Patient Safety Adherence measures (Star Ratings measures D11, D12, D13) take inpatient stays into account in the adherence score calculation that is represented by a proportion of days covered (PDC). While UnitedHealth has access to inpatient stays submitted via medical claims as well as the summarized data in Acumen's Patient Safety Reports, we would like to be able to use the same source data that CMS is using in the PDC calculation so that our PDC score and results are more closely aligned during a contract year. With this data we can also internally and proactively measure a member's actual numerator and denominator and proactively benefit the beneficiary. Finally, with this detail, we can put programs in place to ensure that IP admission dates and discharge date submissions are accurate, meaning that Acumen's monthly reporting will also be more accurate. UnitedHealth has pursued this matter with CMS contractors, as advised by CMS; however, these efforts have been unsuccessful. UnitedHealth requests that CMS provide MA organizations with access to the inpatient stay files. Additional Comment: NCQA Rules Re: "No Touch" Members : UnitedHealth agrees with CMS that member involvement is an important component of Star Ratings; however, there are always some members who choose to have no interaction and are suppressed from all campaigns, referred to as "no touch" members. These "no touch" members are omitted from all care coordination activities. Nonetheless, NCQA specifications include those members in measure denominators unless they are members of an ASO group. We suggest that CMS remove these members from the denominator as they have elected not to engage with us as partners in their care.Additional Comment: 3D Mammograms: NCQA's HEDIS 2016 technical specifications do not recognize 3D mammograms as a legitimate screening tool as they are considered diagnostic in nature. The assumption is that there is already a 2D mammogram screening performed in advance of the 3D screen; therefore, compliance should be captured using existing compliant codes for the 2D screens. A portion of our members elect to pursue a 3D mammogram over a 2D mammogram for screening, not diagnostic purposes. United respectfully requests that CMS allow CPT codes for 3D mammograms (76376 and 76377) to be considered as numerator compliant codes for breast cancer screening.

Attachment A: List of Unique Submitters

Submitting Organizations listed in alphabetical order

Organization Name
Academy of Managed Care Pharmacy (AMCP)
Aetna
AHCCCS
Ahold USA
AIDS Healthcare Foundation
Alliance of Community Health Plans
AltaMed
Altegra Health
American College of Mohs Surgery
American Pharmacists Association
America's Health Insurance Plans
Anthem, Inc
Association for Community Affiliated Plans
BIO
Blue Cross and Blue Shield of Minnesota
Blue Cross Blue Shield of Michigan
Blue Shield of California
BlueCross and BlueShield Association
BlueCross BlueShield of SC
BlueCross BlueShield of Tennessee
Cambia Health Solutions
CAPG
CareSource Management Group
Centene Corporation
Centers Plan for Healthy Living, LLC
Cigna
Clover Health
Commonwealth Care Alliance
Constellation Health, LLC.
CVS Health
Elderplan
Eli Lilly
EmblemHealth
Essence Healthcare
Exact Sciences
Fresenius Health Plans
GlaxoSmithKline
Group Health Cooperative
Health Alliance

Organization Name
Health Care Service Corporation
Health Choice Arizona, Inc.
Health Net, Inc.
Health Partners Plans, Inc.
Healthfirst
HealthPartners
HealthPlus
Humana
Independence Blue Cross
Independent Care Health Plan
Independent Health
Innovacare
Kaiser Permanente
Magellan Health
Martin's Point Health Care
Medica Health Plans
Medicare Payment Advisory Commission
MetroPlus health Plan
Molina Healthcare Inc.
National Council on Aging
North Texas Specialty Physicians
Novo Nordisk
OutcomesMTM
PCMA
Peoples Health Network
Pfizer
PhRMA
PQA
PrescribeWellness
Puerto Rico Healthcare Crisis Coalition, Medicaid and Medicare Advantage Products Association, Puerto Rico Hospital Association, Entrepreneurs for Puerto Rico
Rite Aid Corporation
RxAnte
SCAN Health Plan
Security Health Plan
Senior Whole Health
Silverlink Communications
SMT, Inc
SNP Alliance

Organization Name
SouthWest Catholic Health Network
Tenet Healthcare
Transamerica Life Insurance Company
Triple S Advantage, Inc
Tufts Health Plan
UCare
UnitedHealthcare
Universal American
UPMC Health Plan
VIVA Health, Inc.
VNSNY CHOICE Healthplan
WellCare

Attachment B: Comments per Topic/Sub-Topic by Type of Submitter

Topic Name	Sub Topic Name	Advocacy Group	Consultant	Other	Part C/D Plan Sponsor	Pharmaceutical Manufacturer	Trade / Professional Organization	Total
A. Changes to Measures for 2017	1. Improvement measures (Part C & D)	1		2	21		5	29
A. Changes to Measures for 2017	2. Reviewing Appeals Decisions/Appeals Upheld measures (Part C & D)				13		3	16
A. Changes to Measures for 2017	3. Contract Enrollment Data (Part C & D)				16		4	20
A. Changes to Measures for 2017	4. Transition from ICD-9 to ICD-10 (Part C & D)				9		4	13
A. Changes to Measures for 2017	5. Appeals Upheld measure (Part D)				8		2	10
A. Changes to Measures for 2017	6. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) measure (Part D)			1	29	1	6	37
B. Removal of Measures from Star Ratings	1. Improving Bladder Control (Part C)				13		3	16
B. Removal of Measures from Star Ratings	2. High Risk Medication (Part D)		1	5	40	1	9	56
C. Data Integrity	C. No Subtopics			3	19		7	29
D. Impact of Socio-economic and Disability Status	D. No Subtopics	1	2	5	50	1	9	68
E. 2017 CMS Display Measures	1. Timely Receipt of Case Files for Appeals (Part D) & Timely Effectuation of Appeals (Part D)				9		2	11
E. 2017 CMS Display Measures	2. Medication Reconciliation Post Discharge (Part C)			2	21	1	6	30
E. 2017 CMS Display Measures	3. Hospitalizations for Potentially Preventable Complications (Part C)				28		4	32
E. 2017 CMS Display Measures	4. Statin Therapy for Patients with Cardiovascular Disease (Part C)		1	1	23	1	6	32
E. 2017 CMS Display Measures	5. Asthma Measures (Part C)		1	2	24	1	6	34
E. 2017 CMS Display Measures	6. Statin Use in Persons with Diabetes (SUPD) (Part D)		2	3	24	2	7	38
F. New Measures	1. Care Coordination Measures (Part C)				24	1	7	32
F. New Measures	2. Depression Measures (Part C)		1	2	26		4	33
F. New Measures	3. Appropriate Pain Management (Part C)				12	1	1	14
F. New Measures	4. Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer (Part D)		1	3	20		5	29
F. New Measures	5. Antipsychotic Use in Persons with Dementia (APD) (Part D)			2	26		4	32
G. Changes to Existing Star Ratings and Display Measures and Potential Future	1. Colorectal Cancer Screening (Part C Star Rating)			1	10	1	1	13
G. Changes to Existing Star Ratings and Display Measures and Potential Future	2. Fall Risk Management (Part C Star Rating)	1		1	14		1	17
G. Changes to Existing Star Ratings and Display Measures and Potential Future	3. Pneumococcal Vaccination Status for Older Adults (Part C Display)				17	1	3	21
G. Changes to Existing Star Ratings and Display Measures and Potential Future	4. CAHPS measures (Part C & D)				14		4	18

Topic Name	Sub Topic Name	Advocacy Group	Consultant	Other	Part C/D Plan Sponsor	Pharmaceutical Manufacturer	Trade / Professional Organization	Total
G. Changes to Existing Star Ratings and Display Measures and Potential Future	5. Medication Adherence for Hypertension (RAS Antagonists) (Part D Star Rating)		1	2	12		3	18
G. Changes to Existing Star Ratings and Display Measures and Potential Future	6. MPF Price Accuracy (Part D Star Rating)			1	20		5	26
G. Changes to Existing Star Ratings and Display Measures and Potential Future	7. Drug-Drug Interactions (DDI) (Part D Display)			2	11		4	17
G. Changes to Existing Star Ratings and Display Measures and Potential Future	8. Center for Medicare and Medicaid Innovation Model Tests (Part C & D)			1	13	1	6	21
H. Measurement and Methodological Enhancements	H. No Subtopics		1		19	4	6	30
Total		3	11	39	585	17	137	792