2015 Medicare Advantage and Prescription Drug Plan Spring Conference & Webcast Transcript

2016 Call Letter Updates – Medicare Part D

As I had stated earlier, we do have a panel of presenters for our next session. Our next speakers will provide an overview of changes to be implemented for the Part D Prescription Drug Benefit Program. From the Medicare Drug Benefit and C&D Data Group, Elizabeth Flow-Delwiche, Lucia Patrone, and Andrea Bendewald.

Hi, my name is Elizabeth Flow-Delwiche and I work in the Division of Consumer Assessment and Planned Performance. During this session I will provide information on the timeline for application of termination authority for contracts with ratings with less than three stars in three consecutive years. And I will also highlight revisions to the 2016 star ratings program. Lucia Patrone and Andrea Bendewald will review the following information related to Part D: improving drug utilization review controls, benefit parameters for non-defined standard plans, access to preferred cost-sharing pharmacies, and changes to applying for exception to the auto-ship policy.

CMS has the regulatory authority to terminate contracts of organizations that upon the release of the 2016 Star Ratings have failed in three consecutive years to achieve at least three stars on their Part C or Part D performance.

Contracts that meet the regulatory criteria for termination for the first time with the release of the 2016 Star Ratings, meaning contracts rated at or above three stars for 2013 but below three stars for 2014, 2015, and 2016, will receive non-renewal notices from CMS in February 2016 with an effective of December 31st, 2016. In March 2016, CMS will issue notices to beneficiaries enrolled in plans authored under the non-renewed contracts, advising them to select a new plan during the fall 2016 annual election period to continue their Part C and Part D plan enrollment without interruption. CMS will not calculate or publish 2017 Star Ratings associated with the non-renewed contracts.

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One of CMS' most important strategic goals is to improve the quality of care and general health status for Medicare beneficiaries. For the 2016 Star Ratings, CMS continues to make enhancements to the current methodology to further align it with our policy goals. I will now highlight some of the revisions to the 2016 Star Ratings Program.

CMS will remove the predetermined measure thresholds for the 2016 Star Ratings. Our primary goal in eliminating the thresholds is to improve the accuracy of the overall and Part C and Part D summary Star Ratings, and to make certain the system creates incentives for quality improvement. The cut points will be determined using the same methodology used in the past and we will continue to use the reward factor for contracts with consistently high performance. All of 2016 cut points will be based on the data submitted from all contracts for the rating year.

Low enrollment contracts, as defined in regulation, are contracts where enrollment is such that HEDIS and HOS data collections cannot be used to reliably measure the performance of the health plan. In the past, we believed that contracts with less than 1,000 enrollees would meet the definition, but we have reevaluated whether that threshold is an appropriate implementation of the regulatory standard.

Based on our analyses, CMS has determined that there are sufficient data to reliably measure and report on contracts in the Star Ratings with 500 or more enrollees in July of the HEDIS measurement year. Contracts with 500 and more enrollees, in most cases, will have sufficient data to produce both overall and Part C and D ratings. Beginning with the 2016 Star Ratings, contracts with 500 or more enrollees as of July 2014 will not be considered low enrollment contracts. They will be included in our quality bonus payments to be made in CY 2017. The HEDIS data for contracts with less than 500 enrollees will continue to be posted on the display page as these contacts will still be considered low enrollment contracts.

It is important to note that only the measures where the contract meets the minimum denominator requirements are included in the Star Ratings, thus if a contract with 500 to 999 enrollees does not meet the minimum denominator requirements for a measure the particular measure will not be included in its overall rating calculation. Contracts with between 500 to 999 enrollees have always been included in the Star Ratings for all non-HEIS measures when the contract met the minimum denominator requirements. However, without the HEDIS data, the contracts did not have enough measures for an overall rating.

For the HEDIS measures we will exclude from the cut point determinations and the overall rating calculations any contract-specific measure scores that have low reliability. The contract level reliability measures the signal to noise ratio, which is how much of what is being measured is signal, meaning true variation in performance, rather than noise, meaning measurement error.

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For 2016, the measure scores for any contracts with 500 to 999 enrollees that have a reliability of less than seven-tenths will be excluded from the cut point determinations and the overall rating calculations. A number of measures will be added to the 2016 Star Ratings. Breast cancer screening, this measure is returning to the 2016 Star Ratings after moving it to the 2015 display page for one year since the measure specification changed during the 2016 measurement year. Since this is a process measure it will continue to be assigned a value or weight of one.

Medication therapy management program completion rate for comprehensive medication reviews, this measure is based on the Pharmacy Quality Alliance, PQA, endorsed measure. Completion rate for comprehensive medication review, which is used to calculate the percentage of beneficiaries who met eligibility criteria for the Medication Therapy Management Program and who received a CMR with a written summary in CMS standardized format. As a new measure, it will be assigned a weight of one. And in future years it will continue to receive a weight of one because it is a process measure.

Call center -- foreign language interpreter and TTY availability measures, these measures were excluded from the 2015 Star Ratings due to concerns about data quality. For the 2016 Star Ratings the measure will return. Since this is an access measure and there is no change in methodology, it will receive a weight of one-and-a-half.

Beneficiary access and performance problems, this measure had moved out of the 2015 Star Ratings into the display measures since there were significant methodological changes to the 2013 audit process and scoring. For the 2016 Star Ratings we'll assign this measure a weight of one, as the methodology changes caused this to be considered a new measure for weighting purposes. For the 2017 Star Ratings it will revert to the weight of one-and-a-half as it had in 2014, because it is classified as an access measure.

The improving bladder control measure is collected through the Health Outcomes Survey, HOS. This is a cross-sectional, not a longitudinal, measure. NCQA is making several revisions to the measure. These changes required revising the underlying survey questions in HOS. The revised questions will be collected for the first time in 2015. As a result of these changes there will be no data for the measure for the 2016 and 2017 Star Ratings. We will address the use of the data from the revised measures for the 2018 Star Ratings in a subsequent call letter.

For HEDIS 2015 NCQA retired the three Part C measures listed on the slide. So the data from these measures will no longer be available to be included in the Star Ratings. PQA has elected to retire the measure appropriate treatment of hypertension in diabetes as a result of new guidelines. Consequently, CMS is moving forward with retiring the measure from the 2016 Star Ratings.

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Multiple MA organizations and PDP sponsors believe that plans with a high percentage of dual-eligibles and/or LIS enrollees are disadvantaged in the current Star Ratings program. In the draft 2016 call letter we proposed to take an interim step and reduce the weights on a subset of seven of the measures in the Star Ratings Program. Six of the measures were Part C measures and one was a Part D measure related to PDP contracts only. The proposal to reduce the weights for a selected group of measures was based on our preliminary analyses that revealed for these measures there was both practical and statistically significant evidence of differential outcomes for dual LIS beneficiaries. Five of the six MA measures selected were process measures and they were already receiving a low weight in the Star Ratings system, and then there was one outcome measure for PDPs.

CMS appreciates the views and opinions contained within the responses to the draft call letter and we listened carefully to the multiple stakeholders to guide our decision. Many respondents felt the interim proposal did not appropriately address the issue. In addition, many commenters believed it was premature to make modifications to the Star Ratings methodology and that such changes threatened its integrity and the Star Ratings Program. Many thought that change proposed would not provide immediate relief and posed a number of potential unintended consequences, such as inflating ratings and signaling improvement in the quality of care that may not exist. Many commenters also believed we should continue our internal research, coordinate with ASPE, and work with measure developers.

After consideration of the information collected to date and the comments received in response to the draft call letter, CMS has decided not to move forward with the proposed interim step to reduce the weights on a subset of the measures for the 2016 Star Ratings Program. Given the uncertainty about what factors are driving the associations observed in the preliminary research, further in-depth examination by CMS, our HHS partners, MAOs and Part D sponsors in quality measurement, as well as external measure developers is warranted.

The goal of the research is to provide the scientific evidence as to whether sponsors that enroll a disproportionate of dual LIS beneficiaries are systematically disadvantaged by the Star Ratings. CMS is firmly committed to continue to build the foundation for a solution that appropriately addresses the issue. We believe the appropriate solution must focus on the beneficiaries. The policies implemented must result in high quality of care in health outcomes for all of our beneficiaries. We cannot risk the potential for masking disparities in care or jeopardizing the integrity of the Star Ratings Program by implementing changes that are not grounded in scientific evidence.

Upon completion of additional research, any adjustments for the 2017 Star Ratings would be proposed in the fall request for comments. Depending on the research findings, solutions may include case mix adjustment, different weighting options, excluding certain measures, or payment solutions. As we continue to explore this important issue, we will continue to do so in a transparent manner and welcome continued collaboration with all stakeholders. At this time, Lucia Patrone will begin reviewing "Improving Drug Utilization Review Controls."

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Thank you, Liz. Good morning everybody. My name is Lucia Patrone and I work in the Division of Part D Policy. In the final 2013 call letter and supplemental guidance CMS described several methods for Part D sponsors to prevent overutilization of prescribed medications. In mid-2013 CMS launched the Overutilization Monitoring System, or OMS, to monitor sponsors' drug utilization management programs to prevent the overutilization of opioids and acetaminophen, otherwise known as APAP.

The Part D Overutilization Policy and your efforts have reduced opioid and acetaminophen overutilization. As you can see behind me, a comparison of 2011, 2013, and 2014 shows a significant reduction of opioid and acetaminophen overutilization in Part D since the policy went into effect. From 2011 through 2014 the number of potential opioid over-utilizers, based on the CMS definition in the OMS, decreased by approximately 26% or 7,500 beneficiaries. In addition, from 2011 through 2014 the number of beneficiaries identified as potential acetaminophen over-utilizers decreased by more than 91% or 70,000 beneficiaries. We thank you for your continued efforts to reduce the overuse of opioids and APAP.

In the 2016 advanced call letter we proposed additional steps to reduce the overuse of medications, including a soft formulary level POS edit based upon cumulative morphine equivalent dose, additional rates and measures for the OMS, and expanding the overutilization policies to other drugs. As such, for 2016, we encourage sponsors to implement such an opioid POS edit and to prepare for a more sophisticated POS edit in 2017.

CMS plans on pilot testing the MED POS edit in preparation for 2017, similar to our pilot testing of the overutilization policy in 2012. Any new rates or measures for the OMS in 2016 will be informational only, not requiring a response from plan sponsors, such as the new opioid and APAP daily dose rates and concurrent use of buprenorphine and other opioids. CMS will not expand the overutilization policy to other drugs in 2016 but will, however, consider additional studies for potentially expanding the policy beyond opioids in the future.

Next, I'm going to discuss another topic from the 2016 call letter, access preferred cost-sharing pharmacies. In the 2016 call letter CMS announced our intent to address concerns about beneficiary access and marketing representations relating to pharmacies offering preferred cost-sharing based on the finding of the preferred cost-sharing pharmacy access study. CMS' study looked at Medicare Plan Finder data submitted by plans in the spring of 2014. Through that study we identified two groups of plans, outliers and extreme outliers. Last week, CMS notified the plans in those two weeks of their outlier status. The notification provided next steps for those plans to follow.

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The call letter also instructs all plans to conduct their own geoanalysis of their 2016 networks of pharmacies offering preferred cost-sharing. Plans should follow the call letter access levels to determine whether or not they are required to provide marketing disclosures for low access to pharmacies offering preferred cost-sharing. In October 2015 CMS will conduct its own analysis of the 2016 access using Medicare Plan Finder data submitted by plans in the same month. CMS will use those results to monitor plan's compliance with the marketing disclosures.

The next several slides go over CMS' three-pronged approach to addressing preferred cost-sharing pharmacy access concerns. The first slide, this slide provides that notified outliers will be based on the 2014 access data. Next, CMS will also require plans whose PCSP networks are outliers in 2016 to disclose their plan's outlier status in marketing materials. And finally, we will work with plans who are extreme outliers to address concerns about beneficiary access and marketing representations related to preferred cost-sharing. An HPMS memo will be forthcoming regarding the marketing disclosures plans will need to use. I will now turn it over to Andrea Bendewald who will conclude our presentation.

Thank you, Lucia. My name is Andrea Bendewald and I work in the Division of Formulary and Benefit Operations within the Medicare Drug Benefit Group. I recognize that I'm the last speaker that stands between you and lunch, so I appreciate your attention this morning. I'll be covering the final two topics for today's session, which include the discussion around benefit parameters for non-defined standard plans, and then I will wrap things up with the change to the mail order auto-ship policy.

So I will first begin with our tier labeling changes. A growing number of stakeholders have expressed concerns over the increasing cost-sharing that has been applied to generic drugs. They point to the significant copay differentials that have existed between the cost-sharing thresholds for preferred and non-preferred generic tiers, as well as the perception that certain generic drugs are viewed as non-preferred based on the current tier in labeling and hierarchy. Therefore, the decision was made to change the tier labeling for generic tiers for contract year 2016. This change merges or aligns the generic and non-preferred generic tiers into one standard generic tier option, with the option of having a preferred generic tier with lower cost-sharing for a subset of generic drugs.

It is important for sponsors to note that the PDP and formulary submissions modules for contract year 2016 will not be updated to reflect the generic tier label changes due to the time constraints to make the necessary changes. As such, the tier models in the respective systems are not changing for contract year 2016. Beneficiary interfaces will, however, be updated to reflect the materials that beneficiaries receive and/or view.

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A global summary of benefit or SB hard copy change will be submitted to remove any reference to non-preferred generic tiers. Please be advised, however, that the SBs that are generated out of the PDP will not reflect these changes. It is only the SB that is available from HPMS later in the summer that will reflect the hard copy change. The "Medicare and You" handbook will be reviewed and modified to ensure that there are no references to the non-preferred generic tier. And back-end system patches or workarounds will be done to modify the Medicare Plan Finder display.

Since we have the opportunity to do so here, I thought I would also clarify another point about this change which is a bit more technical. Following a recent Part C and D user call we have received several questions on how this tier label change relates to the drug type label that is included in the formulary file submitted into HPMS.

The drug type label number three is used by sponsors to represent that non-preferred generic tiers are included within a formulary tier. We are confirming that there are no change for contract year 2016 with respect to the drug type labels on the formulary fall layout. For the purposes of your submissions it is important to note that the validations that are currently in place for HPMS and the PDP pertaining to tier models and drug type labels are unchanged for contract year 2016. As you are preparing your submissions, if you are choosing a tier model within HPMS and the PDP that contains the tier name non-preferred generic and you would normally use a drug type label of three in your formulary record layout for that tier, you will continue to do so for contract year 2016. The modification for contract year 2016 is limited to the naming convention for the tier models, specifically for non-preferred generic tiers, which, as I mentioned, will be modified for beneficiary interfaces to simply replace the name "non-preferred generic" with "generic."

Moving on to threshold calculations, we noted in the call letter that the maximum cost-share thresholds were determined based on the 95th percentile of CY2015 bid data, which is consistent with previous years' approach. For contract year 2016 we will be implementing an inflation factor of 5.5% to the copayment cost-share of thresholds for brand tiers and higher consistent with the inflation value that was used in the out-of-pocket or OOPC cost model for 2015 to account for the rising cost of drugs. We note that this inflation factor will not be applied to the generic tiers given the other modifications being made with respect to tier labeling for generics.

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In the draft call letter we proposed a maximum generic tier threshold of $15 with the option of having a preferred generic tier that has more preferred cost-sharing. Based on the comments received, the maximum tier threshold was increased to $20 in the final version of the call letter. We heard you and we listened. As a note, this $20 threshold actually aligns with the 95th percentile of 2015 bid data for the non-preferred generic tier. This increase in the generic threshold will hopefully provide sponsors with the flexibility needed to minimize the up-tiering of generic drugs, especially into the non-preferred brand tiers, a trend that we noted during the contract year 2015 bid review.

We noted in the call letter that we will continue to monitor and evaluate for this trend going into the 2016 formulary and bid review season. This has prompted a few questions as to how CMS intends to conduct that review. What I can share with you at this time is that we will likely be conducting an outlier analysis to determine if there is a continued concern. If a concern exists, it is likely that those concerns will be communicated during stage two of the formulary review process. The communication of any concerns will be done outside of the HPMS usual process to generate outlier concerns throughout the various stages of the formulary review.

I will next provide a few comments on just general benefit review principles. The methodology for developing the contract year 2016 out-of-pocket or OOPC model is consistent with last year's methodology, with the exception of a few enhancements made with respect to plan and category level deductibles, as well as how average drug prices in Part D formulary tiers are calculated. The contract year 2016 OOPC model, along with all supportive documentation, was released to the CMS website at the "OOPC Resources Page" on April 10th, 2015. Details about the release can be found in the April 7th HPMS memo entitled "Out-of-Pocket Cost OOPC Model CY 2016 Bid Submissions."

Using the model, the minimum monthly cost-sharing OOPC difference between basic and enhanced PDP offerings for contract year 2016 will be $18. The minimum monthly cost-sharing OOPC difference between two enhanced PDP offerings will be $30. The methodology to determine these thresholds remains consistent with last year's methodology, and these requirements apply to all standalone PDPs, including those belonging to sponsors under a consolidation plan. We also signaled in the final call letter that for contract year 2017 that we will be considering the implementation of the TBC measure for Part D and we'll look to engage stakeholders as this is rolled out.

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The last benefits-related topic we will discuss is Part D vaccines. Based on the comments to the draft call letter there appeared to be some confusion around this subject, so we wanted to take the opportunity to clarify. We stated in the call letter that we wanted to encourage Part D sponsors to zero dollar or low cost-sharing for vaccines to promote this important benefit, given that adult immunization rates still remain low despite ACIP recommendations and Healthy People 2020 targets. This is not a new requirement. Our intention was to simply draw attention to the support and benefit and encourage sponsors to consider this approach if not already doing so. Our policy is unchanged from contract year 2015.

Having said that, it is important to highlight that there are five and six tier model structures available that provide for the inclusion of a dedicated vaccine-only tier or that allow for a select care/select diabetes tier that could contain vaccine products. Sponsors who choose to offer one of these specific formulary structures must set the cost-sharing at zero for that tier. Again, this is unchanged from our policy for contract year 2015.

I will now transition our discussion to mail order and highlight the changes to applying for exceptions to the auto-ship policy. The final call letter policy change how sponsors apply for two available exceptions to the auto-ship policy. Currently, sponsors must first submit an email request for an exception, listing the individual contract numbers effected. Starting January 1 of next year, sponsors meeting the exception conditions can operate under an exception if they qualify without first submitting a request to CMS. This change only eliminates the need for sponsors to submit the request and contract numbers to CMS. It does not change the exception policy or conditions, including the condition to verify, at least annually, of a beneficiary's interest in continuing automatic shipments. This can be done by either obtaining consent from the beneficiary directly or by citing mail order use under the same plan as noted in the review of exception requirements.

CMS will continue to monitor mail order and auto-ship policies, including related complaints submitted by beneficiaries. As a reminder, under Part D program, choice of pharmacy, including use of mail order, home delivery, or automatic shipment must be voluntary.

Before we conclude and open things for questions, we thought we would just highlight a few important dates. As noted on this slide, the Plan Benefit Package and Bid Pricing Tool Software packages were made available to sponsors on April 10th. HPMS will be made available to accept bids starting this Friday, May 8th. The deadline for formulary submissions, transition attestations, and bid submissions all coincide for Monday, June 1st, with a deadline of 11:59 PM Pacific Time. Part D Supplemental file and MMP additional demonstration drug files submissions are due by 12 noon Eastern Time Friday June 5th. Part C and D bid review activities will be conducted in June and July. Rebate reallocation occurs during the months of August and September. These deadlines to submit planned correction requests for contract year 2016 is September 23rd, and marketing begins October 1st, in advance of the annual election period.

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We provide you with the following contact information and resource mailboxes in the event that you have additional questions following today's event. General questions or questions for which you're unclear where to direct them may be submitted to Lucia, whose contact information is provided here for you. She will be able to assist in directly appropriating them for triage. And I will now turn things back over to Stacey, and we will address any questions that you might have. Thank you.

Okay, thank you. All right, this is your opportunity to ask questions. So our in-house audience, if you have a question, please step up to the microphone in the center aisle. Excellent. We do have a question. Go ahead and ask your question, and the appropriate speaker will respond.

Sure. Good morning. My name is Sarah Lawrence and I'm with Anthem. Given the error with the TTY call center measure was due to a CMS vendor, I'm curious if you could share the process CMS has put in place so ensure that if any future errors occur it will not negatively impact a plan's star ratings?

Thank you for the question. CMS has taken corrective steps to address the data quality concerns, such as increasing the quality assurance procedures used by the contractor to proactively validate the data as the surveys progress. Additional details about the steps that we have taken can be found in the call letter in Appendix F -- excuse me, in Appendix 5 on page 180. Sponsors are encouraged to alert CMS of any issues, comments, or questions about the call center monitoring project. And there is an email address provided in the call letter on page 180, and that email address is callcentermonitoring@cms.hhs.gov. If you have further questions or would like further information about the steps that we have taken after reviewing the call letter, please feel free to email us. You can contact Lucia and she will provide the email to the SME on the topic. Thank you.

Hi, Shawn Bishop again with SB Health Policy. Question about CMS's activities related to your research around the sort of connection between dual status and star ratings. Can you comment on CMS' plans for the research it's conducting and whether or not it will share the research it's conducting and the findings that it's gathering through that research? I think one of the things that we're struggling with is sort of what type of information CMS is finding and what are some of the, you know, analysis that they're conducting because there are other groups that are, you know, outside groups, that are conducting information, but we're not really clear about CMS is learning in its process and when those research findings would be shared, you know, with the public, whether it would come before request for comments or maybe in the request for comments, but will that information be shared with the public?

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Thank you for your question. Yes, CMS will continue to research the possible LIS Dual effect in a transparent manner. At this point, CMS has released a PowerPoint presentation that reviews the research to-date that was conducted both internally and in conjunction with our contractors, as well as a summary of the research results that were submitted in response to the request for information. In the slide presentation we compare, side by side, the results from our internal research to the results of the RFI submissions. The RFI submission summary focuses on the quantitative submissions and it is also limited to the submissions that use statistical significant testing. So I encourage you to look at the presentation, and if you have further questions, please feel free to contact us. Again, we will continue to research this very important issue. And as we're researching and getting results, we will do it in a transparent manner. Thank you.

Good morning. George Koutros with Sanofi. Question related to the Star Ratings, changes for next year. You had mentioned that the cholesterol measures will be retired for 2016, and that follows the retirement by NCQA, so that's straightforward. But in a different vein, in February of this year, NQF released a statement that CMS had decided to withdraw a proposed cholesterol measure to be taken from the resource use into the PQRS physician incentive program. And part of the reasoning was that LDL levels were not included in that proposed measure. So could you comment on current interaction between perhaps consumer assessment and Part B clinical or future interaction between consumer assessment and Part B quality? Thank you.

Thank you for your question. I am not the subject matter expert on the Part D measures, but I will provide the question to the SME and that answer will be posted after the conference. Thank you.

All right, that is all we have time for today. We are out of time for our questions. Thank you all for the questions that you have. And thank you for presenting today, Lucia, Elizabeth, and Andrea.

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