

Project Title

Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE)

Purpose of the Final Public Comment Report

The purpose of this Final Public Comment Report is to provide:

- Comments and responses received through the both public comment periods;
- An overall summary of comments received during both public comment periods; and
- Recommendations from the PACE Technical Expert Panel (TEP) and relevant stakeholders regarding the next steps for the four (4) draft measures.

The Centers for Medicare & Medicaid Services (CMS) and Econometrica, Inc., reviewed all individual comments and provided responses as part of this Final Public Comment Report. All comments and responses can be found as addendums to this report in Appendices A and B.

Schedule of Dates and Comment Reports

- Two Calls for Public Comment were posted on the CMS website to request comments from stakeholders on the quality measures being currently adapted for the PACE project and to ensure and encourage open feedback and communication during the process.
- The initial Call for Public Comment period ran from July 17, 2015, to August 17, 2015, and the Initial Public Comment Report was posted on the CMS website September 10, 2015.
- The second Call for Public Comment ran from September 10, 2015 to September 24, 2015, and included seven (7) follow-up questions based on comments received during the initial Call for Public Comment.
- This Final Public Comment Report includes Econometrica's responses to the initial Call for Public Comment submissions and the individual feedback submitted by stakeholders during the second Call for Public Comment. This feedback was in response to the seven (7) questions posted during the second Call for Public Comment.

Project Overview and Description of Phases

CMS contracted with Econometrica to adapt, implement, and maintain quality measures for the nationwide PACE program. The contract name is Development, Implementation, and Maintenance of Quality Measures for the Programs of All-Inclusive Care for the Elderly. The contract number is HHSM-500-2013-13006I, order number HHSM-500-T0002. The contract was awarded for a one (1)-year base period (or Base Year), with an option for three (3) additional years (Option Years).

Description of Phases:

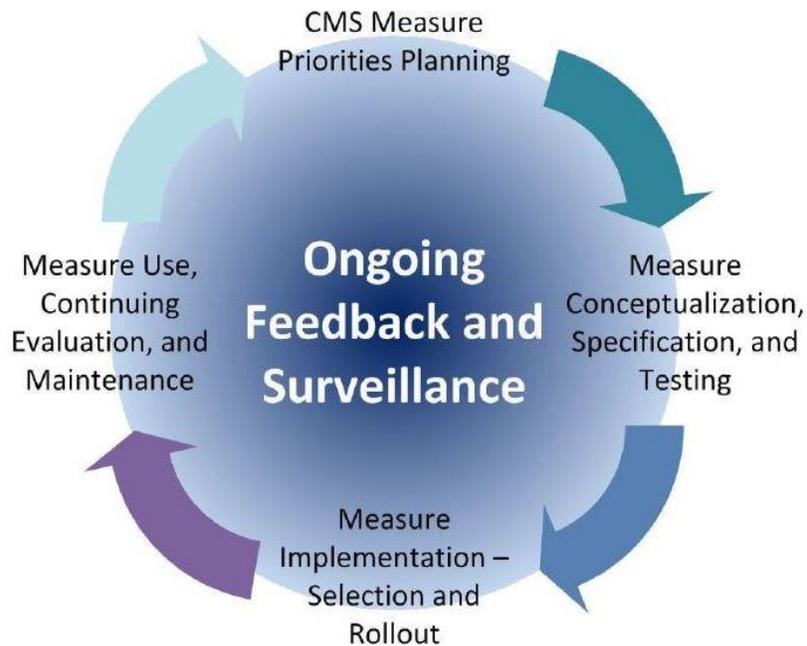
The Base Year period of performance is the first Phase (or Phase One). The Option Years will be referred to Phases Two, Three, and Four (i.e., Option Year 1 is Phase Two).

This effort is being conducted according to the CMS Measure Management System Model, which includes four (4) main steps with ongoing feedback and surveillance throughout (see Figure 1):

1. CMS Measure Priorities Planning.
2. Measure Conceptualization, Specification, and Testing.
3. Measure Implementation – Selection and Rollout.
4. Measure Use, Continuing Evaluation, and Maintenance.

The TEP feedback and two rounds of Public Comment, which are covered in this report, are most relevant to Step #2 above, which includes Measure Conceptualization, Measure Specification, and Measure Testing.

Figure 1: CMS Measures Management System Model



Project Objectives

The primary objectives of this stage of the project are to:

- Analyze existing quality measure sets to determine the extent to which they can be modified, refined, or enhanced to be appropriate to the uniqueness of the PACE program and organizations;

- Focus on four (4) areas of measurement—Falls, Falls With Injury, 30-Day Readmissions, and Pressure Ulcer Prevalence (inclusive of a prevention measure)—within Phase One of the project;
- Conduct field tests to assess the feasibility of data collection, reliability, and validity of these four (4) proposed adapted measures; and
- Continue to refine the measures based on feedback received from all rounds of public comment.

For Phase One, CMS and Econometrica adapted four (4) quality measures, including the drafting of measure specifications for domains suggested by CMS:

1. Falls.
2. Falls With Injury.
3. 30-Day Hospital Readmissions.
4. Pressure Ulcer Prevalence (prevention and outcomes).

These four (4) measures are currently being evaluated for Measure Implementation – Selection and Rollout (shown above), and the two (2) rounds of public comment have informed this process. The purpose of this report is to provide Econometrica’s responses to the comments submitted in the initial Public Comment Round and to summarize the stakeholder responses to the questions posed in the second Public Comment Round. The summary of comments received can be found in the upcoming sections of this report.

Information About the Comments Received

- Public comments were solicited by announcements made during stakeholder group meetings and by email notifications.
- The original Call for Public Comment was posted on the CMS Call for Public Comment website: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html>.
- The second Call for Public Comment requested responses to seven (7) questions based on the original comments received. This call posted on the same CMS website. The questions were:
 1. CMS and Econometrica are considering an acuity methodology, which would include a geographic and participant health status component. Should a substitute measure include acuity adjustment? Recognizing there is no standard measure of acuity, please suggest acuity assessment specific to PACE organizations.
 2. Our testing results suggest that a monthly reporting timeframe for the Falls and Falls With Injuries measures is not sufficient in order to produce meaningful results. CMS and Econometrica believe that a larger “look-back” data reporting period would produce reliable, valid data across the PACE organizations. Currently, our intent is to shift the reporting period from monthly to quarterly. Is

quarterly reporting an appropriate timeframe for reporting falls? Do you believe that a different reporting period should be used?

3. Based on some of the comments we received, it seems like PACE stakeholders have an interest to see a paired measure for Falls. Would a paired (or composite) measure combining Falls and Falls With Injury be more appropriate? How could a paired or composite measure be accomplished?
 4. Some comments received during the initial public comment period suggest that many falls go unreported. CMS and Econometrica are considering ways of involving PACE participants or their caregivers in order to promote effective data reporting. For example, we could develop and implement a form-like process to document falls in the home by the PACE participant or caregiver. What are the benefits of developing a form-like process for PACE participants to track falls that would assist with recall/reporting? Are there other more effective ways of involving PACE participants and their caregivers on reporting falls?
 5. Based on some of the comments received and our testing results, CMS and Econometrica are considering the development of a Fall Prevention measure in future contract years. What factors should CMS consider in developing a prevention measure for falls within PACE?
 6. CMS and Econometrica believe that preventative measures are vital to ensuring quality of care for PACE participants. Through our testing and the public comments, we understand that current processes are prohibitive in terms of capturing data for a Pressure Ulcer Prevention measure. CMS and Econometrica would like to invite feedback on how we can direct and/or incorporate processes in order to promote effective reporting on such a measure. Should CMS adapt a pressure ulcer scoring system (e.g., Braden) and/or a bundling pressure ulcer prevention system to capture data effectively and consistently across PACE organizations?
 7. Several comments from the public were related to the performance of PACE organizations and low admission rates are well considered and appreciated. Given the current focus on readmissions as an area of quality improvement (e.g., Hospital Compare), there are conversations regarding whether the focus should be on reduced admissions, or index stays, which would reduce the rate since the denominator is not as large. Is admission a more appropriate quality measure for PACE than 30-Day Readmissions, or is there a more appropriate measure for use in the context of PACE?
- In total, 234 comments and responses were received during both the initial and second Call for Public Comment periods.
 - 234 comments were received during the public comment periods from unique email submissions through the PACEQMcomments@econometricainc.com email address included in the Call for Public Comment. The breakdown of commenters was as follows:

- 130 comments were from PACE organizations.
- 41 comments were from the National PACE Association
- 41 responses were from the PACE TEP.
- 15 responses were from government agencies.
- Four (4) comments were from State organizations.
- One (1) comment was from a non-governmental organization.
- One (1) comment was from a private consulting firm.
- One (1) comment was from a hospital.

As mentioned in the “Schedule of Dates and Comment Reports” section, the Initial Public Comment Report that was provided to CMS prompted an additional round of questions based on the preliminary feedback during public comment. This feedback was solicited in the form of seven (7) questions posed during the second round of public comments. CMS and Econometrica received responses to these questions on September 24, 2015. These questions and responses are also part of this Final Comment Report and can be found in Appendix B.

Some highlights of the comments received include:

- The uniqueness of PACE is consistently acknowledged;
- Assisted Falls are difficult to categorize and document;
- Collecting data for a quarter (i.e., 3 months) is more reliable than one (1) month;
- Pressure ulcer prevention assessment procedures should align with PACE program guidelines and regulations;
- A bundled tool approach is best for measuring Pressure Ulcer Prevalence.

This report organizes the summary of comments under two (2) main headings: “Stakeholder Comments – General” heading which provides an overview of comments not specific to any measures and the “Stakeholder Comments – Measure-Specific” heading which breakdowns and summarizes comments by measures.

Stakeholder Comments – General

Summary of General Comments

During the public comment periods, two (2) comments expressed the uniqueness of the PACE environment as opposed to other health care settings, and seven (7) comments were suggestions that census numbers should be used and supported instead of caseload, which is a term better suited to other care environments.

Most commenters acknowledged that an acuity assessment tool for the PACE population would be beneficial and that it should have a well-established methodology. This type of adjustment does not currently exist. A risk adjustment and frailty score is available from CMS, but due to the unique nature of the PACE population, modifications would need to be tested, and potentially adjusted, before it could be adapted and possibly utilized.

Response:

Although only a few comments directly expressed the uniqueness of the PACE organizations, this theme can be seen through the majority of the comments. We recognize the unique setting of the PACE program and will consider the population when defining numerators and denominators within each measure construct. All aspects of the PACE program, including the fact that claims are usually not generated, will be considered when constructing all future measures. We will examine and revise/clarify the numerators and denominators before final measure specifications are made.

There is clearly a need to construct distinct quality measures for PACE organizations and integrate useful “clinical” outcome measures that pertain to PACE. Since the PACE environment is so unique compared to other environmentally controlled health care facilities (e.g., inpatient facilities), the incorporation of universally accepted and easily compared quality measures is a challenge. There is often a need to have a process of controlling for factors outside the influence of the providers when outcomes are used as performance measures for assessing health care services and providers. Comparison groups of other PACE programs of similar characteristics for all measures will be used if there is enough reporting (such as program age) to break them apart.

TEP Feedback to Responses:

TEP members agreed that PACE programs are centered on the needs of the individual. CMS and Econometrica are also aware of this and believe that quality measures based on person-centeredness should be equally considered for development.

The TEP agreed that the term “census” was a much more reflective term for the work that PACE does and added that capturing the census at the beginning of the month would be better in terms of collecting data. All revisions to the specifications will be made prior to conducting additional testing activities.

Current Status Disposition:

One of the important aspects of testing is the identification of the need for clarification, including census vs. caseload. Due to the nature of the PACE organization and the capitation payment system, we recognize that census is a better term. Furthermore, considering the fact that disenrollment rarely occurs during a given month, we will implement the recommendation to use the census as of the first day of the month.

Stakeholder Comments – Measure-Specific***Summary of Falls and Falls With Injury Comments***

During the public comment periods, seven (7) comments questioned assisted falls and the difficulty in determining who assisted a participant to reduce injury from a fall, and three (3) comments promoted parsimony within the falls measure set (Falls and Falls With Injury). Other commenters acknowledged that:

- Collecting three (3) months of data (quarterly) would likely be more reliable than only collecting one (1) month of data.

- Falls and Falls With Injury measures could be paired together because Falls With Injury is a part of the data collection for Falls, but that serious injuries should also be reported as an additional data element.
- The possibility of developing/adapting and implementing a new form that would help capture and track falls at home would be difficult to track and administer and that the measure would still be underreported.
- A Fall Prevention measure should include screening for fall risk. As one commenter said, “Ultimately the measure of success with falls prevention would be the rate of falls with injury, making this measure redundant and prone to all kinds of biased reporting.”

Response:

We appreciate the comments related to assisted falls. While assisted falls have been shown to reduce the frequency and severity of injuries resulting from falls, this reporting requirement is an additional burden on the PACE organization due to the challenge of identifying who may have been present and it will not add value to the reported results. The intent is to only collect information beneficial for the PACE organizations and it will be eliminated from the next round of testing.

Our testing results suggested that a monthly reporting timeframe for the Falls and Falls With Injury measures is not sufficient to produce meaningful results. We agree with the almost unanimous view of commenters, provided during the second round of public comment, which recommended quarterly reporting as an appropriate timeframe for reporting falls and could increase the reliability of this measure.

Certainly, the harm evident in a fall with injury is a concern for health care providers. However, Falls With Injury are rare relative to total falls and do not capture the psychological distress that may follow a fall without injury. The quality improvement and prevention activities for falls generally focus on the prevention of falls rather than the prevention of injuries from falls. The comments, regarding a parsimonious measure set, were considered and CMS and Econometrica have determined that the Falls and Falls With Injury will be kept separate.

Because other comments received suggest that many falls go unreported, CMS and Econometrica are considering ways of involving PACE participants and their caregivers to help promote effective data reporting. We agree with comments received during the second round of public comment that suggest that a form-like process to document falls is not necessary in the context of the PACE population due to the possibility that falls would still be underreported at home. We will continue to work on identifying effective ways of involving PACE participants and their caregivers on accurately reporting falls.

The intent of this project and public comment periods is to construct valid, reliable, and feasible measures for the PACE organizations nationally. The measures are adapted from currently endorsed and implemented Falls With Injury measures used in other care settings based on the science, evidence- and literature-base. Current Level II reporting includes fall injury definitions that correspond to PACE injury definitions for levels Major and Death. Current Level II reporting does not have counterparts for Minor or Moderate injury levels. The top two (2)

categories are aligned, but the lower two (2) categories/levels are omitted. Based on CMS direction, Level II definitions could change, but currently the PACE measures include minor and moderate injury levels and are therefore more inclusive than Level II definitions.

TEP Feedback to Responses:

The TEP mainly provided feedback on assisted falls. TEP members noted that most falls are unassisted and generally unwitnessed; therefore, the TEP concurred that recording assisted falls did not seem to be relevant. When the TEP was asked whether Falls and Falls With Injury metrics should be combined, the group consensus was that the measures should be kept separate, since the data on Falls With Injury was important to measure and collect. The TEP commented that both Falls and Falls With Injury measures have high usability because quality improvement activities arise from both measures. The combination of these measures would only send the message that POs should only focus on preventing injury falls and not preventing falls in general.

Current Status Disposition:

Due to the burden of collecting the information, the data related to assisted falls should not be collected in the future. Therefore, based on the recommendations from the public comments, CMS and Econometrica will be changing the reporting period for Falls from monthly to quarterly during the next round of testing. In addition, we recommend that Falls With Injury that are classified as serious should be an important data element to track going forward should this measure be implemented. Finally, we agree with our TEP recommendation that Falls and Falls With Injury measures should be kept separate due to the distinctions between Level I and Level II reporting requirements.

Summary of Pressure Ulcers Comments

During the public comment periods, four (4) comments pointed out that pressure ulcer assessments are conducted every 60 days in home care but only every six (6) months in the PACE programs, unless there is a change of status. Seven (7) comments requested a tool for risk assessment. Six (6) comments asked for measures to be associated with Level II reporting in order to harmonize the measure definitions. Three (3) comments addressed concerns about the measure capturing pressure ulcers acquired by participants in their homes versus those acquired in settings outside of PACE. Six (6) commenters agreed that the Braden scale or similar tool would work in the PACE environment. Others disagreed but suggested that a bundled approach may be better suited for the PACE environment. In other words, by measuring different interventions, we could address preventions. Caregiver support was also mentioned as being important in managing pressure ulcer prevention.

Response:

The draft measure instructions did request information on whether assessments were completed every 60 days based on specifications for previously endorsed and implemented measures for other settings. Given the six (6)-month care planning required for all PACE participants, we are interested in alignment with the PACE regulations whenever possible.

While the Braden scale is the most common tool used for assessing pressure ulcer risk, there are other validated tools. Even though it is possible to capture the specific tool used, not all providers use the same cut point (for any tool) to determine that a participant is at risk. The cut point is the

score that would determine whether a participant was at risk. Data on both the tool used and the cut point used by the PACE site would need to be recorded. The risk assessment tool developers provide includes suggested ranges of values, within which a reasonable cut point may be set. The cut point ranges are part of the tool instructions. Providers can set their own cut point based, theoretically, on the characteristics (e.g., age, infirmity) of the population they serve.

CMS and Econometrica believe that process (e.g., preventive) measures are vital to ensuring quality of care for PACE participants when the process has an evidence-based link to outcomes. Through our testing and the public comments, we understand that current processes are prohibitive in terms of capturing data for a Pressure Ulcer Prevention measure. Through the second round of public comment, CMS and Econometrica gathered feedback on how we can direct and/or incorporate processes in order to promote effective reporting, such as adapting a pressure ulcer scoring system (e.g., Braden) or bundling prevention systems to capture data effectively and consistently across PACE organizations. Commenters generally supported the idea of using a standardized validated tool to capture data for a Pressure Ulcer Prevention measure.

TEP Feedback to Responses:

Regarding the difference in pressure ulcer assessments between home care and the PACE programs, the TEP concurred that staying in alignment with the PACE regulations was the best recommendation. The TEP opposed adding another assessment period of every 60 days to the PACE program's workload. PACE programs already have a regulation in place that provides more frequent assessments should a participant's status change.

The TEP members also weighed in on the adaptation of Pressure Ulcer Prevention. The challenge seems to come when a participant is at risk and a plan is put in place: how is it determined whether the plan was ever implemented? TEP members agreed that a validated tool, possibly the Braden Score, may work in the PACE environment.

Current Status Disposition:

In agreement with our TEP, CMS and Econometrica are considering changing the specifications for the Pressure Ulcer Prevalence measure to a six (6)-month timeframe, shifting the reporting time from 60 days, which is consistent with current PACE regulations. The TEP recommended that we not proceed with further testing on Pressure Ulcer Prevention at this time.

Summary of 30-Day Readmission Comments

During the public comment periods, four (4) comments were received regarding the timing for defining the window for 30-Day All-Cause Readmissions. Six (6) comments requested clarification of what constitutes a 30-Day All-Cause Readmission and the related exclusion criteria. There were also three (3) comments expressing that high-performing PACE organizations may have low admission rates (i.e., index admissions) and, therefore, a lower denominator. Five (5) comments recommended 30-Day Readmissions as an adequate and appropriate measure. Three (3) comments recommended admissions (i.e., the denominator only) as a more appropriate measure for PACE organizations/participants, given the focus of keeping participants in the community. Other commenters suggested having both a measure for 30-Day All-Cause Readmissions and inpatient admissions separately.

Response:

All of the comments were appreciated, including the illustrative examples with sample dates and comments related to the performance of PACE organizations with low index admission rates. After reviewing the comments and accounting for the initial testing phase results, CMS and Econometrica gathered additional feedback that suggested that index admissions for inpatient stays may be a more appropriate measure in the context of the PACE population.

TEP Feedback to Responses:

The TEP provided feedback on the concern about using readmission rates when comparing high-performing PACE organizations with programs that do not have the same access to academia, technology, and an interdisciplinary approach to care. The TEP pointed out that high-performing programs manage to keep many less serious, complicated cases out of the hospital, which can contribute to artificially high readmission rates at average-performing programs.

The TEP members also pointed out the concern about data collection for readmissions, noting that all PACE programs should have equal access to electronic health record (EHR) software. They added that EHR vendors should be held accountable for supporting all sites with their data collection and need to catch up with any new data collection requirements and reporting.

Current Status Disposition:

Given the emphasis on keeping PACE participants in the community through coordinated care, Econometrica will consider a future measure that will examine “days in the community.” Furthermore, we will extend information-gathering activities surrounding this measure in order to better understand how it applies in the community within the context of the unique PACE population. We also agree with the TEP and general public that the 30-Day All-Cause Readmission measure is not appropriate in the context of the PACE organizations and will therefore not be moving forward.

Overall Analysis of the Comments

All of the comments and feedback received from these stakeholders provided meaningful and useful input into the core data element specifications. During the first round of public comment, there was broad support for the intent of the measures, with four (4) commenters/organizations supporting the intent of Falls, Falls With Injury, Pressure Ulcer Prevalence, and 30-Day Readmissions. The Pressure Ulcer Prevention measure was not unanimous among commenters, with one (1) stating that they agreed with the intent “as is” and two (2) stating that they agreed with the intent only after considering the comment.

The second round of public comment confirmed:

- No available instrument for acuity adjustment in the PACE population.
- Broad support to shift the reporting period from monthly to quarterly data collection and reporting for Falls, Falls With Injury, and Pressure Ulcer Prevalence.
- Falls data collection and reporting should and will include Falls With Injury as part of the effort.

- Low support for potentially developing and implementing a form-like process to document falls in the home due to risk of underreporting.
- General support for using a standardized, validated tool to capture data for a Pressure Ulcer Prevention measure, but no unanimous support for a specific scale (e.g., Braden).
- Keeping our focus on participants in community and not 30-Day All-Cause Readmissions, as it is not an appropriate measure for the PACE Organizations.

Crucial conversations regarding a path forward for all measures will continue to be held regarding the analysis and review of all responses from stakeholders. As of the date of this public posting, there have not been any updated or revised measure specifications regarding the first four (4) quality measures focused on during Phase One of this PACE project.

Next Steps

Based on results from feedback received during the public comment periods and TEP recommendations, Econometrica will continue to refine and further adapt and revise the four (4) areas of Phase One measurement discussed in this report: Falls, Falls With Injury, 30-Day All-Cause Readmissions, and Pressure Ulcer Prevalence (prevention and outcomes). In order to accomplish this task, Econometrica will:

- Move forward with additional testing activities surrounding three (3) of the measures, including **Total Falls**, **Falls With Injury**, and **Pressure Ulcer Prevalence** rates (please see main goals below for specifics).
- Perform additional information-gathering activities related to the **30-Day All-Cause Readmissions** and **Pressure Ulcer Prevention** measures to inform Econometrica, in collaboration with CMS, of the need to move forward with these particular measures.
- Conduct information-gathering activities related to all areas of measurement. These activities include, but are not limited to, measure topics suggested for future consideration (e.g., “days in community”), site visits to PACE organizations, focus groups of relevant stakeholders, and additional ad hoc discussions with the TEP.

The main goals of the activities listed above are to:

- Proceed with further testing in an effort to improve the reliability testing results of the Total Falls, Falls With Injury, and Pressure Ulcer Prevalence measures. This will be achieved through an additional round of testing at PACE organizations that volunteered for the initial round of data collection/reporting. The process for the additional round of testing will include collecting less data with fewer variables (e.g., based on feedback, not including who assisted with fall(s)) and will be conducted over a longer period of time (i.e., three (3) months of data vs. one (1) month).
- Gain a better understanding of the 30-Day All-Cause Readmissions measure and whether there might be a better measure to suit the uniqueness of PACE (e.g., participant days in the community) given the unique focus of keeping participants in community.

- Further adapt and explore the Pressure Ulcer Prevention process measure. This will include additional research on tools and consideration of whether the measure could be revised to collect whether a risk scale is used without mandated use of a specific scale.

Econometrica aims to increase communication with the community, especially stakeholders, and remain transparent on the status of all of these areas of measurement. As a result, updates on refinement and further development of these measures or future measure topics may be posted publicly to provide full disclosure and to encourage expert feedback from all PACE stakeholders who wish to respond to these important health care measures.

Appendix A

Public Comment Verbatim Report

Initial Round

Note: All identifiable information have been removed from the comments section. All comments, however, represent the complete, verbatim comments provided during the public comment period.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
1.	8/11/2015	General	<p>1) Attention must be given to the ability of PACE Organizations (PO's) to easily extract data from the medical records either from paper or electronic. If electronic, vendors must be held accountable for meeting reporting requirements and deadlines to assure the PO's are well supported.</p> <p>2) Special attention must be given to the unique aspects of PACE population particularly when considering how to define in numerators and denominators.</p> <p>3) Another unique aspect of the PACE population and the services and care we provide is based on individual preferences. There are three goals of care categories in PACE: Longevity, Functionality and comfort care. Services are provided to our participants based on an individual participant's goals of care and are not population specific.</p> <p>4) Claims are generally not generated for services which should be taken into account when developing measures</p> <p>5) As a measure testing site, numerators and denominators must have unambiguous definitions</p>	<p>Thank you for your comments and the need for clarity in the data collection instructions.</p> <p>1) Further work is needed to determine whether data collection efforts could be accomplished through extraction from an electronic health record system to minimize the burden of reporting these data. We share the desire to limit burden and will consider opportunities to align with vendors at the direction of CMS.</p> <p>2) We recognize the unique setting of the PACE program and will deliberately consider the population when defining numerators and denominators.</p> <p>3) The participant-centered focus of the PACE program is unique, and we seek to construct measures meaningful for this population and their goals of care.</p> <p>4) All aspects of the PACE program, including the fact that claims are usually not generated, will be considered when constructing all future measures.</p> <p>5) We will examine numerators and denominators carefully before final measure specifications are made. One of the important parts of testing is identifying the</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
				need for clarification.
2.	8/13/2015	General	If CMS decides to implement the overall hospital star rating system will each individual measure continue to be posted on the Hospital Compare website, or will the star rating only be displayed?	Thank you for your question. It appears your question is related to the Hospital Compare measures developed by YaleCORE under contract to CMS. This call for Public Comments was specific to PACE. It is not known if an overall star rating system will be implemented for PACE.
3.	8/13/2015	General	<p>As a long-time advocate for and provider of services to persons living with advanced illness or disability in old age, I am quite disheartened by the proposed quality metrics for PACE. Having some quality metrics applied to PACE is a good step, especially as many of the new PACE programs are sponsored by for-profit businesses, so more variation in quality is likely to arise. However, the initial five metrics are really a pallid reflection of the core issues of importance to beneficiaries and families who use PACE. These people look for elements like continuity, reliability, prudent medical services, and comfort. They may be looking to relieve an overwhelmed family caregiver or mainly to avoid placement in a Medicaid-supported nursing home. Indeed, they may have quite personal goals and priorities, and one of the sterling characteristics of PACE has been its commitment to patient-and family-driven comprehensive care plans, enabling the care plan to help the beneficiary and family to live as well as possible with their situation, as measured by their own yardstick.</p> <p>Yet these proposed measures do not even begin to ask about person-driven care plans, or care plans at all. They don't touch on medical care quality or symptoms or reliability of back-up for care at home. It is undoubtedly important to all to avoid falls and pressure ulcers, but even these have varying importance, depending upon the particular PACE participant's concerns and aspirations.</p> <p>The specific metrics that are proposed pose certain practical problems. Pressure ulcers at stage 1 should not be counted as adverse indicators. They are variably detected, easily healed, and it is prudent to encourage them to be reported and treated quickly. None of the other CMS metrics for other types of providers tally</p>	Thank you for your comments. We appreciate your feedback regarding additional options for measuring quality of care and other aspects of the unique PACE programs. This was the first set of draft measures and we will take your recommendations regarding continuity, reliability, comfort, RCA, utilization, and readmissions into consideration during implementation of these draft measures and future rounds of measure development.

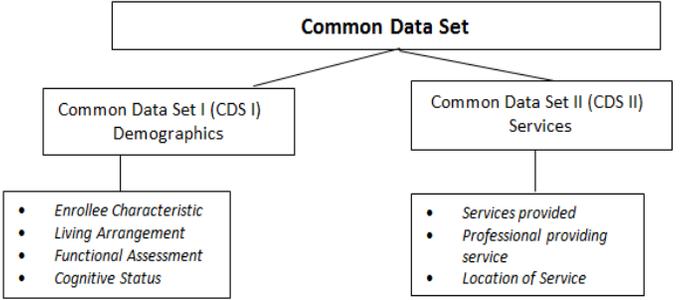
No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			<p>Stage 1 pressure ulcers (though they did in the past, before the adverse consequences of doing so were recognized). Falls will have the persistent problem of under-reporting for people who are living on their own. But these can probably be rectified (for pressure ulcers) and managed (for falls).</p> <p>However, the 30-day readmission rate will have the same “shrinking denominator” problem that the CMS readmission rates have had in all other applications or the readmission rate. A very good PACE program will have a low admission rate, and their readmission RATE (if calculated as proposed) may well be high, because the only people being admitted to hospitals are people for whom hospitals actually offer substantial gains and whose health is very fragile, and for whom achieving stability is challenging. On the other hand, a weak PACE program might well still hospitalize a larger number of elders who really could have been served in other settings, whether for conventional medical care or for more palliative goals; but their readmission RATE might be low because their admission rate is so high. In short, the readmission rate, defined as some form of readmissions/discharges, is singularly useless as an indicator of care quality. Perhaps PACE would be a good setting in which to start evolving toward more useful metrics -- perhaps process measures like having root cause analyses in place with responses to identified opportunities, or overall hospital utilization measures. In the meantime, CMS should not propagate this seriously dysfunctional metric to yet one more setting.</p> <p>In conclusion, CMS should not implement the readmission rate metric, should delete Stage 1 pressure ulcers from the numerator in that measure, and should commit to developing and deploying metrics that are of more use in distinguishing better and worse PACE programs in the future.</p>	

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
4.	8/13/2015	General	<p>Thank you for the opportunity to comment on the proposed quality measures for the Programs of All- Inclusive Care for the Elderly (PACE) program. We strongly support publically reported quality measure for this valuable program but encourage consideration of how quality measures can be used across programs. There is a need for quality measures reflecting the unique needs of PACE participants but also allow comparison across programs serving this frail and often dual-eligible population, including Special Needs Plans and the CMS Medicare Medicaid Plans.</p> <p>In developing measures proposed here, we encourage CMS to consider how measures used by Special Needs Plans and Medicare-Medicaid Plans can be adapted for PACE before developing de-novo measures. For example, this project proposes to develop a 30 day all-cause readmission measure.</p> <p>However Special Needs Plans and Medicare-Medicaid plans already report on a readmissions measure. A de-novo measure not aligned with existing measures would prevent CMS and beneficiaries from making apples-to-apples comparison among plans in the other programs. Without comparable measures across programs, beneficiaries cannot make truly informed choices.</p> <p>We also recognize that those of us who develop measures have a responsibility to do so with an eye to the importance of comparability and harmonization. This is especially important for the many beneficiaries have both serious health concerns and limited health literacy. They and their families must be able to make direct comparisons across programs. It is also essential for providing policymakers and practitioners the tools they need to measure quality, identify the most effective models of care, direct patients to the most appropriate options and drive improvements throughout the health care system.</p>	<p>Thank you for your comments. We appreciate your feedback regarding additional options for measuring quality of care and other aspects of the unique PACE programs. These measures are being developed with the ultimate goals of having quality indicators that are fully vetted. We also fully appreciate that measures should be developed with an eye to the importance of comparability across programs serving this frail and often dual-eligible population, including Special Needs Plans and the CMS Medicare Medicaid Plans.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
5.	8/14/2015	General	<p>1. XXXX strongly encourages that definitions be considered from the perspective that the PACE population is always “at-risk”.</p> <p>2. Regarding readmissions – XXXX suggests that more criteria be defined and that consideration be given to readmissions for the same reason/condition.</p> <p>3. What is the baseline that is being developed/used for comparison for these measures? Best practices should be published and encouraged based on the benchmarks/findings.</p> <p>4. Risk stratification based on PACE characteristics should be more defined.</p> <p>5. XXXX has suggestions for additional quality measures that we would like to share.</p>	<p>Thank you for your comments. One of the important parts of testing is the identification of the need for clarification.</p> <p>1) We will consider options for providing clarity in categorizing “at risk” and risk stratification, as participation in this unique program is risk-based.</p> <p>2) The focus was on all-cause readmissions as opposed to same Diagnosis Related Group.</p> <p>3) You also asked what comparison baselines are to be used for each measure. There is no baseline of expected rates for readmission and there will be variability among sites. The comparison data would be the mean or median of data from all PACE sites. Quality improvement should be encouraged once the rates are known.</p> <p>4) Risk adjustment/stratification will be further considered and we appreciate the feedback.</p> <p>5) Please submit additional ideas to PACEAdmin@econometricainc.com.</p>
6.	8/14/2015	General	<p>We respectfully request that in this pursuit, measures are designed with minimal burden in data collection and high value for our participant’s care. For example, XXXX supports the areas of focus for the proposed measures: Fall and Injury Prevention, Pressure Ulcer Prevention, and Reducing Hospital Readmissions. However, we are concerned about the level of data entry proposed on a monthly basis. As a large PACE Organization serving over 1100 enrollees, we believe that the administrative burden of monthly data entry without a mechanism for uploading spreadsheets or reports is very significant. We recommend that only the data elements needed to calculate the measures be submitted and that data be submitted on a quarterly basis. Further, we strongly urge you to explore data reporting that is done on an aggregate basis versus per participant data entry.</p>	<p>Thank you for your comments. We appreciate your interest in limiting reporting burden. We are moving forward with testing activities that will help us determine an appropriate timeline for reporting. Reporting will most likely be collected through HPMS following implementation of the measure set. Testing will inform more and better options for data collection (e.g., aggregate).</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
7.	8/14/2015	General	XXXX represents 11 PACE programs which serve approximately 1,400 frail, elderly individuals. On their behalf, we offer the following in response to the Centers for Medicare & Medicaid Services' (CMS) request for comment on proposed PACE quality measures. XXXX supports CMS' efforts to improve the quality of health care for PACE participants in the United States. As the PACE population is dynamically evolving, we are aware of the increasingly complex nature of measuring quality accurately and providing this information so that it is reliable, valid, and meaningful. We offer the following comments related to the potential implementation of these measures. As a member of the National PACE Association, we have drawn heavily upon their findings and comments, which were developed by a participatory process.	Thank you for your comments and concern for the PACE program and its participants.
8.	8/14/2015	General	XXXX appreciates CMS' efforts to develop, adapt, and implement quality measures for PACE. It will be vital to consider the unique aspects of PACE that allow for PACE-specific comparison, while balancing the needs of the National Quality Forum, states, and other stakeholders to compare PACE to other service delivery options (e.g., managed care). Given the variability in PACE size, participant needs and abilities, and programmatic differences compared to other settings of care (i.e., nursing facilities), simply adapting existing quality measures may not be advisable. For example, the denominator of National Database of Nursing Quality Indicators <i>Falls</i> quality measure is based on patient days in a facility which is not applicable to PACE. We recommend that Econometrica review PACE regulations and guidance documents to glean insight regarding how to best define and identify the PACE participant. We encourage CMS/Econometrica to harmonize the measure definitions of the proposed measure set with the definitions and reporting requirements associated with Level II reporting. This will mitigate the use of varying definitions for the same data element.	Thank you for your comments and for acknowledging the variability and different characteristics across PACE providers within these unique programs. We also appreciate your comment about reviewing PACE regulations and guidance documents to glean insight regarding how to best define and identify PACE participants. The development team is currently taking PACE guidance and regulations into account.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
9.	8/14/2015	General	Additionally, PACE quality measures should reflect participants' individual preferences and goals. In PACE, the goals of care for participants are categorized into three broad areas: promotion of longevity, optimization of function, and comfort care. Given the heterogeneity of the PACE population, we encourage to CMS/Econometrica to consider the impact of differences in participant care goals, as well as the characteristics of participants on the measure results.	Thank you for your comment to consider the impact of differences in participant care goals, as well as the characteristics of participants on the measure results. These differences and site characteristics are being accounted for in our testing phase.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
10.	8/14/2015	General	<p>Lastly, as part of the measure testing phase, XXXX recommends that CMS/Econometrica explore and attempt to understand the degree to which standardized and complete data is available from PACE organizations (POs) needed to calculate valid and reliable measures. Unlike nursing homes, home health care agencies and many other provider-based care options for frail elderly, PACE lacks a common assessment instrument and data standard. We have struggled with this within our own state boundaries, and are deeply appreciative of the work done by the National PACE Association to address this need. The National PACE Association has developed a common data platform across all PACE organizations referred to as the <i>Common Data Set (CDS)</i> [see Figure 1]. The CDS contains a standardized dictionary of definitions for data elements to collected – demographics (CDS I) and services (CDS II). The creation of a standardized participant specific data set for will allow for better defining the PACE population; create opportunities to measure the value and performance of PACE; support improved and more efficient benchmarking; distinguish PACE from emerging delivery models; and foster the evolution and adoption of EHRs for PACE.</p> <p><i>Figure 1.</i></p>  <pre> graph TD CDS[Common Data Set] --> CDS_I[Common Data Set I (CDS I) Demographics] CDS --> CDS_II[Common Data Set II (CDS II) Services] CDS_I --> CDS_I_1[• Enrollee Characteristic] CDS_I --> CDS_I_2[• Living Arrangement] CDS_I --> CDS_I_3[• Functional Assessment] CDS_I --> CDS_I_4[• Cognitive Status] CDS_II --> CDS_II_1[• Services provided] CDS_II --> CDS_II_2[• Professional providing service] CDS_II --> CDS_II_3[• Location of Service] </pre>	<p>Thank you for your comments regarding the current need for a standardized assessment instrument and reliable measures, which is our focus on this project. We also appreciate and recognize the Common Data Sets that the NPA has established and acknowledge all its efforts in defining the PACE population. The development team will take these recommendations into consideration going forward.</p>

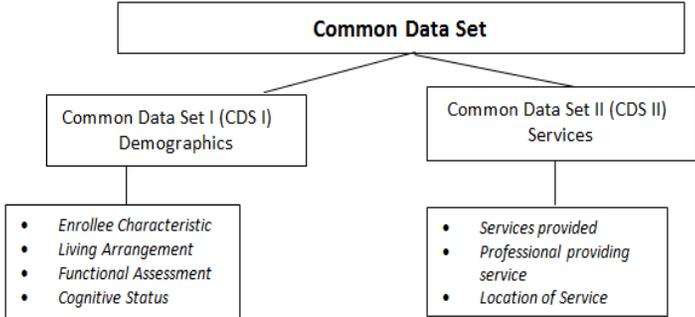
No.	Date Posted	Measure Set or Measure	Text of Comments	Responses						
11.	8/14/2015	General	<p>Additionally, PACE organizations may not generate claims for all services their employees render to PACE enrollees because PACE is a provider-based managed care model. This lack of data may fundamentally impede the ability to calculate certain measures. Much of this data will need to be captured and reported electronically, so it will be important to understand the degree to which POs use and can generate data from their electronic health record (EHR) systems. We encourage CMS to consider the data collection and reporting burden that POs will incur in implementing these measures. We request that CMS be transparent in communicating the purpose of measure reporting (i.e. quality improvement; accountability; public reporting). We also encourage that CMS share trend data and PO-specific performance results that can be used to inform service delivery.</p>	<p>Thank you for your comment to consider the data collection reporting burden required by POs on the selected measures. These considerations are accounted for in our testing phase. Draft measures will be constructed with consideration of the unique programs in mind (e.g., lack of claims). We plan to be more transparent by increasing public comment opportunities and having more input from stakeholders.</p>						
12.	8/14/2015	General	<p>The following table, prepared by the XXXX, presents a list of settings in which PACE participant's reside, attend, obtain medical treatment, and/or visit that has been standardized across PACE. As CMS/Econometrica finalizes the measure specifications, we request that consideration be given to the locations identified on the <i>Place of Service</i> list in order to promote consistency in data reporting and use of existing standardized definitions used in PACE.</p> <p>Table 1. Place of Service</p> <table border="1" data-bbox="569 1003 1362 1403"> <thead> <tr> <th data-bbox="569 1003 787 1068">Place of Service</th> <th data-bbox="787 1003 1362 1068">Place of Service Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="569 1068 787 1312">Office</td> <td data-bbox="787 1068 1362 1312">Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.</td> </tr> <tr> <td data-bbox="569 1312 787 1403">Home</td> <td data-bbox="787 1312 1362 1403">Location, other than a hospital or other facility, where the patient receives care in a private residence.</td> </tr> </tbody> </table>	Place of Service	Place of Service Description	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.	<p>Thank you for your comment and for providing the Place of Service Table as part of your submission. As we finalize the measure specifications, the development team will take this table into consideration in order to promote consistency in data reporting and use of existing standardized definitions used in PACE.</p>
Place of Service	Place of Service Description									
Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.									
Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.									

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			Assisted Living Facility	Congregate residential facility with self-contained living units providing assessment of each resident's needs and on-site support 24 hours a day, 7 days a week, with the capacity to deliver or arrange for services including some health care and other services.	
			Group Home	A residence, with shared living areas, where participants receive supervision and other services such as social and/or behavioral services, custodial service, and minimal services (e.g., medication administration).	
			Temporary Lodging	A short term accommodation such as a hotel, camp ground, hostel, cruise ship or resort where the patient receives care, and which is not identified by any other POS code.	
			Inpatient Hospital	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.	
			Outpatient Hospital	A portion of a hospital which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.	
			Emergency Room - Hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.	
			Skilled Nursing Facility	A facility which primarily provides inpatient skilled nursing care and related services to patients who require medical, nursing, or rehabilitative services but does not provide the level of care or treatment available in a hospital.	
			Nursing	A facility which primarily provides to residents	

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			Facility	skilled nursing care and related services for the rehabilitation of injured, disabled, or sick persons, or, on a regular basis, health-related care services above the level of custodial care to other than mentally retarded individuals.	
			Custodial Care Facility	A facility which provides room, board and other personal assistance services, generally on a long-term basis, and which does not include a medical component.	
			Hospice	A facility, other than a patient's home, in which palliative and supportive care for terminally ill patients and their families are provided.	
			Independent Clinic	A location, not part of a hospital and not described by any other Place of Service code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only.	
			Federally Qualified Health Center	A facility located in a medically underserved area that provides Medicare beneficiaries preventive primary medical care under the general direction of a physician.	
			Inpatient Psychiatric Facility	A facility that provides inpatient psychiatric services for the diagnosis and treatment of mental illness on a 24-hour basis, by or under the supervision of a physician.	
			Psychiatric Facility - Partial Hospitalization	A facility for the diagnosis and treatment of mental illness that provides a planned therapeutic program for patients who do not require full time hospitalization, but who need broader programs than are possible from outpatient visits to a hospital-based or hospital-affiliated facility.	
			PACE Day Center	A facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal	

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13.	8/17/2015	General	<p>General Comments</p> <p>These measures appear to be existing nursing home measures that have only been slightly tweaked to fit the PACE model of care. We feel CMS and Econometrica should look at what quality looks like in PACE vs. other healthcare delivery systems such as ACOs and MCOs and not compare to nursing home populations. We cannot reiterate enough the concept that unlike nursing homes or acute care hospitals – the majority of POs do not have physical custody of the participants who live at home. Many times bad outcomes occur at homes that are associated with poor judgment on part of the participant or caregiver in spite of many educational attempts. We would be in favor of referring to the CDC for some guidance in falls in the community that is more akin to our population and the many challenges we face.</p> <p>Thank you for allowing us input on these measures.</p>	<p>Thank you for your comments and for acknowledging the importance of comparison groups in measurement. We agree that PACE is unique because it is a capitated program with licensed home health, adult day centers, and clinic care, allowing the opportunity to provide truly participant-centered coordinated care for frail elders. The measures chosen for the first round were selected to be adapted to PACE programs and accordingly may be comparable across different care settings.</p>										

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14.	8/17/2015	General	<p>XXXX appreciates CMS' efforts to develop, adapt, and implement quality measures for PACE. XXXX cautions CMS and its contractors as they seek to adapt existing quality measures given the variability in PACE size, participant needs and abilities, and programmatic differences compared to other settings of care (i.e., nursing facilities). For example, the denominator of National Database of Nursing Quality Indicators <i>Falls</i> quality measure is based on patient days in a facility and which is not applicable to PACE. It will be vital to consider the unique aspects of PACE that allow for PACE-specific comparison, while balancing the needs of the National Quality Forum, states, and other stakeholders to compare PACE to other service delivery options (e.g., managed care). We recommend that Econometrica review PACE regulations and guidance documents to glean insight regarding how to best define and identify the PACE participant. We encourage CMS/Econometrica to harmonize the measure definitions of the proposed measure set with the definitions and reporting requirements associated with Level II reporting. This will mitigate the use of varying definitions for the same data element.</p>	<p>Thank you for your comments and for acknowledging the variability and different characteristics across PACE providers within these unique programs. We also appreciate your comment about reviewing PACE regulations and guidance documents to glean insight regarding how to best define and identify PACE participants. The development team is currently taking PACE guidance and regulations into account.</p>
15.	8/17/2015	General	<p>Additionally, PACE quality measures should reflect participants' individual preferences and goals. In PACE, the goals of care for participants are categorized into three broad areas: promotion of longevity, optimization of function, and comfort care. Given the heterogeneity of the PACE population, we encourage to CMS/Econometrica to consider the impact of differences in participant care goals, as well as the characteristics of participants on the measure results.</p>	<p>Thank you for your comment to consider the impact of differences in participant care goals, as well as the characteristics of participants on the measure results. These differences and site characteristics are being accounted for in our testing phase.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
16.	8/17/2015	General	<p>Lastly, as part of the measure testing phase, XXXX recommends that CMS/Econometrica explore and attempt to understand the degree to which standardized and complete data is available from PACE organizations (POs) needed to calculate valid and reliable measures. Unlike nursing homes, home health care agencies and many other provider-based care options for frail elderly, PACE lacks a common assessment instrument and data standard. We have struggled with this within our own state boundaries, and are deeply appreciative of the work done by the National PACE Association to address this need. The National PACE Association has developed a common data platform across all PACE organizations referred to as the <i>Common Data Set (CDS)</i> [see Figure 1]. The CDS contains a standardized dictionary of definitions for data elements to collected – demographics (CDS I) and services (CDS II). The creation of a standardized participant specific data set for will allow for better defining the PACE population; create opportunities to measure the value and performance of PACE; support improved and more efficient benchmarking; distinguish PACE from emerging delivery models; and foster the evolution and adoption of EHRs for PACE.</p> <p><i>Figure 1.</i></p>  <pre> graph TD CDS[Common Data Set] --> CDS_I[Common Data Set I (CDS I) Demographics] CDS --> CDS_II[Common Data Set II (CDS II) Services] CDS_I --> CDS_I_1[• Enrollee Characteristic] CDS_I --> CDS_I_2[• Living Arrangement] CDS_I --> CDS_I_3[• Functional Assessment] CDS_I --> CDS_I_4[• Cognitive Status] CDS_II --> CDS_II_1[• Services provided] CDS_II --> CDS_II_2[• Professional providing service] CDS_II --> CDS_II_3[• Location of Service] </pre>	<p>Thank you for your comments regarding the current need for a standardized assessment instrument and reliable measures, which is our focus on this project. We also appreciate and recognize the Common Data Sets that the NPA has established and acknowledge all its efforts in defining the PACE population. The development team will take these recommendations into consideration going forward.</p>

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17.	8/17/2015	General	<p>Further, as a provider-based managed care model, PACE organizations do not generally generate claims for all services rendered by their employees to PACE enrollees. As such, this lack of data may fundamentally impede the ability to calculate certain measures. For the purpose of reporting, since much of the data will need to be captured electronically, it will be important to understand the degree to which POs use and can generate data from their electronic health record (EHR) systems. We encourage CMS to consider the data collection and reporting burden that POs will incur in implementing these measures. We request that CMS be transparent in communicating the purpose of measure reporting (i.e., quality improvement; accountability; public reporting). We also encourage that CMS share trend data and PO-specific performance results that can be used to inform service delivery.</p>	<p>Thank you for your comment to consider the data collection reporting burden required by POs on the selected measures. These considerations are accounted for in our testing phase. Draft measures will be constructed with consideration of the unique programs in mind (e.g., lack of claims). We plan to be more transparent by increasing public comment opportunities and having more input from stakeholders.</p>						
18.	8/17/2015	General	<p>The following table presents a list of settings in which PACE participant's reside, attend, obtain medical treatment, and/or visit that has been standardized across PACE. As CMS/Econometrica finalizes the measure specifications, we request that consideration be given to the locations identified on the <i>Place of Service</i> list in order to promote consistency in data reporting and use of existing standardized definitions used in PACE.</p> <p><i>Table 1. Place of Service</i></p> <table border="1" data-bbox="562 1016 1369 1391"> <thead> <tr> <th data-bbox="569 1016 814 1052">Place of Service</th> <th data-bbox="814 1016 1362 1052">Place of Service Description</th> </tr> </thead> <tbody> <tr> <td data-bbox="569 1052 814 1300">Office</td> <td data-bbox="814 1052 1362 1300">Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.</td> </tr> <tr> <td data-bbox="569 1300 814 1391">Home</td> <td data-bbox="814 1300 1362 1391">Location, other than a hospital or other facility, where the patient receives care in a private residence.</td> </tr> </tbody> </table>	Place of Service	Place of Service Description	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.	<p>Thank you for your comments and for providing the Place of Service Table as part of your submission. As we finalize the measure specifications, the development team will take this table into consideration in order to promote consistency in data reporting and use of existing standardized definitions used in PACE.</p>
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			Group Home	A residence, with shared living areas, where participants receive supervision and other services such as social and/or behavioral services, custodial service, and minimal services (e.g., medication administration).	
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			Inpatient Hospital	A facility, other than psychiatric, which primarily provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services by, or under, the supervision of physicians to patients admitted for a variety of medical conditions.	
			Outpatient Hospital	A portion of a hospital which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.	
			Emergency Room - Hospital	A portion of a hospital where emergency diagnosis and treatment of illness or injury is provided.	

No.	Date Posted	Measure Set or Measure	Text of Comments		Responses
			Skilled Nursing Facility	A facility which primarily provides inpatient skilled nursing care and related services to patients who require medical, nursing, or rehabilitative services but does not provide the level of care or treatment available in a hospital.	
			Nursing Facility	A facility which primarily provides to residents skilled nursing care and related services for the rehabilitation of injured, disabled, or sick persons, or, on a regular basis, health-related care services above the level of custodial care to other than mentally retarded individuals.	
			Custodial Care Facility	A facility which provides room, board and other personal assistance services, generally on a long-term basis, and which does not include a medical component.	
			Hospice	A facility, other than a patient's home, in which palliative and supportive care for terminally ill patients and their families are provided.	
			Independent Clinic	A location, not part of a hospital and not described by any other Place of Service code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only.	
			Federally Qualified Health Center	A facility located in a medically underserved area that provides Medicare beneficiaries preventive primary medical care under the general direction of a physician.	
			Inpatient Psychiatric Facility	A facility that provides inpatient psychiatric services for the diagnosis and treatment of mental illness on a 24-hour basis, by or under the supervision of a physician.	

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			Psychiatric Facility - Partial Hospitalization	A facility for the diagnosis and treatment of mental illness that provides a planned therapeutic program for patients who do not require full time hospitalization, but who need broader programs than are possible from outpatient visits to a hospital-based or hospital-affiliated facility.	
			PACE Day Center	A facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.	
			Inpatient Substance abuse Facility / Behavioral Care Facility	Including, but not limited to, detox lockdown.	
			Rehabilitation Unit/Facility	A free-standing rehabilitation hospitals and rehabilitation units in acute care hospitals that provides an intensive, multi-disciplinary physical or occupational therapy.	
			In Transport	Use of vehicle to transport participants to/from locations to obtain PACE-related services.	
			Community	Parks, concert halls, theatres, etc.	

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
19.	8/17/2015	General	<p>We concur with the comment document put together on our behalf by XXXX. We write to offer our additional feedback in response to the Centers for Medicare & Medicaid Services' (CMS) request for comment on its four proposed PACE quality measures. We are aware of the increasingly complex nature of measuring quality accurately and providing this information so that it is reliable, valid, and meaningful. XXXX has carefully reviewed the draft quality measures and all related materials provided and provided comments related to the potential implementation of these measures.</p> <p>XXXX program would like to supplement XXXX's position from the perspective of a non-profit and as an independent organization which is not an aligned part of a health care system.</p>	<p>Thank you for your comments. The development team will consider your comments.</p>
20.	8/17/2015	General	<p>XXXX agrees with the general comments XXXX made but would like to highlight the following: We recommend that Econometrica review PACE regulations and guidance documents to glean insight regarding how to best define and identify the PACE participant. We encourage CMS/Econometrica to harmonize the measure definitions of the proposed measure set with the definitions and reporting requirements associated with Level II reporting. This will mitigate the use of varying definitions for the same data element.</p>	<p>Thank you for your comment to review PACE regulations and guidance documents to glean insight regarding how to best define and identify PACE participants. The development team is currently taking PACE guidance and regulations into account.</p>
21.	8/17/2015	General	<p>PACE quality measures should reflect participants' individual preferences and goals. In PACE, the goals of care for participants are categorized into three broad areas: promotion of longevity, optimization of function, and comfort care. Given the heterogeneity of the PACE population, we encourage to CMS/Econometrica to consider the impact of differences in participant care goals, as well as the characteristics of participants on the measure results.</p>	<p>Thank you for your comment to consider the impact of differences in participant care goals, as well as the characteristics of participants on the measure results. These differences and site characteristics are being accounted for in our testing phase.</p>

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22.	8/17/2015	General	<p>The last comment section has particular resonance with XXXX. Due to financial limitations, we originally adopted an EHR which had been adapted from a clinical office perspective. This has not been efficacious for us, does not fit the PACE model needs and we cannot obtain needed quality measure statistics. Pulling data for the current HPMS and DataPACE 2 reports is cumbersome. The ability to benchmark with current HPMS measures is restricted by the use of different definitions across different CMS regions and even within regions. XXXX is in the process of transitioning to a PACE supported EHR. Do we at PACE, believe a standardized common assessment tool similar to MDS is needed or do we use the Common Data Set (CDS) which is evolving into CDS III? XXXX believes, as the market of certified PACE EHR systems has expanded and with the evolution of CDS III, NPA is moving in a direction from which data will be easily assessable, reportable and standardized for comparisons.</p>	<p>Thank you for your comments regarding the current need for a standardized assessment instrument and reliable measures, which is our focus on this project. We also appreciate and recognize the Common Data Sets that the NPA has established and acknowledge all its efforts in defining the PACE population. The development team will take these recommendations into consideration going forward.</p>
23.	8/17/2015	General	<p>The ability to benchmark with current HPMS measures is restricted by the use of different definitions across different CMS regions and even within regions. XXXX believes unless this systemic problem is addressed the proposed measures will suffer the same fate.</p>	<p>Thank you for your comments. The development team focused on developing and testing measure definitions and data collection tools that could be applied consistently across the various PACE sites. Specifically, the data collection instructions and tools for each measure were reviewed for content validity using a panel of experts. In addition, we assessed each measure's reliability by requesting PACE sites to collect the required data and analyzed whether the measures truly performed as expected. Definitions and instructions were consistently followed throughout the process. Changes were made to the measures based on the findings to better ensure that the measures can be implemented in a reliable and valid manner.</p>

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24.	8/17/2015	General	<p>XXXX appreciates the opportunity to publicly comment on the proposed Quality Measures for PACE programs. We recognize the importance of consistency of approach to the measurement of key performance indicators related to falls, pressure ulcers, and hospital readmissions. Additionally, we acknowledge the utility of benchmark data when trying to determine the efficacy of our internal quality improvement initiatives. After reviewing the information provided by Econometrica, Inc. as well as the descriptions and calculation methods for the proposed measures, we respectfully offer the following comments and questions for your consideration.</p> <p>Many PACE programs have monitored quality performance using self-designed measures. It may be challenging for organizations to switch to new measures whose results cannot be mapped or compared to internal historical results.</p>	<p>Thank you for your feedback involving the concern of switching from self-designed quality measures to new quality measures. Our intent is to satisfy the current need for universal measures among all PACE programs and, at the same time, limit any burden the data collection may require on any particular PACE program.</p>
25.	8/17/2015	General	<p>Several of the proposed measures require PACE plans to collect detailed data from hospitals, skilled nursing facilities (SNF), and other settings that do not fall within the direct governance of the program. This may be challenging for PACE organizations, particularly those who have not established interoperability between electronic systems.</p>	<p>Thank you for your comment to consider the data collection reporting burden required by POs on the selected measures.</p>
26.	8/17/2015	General	<p>The inclusion of data from hospital, emergency department, and SNF may not be as impactful to care planning; including data on events that occur in these settings may (have) a negative trend that cannot be directly affected by PACE efforts.</p>	<p>Thank you for your comment in that what happens in other settings cannot be directly affected by PACE efforts. The development team will take these recommendations into consideration going forward.</p>
27.	8/17/2015	General	<p>From a technical perspective, the calculation formulas for several of the measures do not match the narrative descriptions for the numerator and denominator.</p>	<p>Thank you for your comment on the need for the measure calculation formula to match the narrative description. The final measure instructions and specifications will be explicit and consistent on calculation and the narrative description.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
28.	8/17/2015	General	The data collection forms contain more demographic information than is required to compute measure performance. We would like clarification on how this data will be used and what the risk stratification process entails. The measure guidance indicates “ <i>The need and type of case mix adjustment that could be applied to these measures will be addressed at a later stage.</i> ”	Thank you for your comment on the need for participant demographics to be collected. Demographics may become part of a risk or acuity adjustment or stratification to be defined and potentially implemented after data collection has become routine. Having these data available for analysis will allow us to test various adjustment alternatives prior to any decisions being made about adjustment or stratification.
29.	8/17/2015	General	Since PACE is significantly different from other care based options for the elderly, and as CMS/Econometrica develops and reviews the comments please keep in mind the various programs size and differences as compared to other settings of care.	Thank you for your comment reinforcing the unique aspects of the PACE programs. Our intent is to develop measures that are meaningful to the participants and POs, which can be collected nationally in a standardized manner with consistent definitions.
30.	8/17/2015	General	XXXX supports XXXX’s view of recommending that Econometrica review PACE regulations and guidance documents to glean insight regarding how to best define and identify the PACE participant. To avoid duplication and confusion we also encourage CMS/Econometrica to harmonize the measure definitions of the proposed measure set with the definitions and reporting requirements associated with Level II reporting. This will mitigate the use of varying definitions for the same data element.	Thank you for your comments and for acknowledging the variability and different characteristics across PACE providers within these unique programs. We also appreciate your comment about reviewing PACE regulations and guidance documents to glean insight regarding how to best define and identify PACE participants. The development team is currently taking PACE guidance and regulations into account.
31.	8/17/2015	General	We also recommend that CMS/Econometrica understand the degree to which standardized and complete data is available from PACE organizations. Unlike nursing homes, home health care agencies and many other care options for frail elderly, PACE lacks a common assessment instrument and data standard.	Thank you for your comments regarding the current need for a standardized assessment instrument and reliable measures, which is our focus on this project. The development team will take these recommendations into consideration going forward.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
32.	8/17/2015	General	<p>Continuous enrollment specifies the minimum amount of time that a person must be enrolled in a health plan before becoming eligible for a measure. Continuous enrollment allows the health plan enough time to render services in which to be evaluated; it ensures that the quality performance measurement is of the entity that had sufficient time to affect the outcome. Continuous enrollment criteria is applied throughout the quality performance measurement realm and it should also be applied to the quality measures related to the PACE population. A minimum duration of continuous enrollment should be identified.</p>	<p>Thank you for your comment related to enrollment. There have been other comments related to caseload, and further consideration will be given to how it will be defined (e.g., number on the first of the month).</p>
33.	8/17/2015	General	<p>Extending the collection of falls and pressure ulcer data to settings such as hospital and nursing homes for PACE participants should be qualified within the impact of adverse outcomes. Those settings have their own licensures and survey requirements, should consider that PACE influence from a quality perspective could have limitations.</p>	<p>Thank you for your comment related to the data collection of falls and pressure ulcers to other settings. Your suggestions will be considered by our development team. We agree that PACE is unique because it is a capitated program with licensed home health, adult day centers, and clinic care, allowing the opportunity to provide truly participant-centered coordinated care for frail elders. The measures chosen for the first round were selected to be adapted to PACE programs and accordingly may be comparable across different care settings.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
34.	8/11/2015	Falls	<p>1) I want to point out that since falls are collected regardless of location of the fall, i.e., home, out shopping in the community, etc., PO's do their best to mitigate the risk of falls, however, it needs to be taken into account the fact that the PACE environments are not as well controlled to mitigate risk as much as a more controlled environment such as a hospital or even a nursing home facility.</p> <p>2) With that said, it may make more sense to report on a more catastrophic injury related to a fall, consistent with a reporting Level IV or V under the CMS Level II reporting guidelines since falls with that level of injury would require a level II submission and may neutralize for the differences in the populations and living situations</p> <p>3) One other comment regarding falls is that in PACE, participants come to us with compromised functionality and we work with our rehab departments to provide them with therapy to improve their function. As function improves, falls risk may also increase as a previously non-ambulating participant might now be walking short distances with say an assistive device, but may still be at a higher risk for a fall due to that increased mobility.</p> <p>4) Calculation methodology: Caseload size should be replaced with census size as we do not have caseloads</p>	<p>Thank you for your comments on the Falls draft measures.</p> <p>We agree that PACE is unique because while it is a truly participant-centered coordinated care program for frail elders, the goal is for participants to remain in the more independent community and not a dependent care setting like a nursing home.</p> <p>1) We appreciate the relevant aspect of promoting longevity in the community and recognize the opportunity to track falls in any setting as a potential strength of the measure. All POs will be reporting falls from any and all settings, as the goal is to develop measures that could be applied consistently across the various PACE sites.</p> <p>2) The goal is to develop standardized, consistent, rigorously defined draft measures. The potential for the definitions and specifications to be incorporated into future Level II reporting will be determined by CMS.</p> <p>3) We understand that all PACE participants are at risk for falls and are aware of the inherent risk with improved function that results from better, more coordinated care.</p> <p>4) Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward.</p>
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No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
35.	8/14/2015	Falls	<p>Measure Intent XXXX supports the intent of the Fall measures as injury from falls can create serious outcomes for our participants. In that light, we encourage that the measures used by CMS focus on preventing or reducing injury from falls, rather than overall rate of falls. We believe PACE programs will be better served by a second measure that addresses serious injury from falls (Rating of 3-5) or rate of fracture from falls rather than an overall fall rate measure. PACE serves a frail population with the intent of maximizing their independence. In the course of supporting participant autonomy, falls are likely to occur in the population we serve. Preventing injury is what enhances Quality of Life for our participants. In addition, we believe that there may be inherent differences in reporting across States. By focusing on rate of serious injuries or fractures, we presume that there will be more consistency in rates between PACE organizations.</p>	<p>Thank you for your comments. We appreciate the perspective of the participant population and characteristics. The goal is to develop standardized, consistent, rigorously defined draft measures across all PACE organizations in every State. The potential for the definitions and specifications to be incorporated into future Level II reporting will be determined by CMS. Falls prevention will be considered as a measure for future rounds of measure development.</p>
36.	8/14/2015	Falls	<p>Measure Definitions For <u>Fall rate</u>, it would be more appropriate in the PACE setting to use Number of Participants served in a quarter or Members per Month rather than participant days, which is more of an acute or nursing home approach to population measurement.</p>	<p>Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward. The timeframe for reporting (monthly vs. quarterly) is also being considered.</p>
37.	8/14/2015	Falls	<p>For the inclusion criteria - The list of locations included is not inclusive and levels of definitions vary from state to state. This bullet point should be further defined, or should state only "ALL PACE participant falls with injury in any location". Additionally, all PACE sites do not track falls in the inpatient setting. Falls in the inpatient acute setting should be considered an exclusion from the measure.</p>	<p>Thank you for your comment to clarify the location of participants who fall. We are aiming to collect data on ALL participant falls, including those in inpatient/congregate care.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
38.	8/14/2015	Falls	<p>Feasibility of Data Collection The original Data Entry instructions and plan are very cumbersome and would create significant burden for the PACE sites. Several unnecessary data elements were listed such as:</p> <ul style="list-style-type: none"> • Participant age • Participant gender • Who documented the fall • Location of the fall • If the fall was assisted or unassisted <p>None of these elements contribute to the calculation of the proposed measure but would take significant staff time to gather and input, using resource that could be used for other participant care needs or improvement projects. We again request that only the data elements needed to calculate the Quality Measures be required for entry. PACE Organizations typically track this information in their Unusual Occurrence Reporting systems and we feel these additional data elements represent a duplication of effort.</p>	<p>Thank you for your comments on the feasibility of data collection, including the listing of data elements not used in the calculation of the core measures. The feedback we received from PACE organizations and public comments on the availability of data and the time required to extract data for the measures will be part of our considerations on final measure specification. We will take your suggestion to limit the categories of data collection (e.g., assisted falls) into consideration as the measures are refined.</p>
39.	8/17/2015	Falls	<p>Lastly, the specifications indicate that PACE organizations document whether a fall was assisted by clinician or trained family member. XXXX concurs with XXXX in requests insight on what value is offered by reporting an <i>assisted fall</i>.</p>	<p>Thank you for your comments on assisted falls. Assisted falls have been shown to reduce the frequency and severity of injuries resulting from falls. Clearly, we would not intend to reduce focus on fall prevention by collecting data on whether falls were assisted. Both are important safety activities. We will take your comments into consideration when preparing the final specifications of the falls measures.</p>
40.	8/17/2015	Falls	<p>We want to thank CMS and Econometrica in the work you have done on developing some valid quality metrics for PACE organizations. We appreciate the time and effort it takes to undertake such an important and vital project. I think all PACE quality directors want good solid metrics that we can have confidence as well as resources for benchmarking. Here at XXXX we had our medical director, Dr. D. review these metrics as he is a geriatrician with a vast amount of experience with</p>	<p>Thank you for your comments. We appreciate input from Dr. D and considerations related to unintended consequences, which are inherent in measurement.</p> <p>1) We will consider retaining whether or not the fall was assisted without collecting information about who documented the fall.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			<p>research. He is one of the principal investigators in the SUPPORT study (JAMA, NOV 1995) as well as several other studies in the field of geriatrics.</p> <p>Below is a list of concerns about the measures we have identified and their unintended impact on PACE organizations.</p> <p>Falls</p> <ul style="list-style-type: none"> • Not sure it is feasible to assess who documented the fall as within PACE several different disciplines would be responsible for documenting the fall. Many of the front line staff in PACE (Drivers, home health aides, etc.) does report falls so we feel this element is confusing. • We feel that an average monthly census would be better to ascertain on a quarterly basis. Perhaps a better defined method would be use the census on the first day of the month. PACE does not see a lot of variation in census during the month due to enrollments being limited to the first of the month and disenrollment at the end of the month. The difference between actual census and average census is statistically insignificant. • The purpose of determining if the fall was assisted by clinician or trained family member. The participants may live or be with a variety of people in the community so it would be impossible to train everyone who may be with that participant at the time. CMS/Econometrica must realize that the PO does not have physical custody of the participant at all times. Also the definition of clinician implies this role is more akin to a nurse or member of rehab rather than a C.N.A. or driver. Would like to see if fall was assisted or not in this metric. 	<p>2) Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward. The timeframe for reporting (monthly vs. quarterly) is also being considered.</p> <p>3) Thank you again for submitting your comments. We understand the difficulty in assessing who documented the fall. We will consider retaining whether or not the fall was assisted without collecting information about who reported the fall as the measure is refined.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
41.	8/17/2015	Falls	<p><u>Feasibility of Data Collection</u> XXXX is unclear of the rationale for documenting who reported the fall (e.g., MD, RN, etc.). It is our sense that this data element does not provide meaningful information and should be removed as it creates an undue administrative burden. We recommend that date and time be reported rather than who reported the fall as these elements will aid in quality improvement efforts (i.e., trending and identification of frequent fallers).</p>	<p>Thank you for your comments. We understand the concern for burden of collecting who reported the fall. We will consider retaining whether or not to collect information about who reported the fall. One of the important parts of testing is identifying the need for clarification on which data elements add the most value.</p>
42.	8/17/2015	Falls	<p>Given the number of participants living alone in the community, it is likely that incidental falls will be underreported due to participant concern of relinquishing independence and potential placement in an institutional setting of care. If CMS elects to maintain this reporting requirement, XXXX recommends that “participant/caregiver” be added to the list of <i>documented by</i> to promote reporting of falls in the home.</p>	<p>Thank you for your comment on possible underreporting. One of the important parts of testing is the identification of the need for clarification, and these categories can be added if the information continues to be collected as constructed.</p>
43.	8/17/2015	Falls	<p>XXXX perceives an administrative burden associated with calculating the daily participant census for PACE organizations. This proposed calculation approach is often used for nursing home measures and should not be applied in PACE. We recommend that CMS/Econometrica consider a feasible method for determining the quarterly census value (i.e., per member per month OR total participants served in quarterly).</p>	<p>Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward. The timeframe for reporting (monthly vs. quarterly) is also being considered.</p>
44.	8/17/2015	Falls	<p>Lastly, the specifications indicate that PACE organizations document whether a fall was assisted by clinician or trained family member. Inclusion of these data elements may encourage a clinician and/or family member to aid in a participant fall rather than mitigate/prevent a fall occurrence as an unintended consequence. XXXX requests insight on what value is offered by reporting an <i>assisted fall</i>.</p>	<p>Thank you for your comment on assisted falls. Assisted falls have been shown to reduce the frequency and severity of injuries resulting from falls. Clearly, we would not intend to reduce focus on fall prevention by collecting data on whether falls were assisted. Both are important safety activities. We will take your comments into consideration when preparing the final specifications of the falls measures.</p>

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45.	8/17/2015	Falls	<p><u>Calculation Methodology</u> With regard to the stratification variables, we request insight on how CMS will operationalize the term “caseload size.” We recommend that “caseload size” be replaced with “census size”. Given the varying size of POs census, stratifying based on census size may ensure comparable results.</p>	<p>Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward. The timeframe for reporting (monthly vs. quarterly) is also being considered.</p>
46.	8/17/2015	Falls	<p>As CMS/Econometrica finalizes the stratification variables, we recommend stratifying the measure results by location of fall and injury level.</p>	<p>Thank you for your comment. Your suggestion of stratifying measure results by location of fall and injury level will be considered.</p>
47.	8/17/2015	Falls	<p><u>Feasibility of Data Collection</u> XXXX is unclear of the rationale for documenting who reported the fall (e.g., MD, RN, etc.). It is our sense that this data element does not provide meaningful information and should be removed as it creates an undue administrative burden. We recommend that date and time be reported rather than who reported the fall as these elements will aid in quality improvement efforts (i.e., trending and identification of frequent fallers). XXXX additional comment: We believe the root cause analysis includes date, time (can be problematic, especially time, as each participant has their own living patterns including sleeping, napping, and medication schedules) and location among other variables. We do not believe it is appropriate when reporting a statistical measure for quality/benchmarking purposes that root cause variables be included. For stratification I do agree with location and believe a table as done with PU would be user friendly.</p>	<p>Thank you for your comments. We understand the concern for burden of collecting who reported the fall. We will consider retaining whether or not to collect information about who reported the fall. One of the important parts of testing is identifying the need for clarification on which data elements add the most value.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
48.	8/17/2015	Falls	<p>XXXX perceives an administrative burden associated with calculating the daily participant census for PACE organizations. This proposed calculation approach is often used for nursing home measures and should not be applied in PACE. We recommend that CMS/Econometrica consider a feasible method for determining the quarterly census value (i.e., per member per month OR total participants served in quarterly).</p> <p>Lastly, the specifications indicate that PACE organizations document whether a fall was assisted by clinician or trained family member. Inclusion of these data elements may encourage a clinician and/or family member to aid in a participant fall rather than mitigate/prevent a fall occurrence as an unintended consequence. XXXX requests insight on what value is offered by reporting an assisted fall. XXXX believes this is another example of a Root Cause Analysis variable.</p>	<p>Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward. The timeframe for reporting (monthly vs. quarterly) is also being considered.</p> <p>Regarding your comment on assisted falls, we would like to point out that assisted falls have been shown to reduce the frequency and severity of injuries resulting from falls. Clearly, we would not intend to reduce focus on fall prevention by collecting data on whether falls were assisted. Both are important safety activities. We will take all your comments into consideration when preparing the final specifications of the falls measures.</p> <p>The value of collecting who assisted the fall will be considered as the measure is refined. We encourage diagnostic exercises, such as RCA, for falls.</p>
49.	8/17/2015	Falls	<p>Given the number of participants living alone in the community, it is likely that incidental falls will be underreported due to participant concern of relinquishing independence and potential placement in an institutional setting of care. If CMS elects to maintain this reporting requirement, XXXX recommends that "participant/caregiver" be added to the list of <i>documented by</i> to promote reporting of falls in the home.</p>	<p>Thank you for your comment on possible underreporting. One of the important parts of testing is identifying the need for clarification, and these categories may be added if the information continues to be collected as constructed.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
50.	8/17/2015	Falls	<p>Lastly, the specifications indicate that PACE organizations document whether a fall was assisted by clinician or trained family member. Inclusion of these data elements may encourage a clinician and/or family member to aid in a participant fall rather than mitigate/prevent a fall occurrence as an unintended consequence. XXXX requests insight on what value is offered by reporting an assisted fall. XXXX believes this is another example of a Root Cause Analysis variable.</p>	<p>Thank you for your comment on assisted falls. Assisted falls have been shown to reduce the frequency and severity of injuries resulting from falls. Clearly, we would not intend to reduce focus on fall prevention by collecting data on whether falls were assisted. Both are important safety activities. We will take all your comments into consideration when preparing the final specifications of the falls measures. The value of collecting who assisted the fall will be considered as the measure is refined. We encourage diagnostic exercises, such as RCA, for falls.</p>
51.	8/17/2015	Falls	<p>As CMS/Econometric finalizes the stratification variables, we recommend stratifying the measure results by location of fall and injury level. XXXX strongly concurs with this last statement.</p>	<p>Thank you for your comment. Your suggestion of stratifying measure results by location of fall and injury level will be considered.</p>
52.	8/17/2015	Falls	<p>Measure Intent XXXX supports the intent of the Fall Rate measure as evidence suggests that falls are one of the most common adverse patient events. We also support the intent of the Falls with Injury Rate measure to prevent the occurrence of falls that result in fatal and non-fatal injuries among PACE participants. In the future, we recommend that CMS/Econometrica consider developing a Fall Risk Assessment & Prevention measure that can be paired with this measure to assess POs ability to mitigate falls among those at risk.</p>	<p>Thank you for your comments. We appreciate this perspective, and consideration will be given to future development of a draft measure for falls prevention. We also want to acknowledge your comment on the Falls and Falls With Injury rates. Certainly the harm evident in a fall with injury is a concern for health care providers. Falls with injury are rare relative to total falls and do not capture the psychological distress that may follow a fall without injury. The quality improvement and prevention activities for falls generally focus on the prevention of falls rather than the prevention of injuries.</p>

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53.	8/17/2015	Falls	To promote parsimony within the measure set, we recommend that the data elements required for the Falls Rate and Falls with Injury measures be combined and that the results be reported as a single measure – Falls with Injury.	Thank you for your comment. We will take your recommendation, and the desirability of a parsimonious measure set, into consideration when preparing the final specifications of the falls measure specifications. The intent was to capture all falls as well as falls that result in injury. Total falls is an important measure because falls without physical injury are informative. Participants who fall without injury may suffer psychological consequences from the fall and any fall predisposes the participant to a future fall, which might result in injury. The approach to reducing injurious falls is to prevent all falls. If this measure is e-specified for electronic collection, there will be one (1) measure (i.e., falls) that will also collect the injury information.
54.	8/17/2015	Falls	<p>Measure Definitions</p> <p>In reviewing the definition of “fall”, we note that CMS/Econometrica has broadened the definition compared to the Level II reporting guidance definition. Given the health status and complexity of PACE participants, we recommend that when analyzing the measure results that CMS/Econometrica considers confounding conditions and/or circumstances which may increase the risk of participant falls (i.e., ADLs, cognition, and medical complexity). An assessment of the impact of these characteristics will inform the need for the future risk adjustment. Additionally, we recommend that CMS/Econometrica reference the CMS-funded report Outcome-based Continuous Quality Improvement System and Core Outcome and Comprehensive Assessment (COCOA-B) Data Set for the Program of All-Inclusive Care for the Elderly (PACE) report as it describes a preliminary method for risk adjusting outcome data so comparisons can be made among PACE programs.</p>	Thank you for your comments. We focused on developing and testing measure definitions and data collection tools that could be applied consistently across the various PACE sites. We acknowledge that the definition is not currently aligned with the Level II reporting, and this will be adjudicated in the future, as necessary.

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55.	8/17/2015	Falls	<p>Feasibility of Data Collection XXXX is unclear of the rationale for documenting who reported the fall (e.g., MD, RN, etc.). It is our sense that this data element does not provide meaningful information and should be removed as it creates an undue administrative burden. We recommend that date and time be reported rather than who reported the fall as these elements will aid in quality improvement efforts (i.e., trending and identification of frequent fallers).</p>	<p>Thank you for your comments. We understand the concern for burden of collecting who reported the fall. We will consider retaining whether or not to collect information about who reported the fall. One of the important parts of testing is identifying the need for clarification on which data elements add the most value.</p>
56.	8/17/2015	Falls	<p>Given the number of participants living alone in the community, it is likely that incidental falls will be underreported due to participant concern of relinquishing independence and potential placement in an institutional setting of care. If CMS elects to maintain this reporting requirement, XXXX recommends that “participant/caregiver” be added to the list of <i>documented by</i> to promote reporting of falls in the home.</p>	<p>Thank you for your comment on possible underreporting. One of the important parts of testing is identifying the need for clarification, and these categories can be added if the information continues to be collected as constructed.</p>
57.	8/17/2015	Falls	<p>XXXX perceives an administrative burden associated with calculating the daily participant census for PACE organizations. This proposed calculation approach is often used for nursing home measures and should not be applied in PACE. We recommend that CMS/Econometrica consider a feasible method for determining the quarterly census value (i.e., per member per month OR total participants served in quarterly).</p>	<p>Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward. The timeframe for reporting (monthly vs. quarterly) is also being considered.</p>
58.	8/17/2015	Falls	<p>Lastly, the specifications indicate that PACE organizations document whether a fall was assisted by clinician or trained family member. Inclusion of these data elements may encourage a clinician and/or family member to aid in a participant fall rather than mitigate/prevent a fall occurrence as an unintended consequence. XXXX requests insight on what value is offered by reporting an <i>assisted fall</i>.</p>	<p>Thank you for your comment on assisted falls. Assisted falls have been shown to reduce the frequency and severity of injuries resulting from falls. Clearly, we would not intend to reduce focus on fall prevention by collecting data on whether falls were assisted. Both are important safety activities. We will take your comments into consideration when preparing the final specifications of the falls measures.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
59.	8/17/2015	Falls	<p>Calculation Methodology</p> <p>With regard to the stratification variables, we request insight on how CMS will operationalize the term “caseload size.” We recommend that “caseload size” be replaced with “census size”. Given the varying size of POs census, stratifying based on census size may ensure comparable results.</p>	Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward. The timeframe for reporting (monthly vs. quarterly) is also being considered.
60.	8/17/2015	Falls	As CMS/Econometrica finalizes the stratification variables, we recommend stratifying the measure results by location of fall and injury level.	Thank you for your comment. Your suggestion of stratifying measure results by location of fall and injury level will be considered.
61.	8/17/2015	Falls	There is an apparent discrepancy between the measure formula and the numerator statement. The measure formula states (<i>Number of falls * 1000</i>) whereas the numerator statement indicates <i>Participants in the PACE program who experienced a fall during the month</i> . It is unclear if the numerator is counting distinct participants or distinct falls.	Thank you for your comment regarding the definition of the numerator of the falls measure. The correct concept is the number of falls, not the number of participants who fell. This will be clarified in the final specifications.
62.	8/13/2015	Falls and Falls With Injury	Falls verses falls with injuries: We already address all falls including those with injuries, will we be doing something different with the falls now. I am unclear on what differently is wanted. Will there be another in-service before this is rolled out?	Thank you for your comment and question. You asked for clarification on falls versus falls with injury. The initial descriptive and instructional webinars were held prior to testing of the measures. Regarding the reporting of falls, the Level II reporting will continue separately until a decision is made by CMS and any related guidance is sent.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
63.	8/17/2015	Falls and Falls With Injury	<p><u>Measure Intent</u> XXXX supports the intent of the <i>Fall Rate</i> measure as evidence suggests that falls are one of the most common adverse patient events. We also support the intent of the <i>Falls with Injury Rate</i> measure to prevent the occurrence of falls that result in fatal and non-fatal injuries among PACE participants.</p> <p>In the future, we recommend that CMS/Econometrica consider developing a <i>Fall Risk Assessment & Prevention</i> measure that can be paired with this measure to assess POs ability to mitigate falls among those at risk.</p> <p>To promote parsimony within the measure set, we recommend that the data elements required for the Falls Rate and Falls with Injury measures be combined and that the results be reported as a single measure - Falls with Injury.</p>	<p>Thank you for the comments. We appreciate this perspective, and consideration will be given to future development of a draft measure for falls prevention.</p> <p>We also want to acknowledge your comment on the Falls and Falls With Injury rates. Certainly the harm evident in a fall with injury is a concern for health care providers. Falls with injury are rare relative to total falls and do not capture the psychological distress that may follow a fall without injury. The quality improvement and prevention activities for falls generally focus on the prevention of falls rather than the prevention of injuries.</p> <p>We will also take your recommendation, and the desirability of a parsimonious measure set, into consideration when preparing the final specifications of the falls measure specifications. The intent was to capture all falls as well as falls that result in injury. If this measure is e-specified for electronic collection, there will be one (1) measure (i.e., falls) that will also collect the injury information.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
64.	8/17/2015	Falls and Falls With Injury	<p><u>Measure Definitions</u></p> <p>In reviewing the definition of “fall”, we note that CMS/Econometrica has broadened the definition compared to the Level II reporting guidance definition. Given the health status and complexity of PACE participants, we recommend that when analyzing the measure results that CMS/Econometrica considers confounding conditions and/or circumstances which may increase the risk of participant falls (i.e., ADLs, cognition, and medical complexity). An assessment of the impact of these characteristics will inform the need for the future risk adjustment. Additionally, we recommend that CMS/Econometrica reference the CMS-funded report <i>Outcome-based Continuous Quality Improvement System and Core Outcome and Comprehensive Assessment (COCOA-B) Data Set for the Program of All-Inclusive Care for the Elderly (PACE)</i> report as it describes a preliminary method for risk adjusting outcome data so comparisons can be made among PACE programs.</p>	<p>Thank you for your comments. We focused on developing and testing measure definitions and data collection tools that could be applied consistently across the various PACE sites. We acknowledge that the definition is not currently aligned with the Level II reporting, and this will be adjudicated in the future, as necessary.</p>
65.	7/21/2015	Falls and Falls With Injury	<p><u>Measure Information Form:</u></p> <p>There are concerns with information that is NOT captured in Table 3 under Section B. “Measure Information Form for Falls With Injury Rate”.</p> <ul style="list-style-type: none"> • The data captures the status of the participant 24 hours after the fall/injury. • Injuries to the head may not produce immediate effects that are visible on a CT scan. Thus, a participant who suffered a trauma to the head may receive a fall “injury level” captured as “None=1”, particularly if no one was there to observe the event or the participant has no memory for the events related to the fall. • However, the aftermath of inflammation, diffuse axonal injury, and intracellular response to a fall injury, that includes trauma to the brain, may not happen until days or weeks <i>after</i> the injury. • The American Heart Association has determined that there 	<p>Thank you for your comments on the Falls With Injury measure Information Form. We concur that head injuries resulting from a fall may not be apparent within 24 hours and that serious future conditions may result from a fall with injury to the head. Your suggestion for capturing “suspected trauma or impact to the head” has merit. We will consider adding your language as a separate category of no injury within 24 hours.</p> <p>Thank you as well for your suggestion to add Vision Exams and Vision Improvement to the clinical practice guidelines. We appreciate your providing this detailed information and the citations for reference.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			<p>is a 10-fold increased risk of stroke within 3 months of a single traumatic brain injury (TBI), indicating that the brain's vasculature is in a highly vulnerable state following injury to the head/brain. This increased risk is still significant 1 year and 5 years post-injury.</p> <p>http://stroke.ahajournals.org/content/early/2011/07/28/STROKEAHA.111.620112.abstract</p> <ul style="list-style-type: none"> • For the frail elderly, who live with weakened vasculature, these rates may be even higher and are not necessarily being captured, reported, or related back to a previous fall injury. • Current research indicates that repetitive trauma to the head increases the risk of developing chronic traumatic encephalopathy and other forms of dementia. <p>http://www.bu.edu/cte/about/frequently-asked-questions/. A previous fall, history of falls, or any repetitive or cumulative injuries (e.g. domestic violence, assaults, MVAs) may be factors that trigger the degeneration of brain tissue. A single fall in an individual with a history of cumulative injuries to the brain may contribute to the sudden onset of "dementias of unknown origin".</p> <ul style="list-style-type: none"> • Data Collection on Injury Level provides an excellent opportunity to better capture individuals who have had an impact to the head that may lead to more serious complications. • The inclusion criteria MUST be expanded to include the following information to assist in more intensive medical monitoring and treatment, as appropriate: <ul style="list-style-type: none"> ○ <i>"Incident involved an observed, reported, noticeable or suspected trauma or impact to the head"</i> (regardless of CT findings within 24 hours of injury and an Injury Level of None=1). • Adding this additional level of analysis opens avenues for capturing data related to complications due to head trauma. <p>Measure Justification Form: Clinical Practice Guideline</p>	

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			<p>Recommendations</p> <p>Overall, the discussion of “Rationale” was helpful in providing a context for injuries to the head, including potential cognitive impairment, emotional distress related to a fall and subsequent increased risk of future falls and the need for safety and prevention. Prevention measures were noted to include fall safety education programs; exercise to improve mobility, strength and balance; medication reviews and management; and home safety assessments and modifications.</p> <p>However, one other important recommendation by the CDC (http://www.cdc.gov/HomeandRecreationalSafety/images/CDC_Guide-a.pdf) was not included:</p> <ul style="list-style-type: none"> • Vision Exams and Vision Improvement, specifically, having eyes checked at least once a year and routinely updating eyeglasses or other assistive devices. 	
66.	8/14/2015	Falls and Falls With Injury	For Falls with Injury, XXXX supports the Injury Level definitions.	Thank you for your comment and support.
67.	8/17/2015	Falls and Falls With Injury	In conjunction with XXXX, XXXX also supports the intent of the <i>Falls with Injury Rate</i> measure to prevent the occurrence of falls that result in fatal and non-fatal injuries among PACE participants.	Thank you for your comment and support.
68.	8/17/2015	Falls and Falls With Injury	We concur with their recommendation that the data elements required for the <i>Falls Rate</i> and <i>Falls with Injury</i> measures be combined and that the results be reported as a single measure.	Thank you for your comment. We will take your recommendation, and the desirability of a parsimonious measure set, into consideration when preparing the final specifications of the falls measure specifications.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
69.	8/17/2015	Falls and Falls with Injury	We also request that the definition of a “fall” be in agreement with that of the Level II reporting to decrease confusion among plans as CMS/Econometrica has broadened the definition. XXXX is unclear on why who reported the fall is important. This presents an undue administrative burden and that information is irrelevant to the prevention and care planning of the occurrence. Reporting the falls with injury provides more concrete data on adverse patient events.	Thank you for your comments. We focused on developing and testing measure definitions and data collection tools that could be applied consistently across the various PACE sites. We acknowledge that the definition is not currently aligned with the Level II reporting, and this will be adjudicated in the future, as necessary. We understand the concern for burden of collecting who reported the fall. We will consider whether or not to continue collecting information about who reported the fall.
70.	8/3/2015	Pressure Ulcers	It appears that the measure is based upon current OASIS Home Care assessments that are performed every 60 days since the measure asked if a Risk Assessment had been conducted within the past 60 days. We do not perform every 60 day assessments. Assessments are completed every 6 months unless there is a change of status.	Thank you for your comment and observation that pressure ulcer risk assessments are conducted every 60 days in home care but only every 6 months in PACE programs. We will consider your comment as we refine the PACE quality measures and consider alignment with other federally funded programs.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
71.	8/11/2015	Pressure Ulcers	<p>1) The numerator and denominator are ambiguous. It is not clear which participants and at what time a PU should be collected.</p> <p>2) There should be a consistent risk measurement tool recommended PO's use so there is consistency with how PO's are measuring risk.</p> <p>3) Only newly acquired PU's should be collected once enrolled in our program.</p> <p>4) Only information from the most recent risk assessment should be used in the calculation</p>	<p>Thank you for your comments on the Pressure Ulcers draft measures.</p> <p>1) We will examine numerators and denominators carefully before final measure specifications are made and eliminate ambiguity. One of the important parts of testing is identifying the need for clarification.</p> <p>2) Initially flexibility was intended, as opposed to prescription of a risk management tool for POs, but implementation of a consistent tool will be considered.</p> <p>3) No, they are prevalent ulcers. Participants who transfer in with an existing pressure ulcer would be excluded.</p> <p>4) We will examine the clarity, as the intent is from the most recent risk assessment.</p>
72.	8/13/2015	Pressure Ulcers	I have some concerns with the Rate and preventions of pressure ulcers. Will we take in consideration that someone has a debilitating disease and due to poor intake skin status may change?	Thank you for the question regarding exclusions from pressure ulcer prevention. There are no exclusions for change in skin status due to poor intake. It is intended to capture all incident, or PACE-Acquired Pressure Ulcers.
73.	8/14/2015	Pressure Ulcers	<i>Measure Intent</i> XXXX supports the intent of the <i>Pressure Ulcer (PU) Prevalence Rate</i> measure to determine the number of PACE participants with the presence of a PU.	Thank for your comment and support of the intent of this important draft measure.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
74.	8/14/2015	Pressure Ulcers	<p><u>Measure Definitions</u> XXXX has concerns about how to operationalize the definition of a documented pressure ulcer of any stage across PACE. Is this defined as a documented pressure ulcer that has been diagnosed?</p> <p>Is this a point in time measure of a Pressure Ulcer that is present at end of quarter? Or a Pressure Ulcer Documented at any time in the quarter but may have resolved?</p> <p>For the Denominator, XXXX has concerns about the use of the term “average Number of PACE participants”? We suggest that this should be further defined as “Total Participants served in the Quarter” if we are capturing all Pressure Ulcers from the Quarter or “Number of Participants served on the last day of the quarter” if we are capturing active Pressure Ulcers at the end of the Quarter.</p> <p>The later Denominator is defined as “Number of PACE Participants whose medical records were reviewed for evidence of a PU at the end of month”. Please clarify if this is a total population measure or a targeted population measure.</p>	<p>Thank you for your questions on the definition of reportable pressure ulcers. Yes, pressure ulcers are defined as being documented in the medical record. In the feasibility study, we asked for data on all stages of pressure ulcers, including Stage 1. No determination has been made yet as to whether all stages will be included in the final measure.</p> <p>The PACE measure is a prevalence measure and includes any pressure ulcer existing within the quarter, not on the last day of the quarter. Include pressure ulcers that have resolved and stage them as the worst stage during their existence.</p> <p>We agree that the total number of participants served during the quarter would be an appropriate denominator and we will investigate your recommendation further. The feasibility study guidance to include in the denominator all participants whose records had been reviewed addressed the fact that not all PACE sites that volunteered for the study were able to report data on all participants due to the short duration of the study. Final instructions will not use this term. Yes, ulcers—no matter whether acquired before enrollment in PACE or after becoming a PACE participant—and the quality of skin care for PACE participants (PACE-acquired pressure ulcers) were important concepts to capture. The denominator for both rates is the number of PACE participants during the reporting period.</p>
75.	8/14/2015	Pressure Ulcers	XXXX supports the removal of DTI as reportable event.	Thank you for your comment regarding deep tissue injury (DTI).

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
76.	8/14/2015	Pressure Ulcers	<p><u>Feasibility of Data Collection</u> This is difficult to determine until the measure is more clearly defined. XXXX would again like to encourage development of quarterly measurements and reporting.</p>	<p>Thank you for your comment. One of the important parts of testing is identifying the need for clarification. We are moving forward with testing activities that will help us determine an appropriate timeline for reporting.</p>
77.	8/14/2015	Pressure Ulcers	<p>We would also recommend requiring only necessary data elements to decrease the significant burden for the PACE sites. Several unnecessary data elements were listed such as:</p> <ul style="list-style-type: none"> • Participant age • Participant gender • Total number of Pressure Ulcers acquired after PACE enrollment <p>None of these elements contribute to the calculation of the proposed measure but would take significant staff time to gather and input, using resource that could be used for other participant care needs or improvement projects. We again request that only the data elements needed to calculate the Quality Measures be required for entry.</p>	<p>Thank you for your comment regarding burden. The feedback we received from the PACE organizations and public comments on the availability of data and the time required to extract data for the measures will be part of our considerations on final measure specification. We will take your suggestion to limit the categories of data collection into consideration as the measures are refined.</p>
78.	8/14/2015	Pressure Ulcers	<p><u>Measure Intent</u> XXXX supports the intent of the <i>Pressure Ulcer Risk Assessment measure</i> to determine appropriate care planning for PACE participants at risk of a PU.</p>	<p>Thank for your comment and support of the intent of this important draft measure.</p>
79.	8/14/2015	Pressure Ulcers	<p>As written, the denominator appears to represent participants with pressure ulcers after the exclusions are factored. XXXX has concerns that this definition does not address the intent of the measure.</p>	<p>Thank you for your comment on Pressure Ulcer Risk Assessment. One of the important parts of testing is identifying the need for clarification, including correctly specifying the denominator. You are correct that the prevention measure uses a denominator of Participants With a Pressure Ulcer. We will consider your concern. As the PACE measures are refined, the denominator will be clarified.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
80.	8/14/2015	Pressure Ulcers	<u>Measure Definitions</u> XXXX has concerns about how to operationalize the definition of a documented pressure ulcer risk assessment across PACE. To ensure the consistency of the measure results, XXXX supports the XXX recommendation of a structured, systematic pressure ulcer risk assessment tool be specified (e.g. Braden risk assessment tool). Additionally, the measure would need to define what score indicates that a participant is at risk and how we would determine that a plan is in place.	Thank you for your comment regarding measure definitions. While it is possible to capture the tool used for risk assessment, and the Braden Risk Assessment tool is the most commonly used, identification of a threshold score for the determination of “at risk” status may vary legitimately across PACE populations. These issues may be considered if a PACE measure for pressure ulcer risk status and prevention is undertaken in a future project year.
81.	8/14/2015	Pressure Ulcers	For the Numerator statement, the second point of “participants who are at risk have a pressure ulcer prevention plan of care” is the best definition for the PACE population.	Thank you for your comment.
82.	8/14/2015	Pressure Ulcers	For data integrity, the denominator should be changed from participants with a documented PU to participants who are documented as being at risk for a PU. With the current definitions, there is misalignment between the numerator and the denominator. In some cases, a participant may be at risk and have a skin care plan of care in place but not have a PU at this time. This scenario (which is common to PACE) would create an invalid percentage based on the current definitions.	Thank you for your comment regarding data integrity. Your suggestion will be considered when the pressure ulcer prevention measure is finalized. One of the important parts of testing is identifying the need for clarification.
83.	8/14/2015	Pressure Ulcers	We would appreciate clarification on the value of determining the number of days since last Pressure Ulcer Risk assessment. Once a participant is deemed to be at risk for Pressure Ulcers, what is to be gained by repeated risk screenings? A more meaningful measure might be that all participants have had risk screening at least every six months (or within some other time frame).	Thank you for your observation that pressure ulcer risk assessments are conducted every 60 days in home care but only every 6 months in PACE programs. Your comment will be considered as we finalize the PACE quality measures.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
84.	8/14/2015	Pressure Ulcers	<p><u>Feasibility of Data Collection</u> XXXX has concerns about the burden of data collection in this area. It is not possible to run automated reports off a plan of care in most EHR's. For most PACE sites, determining plan of care would require manual chart audits which are cumbersome and time-consuming. Any time taken in this effort takes away from direct patient care. Assessing implementation of the plan would require manual chart review for documentation of plan <u>and</u> documentation of home visits to ensure interventions and devices are in place. Most prevention plans require multiple elements. Would all interventions need to be assessed as implemented to count? For example: If a therapeutic support surface were ordered but the participant did not always agree to using it, would that count as implemented or not? Or if a turning and positioning or toileting schedule were recommended but the caregiver did not chart it, would that be considered implemented or not?</p>	<p>Thank you for your comments. We focused on developing and testing measure definitions and data collection tools that could be applied consistently across the various PACE sites. Part of our testing efforts included determining whether it was feasible to collect these data and the amount of time required to compile the information. Ideally, many of these measures could be collected through extraction from an electronic health record system to minimize the burden of reporting these data. Additional work is required to enable this data collection strategy. You asked if all interventions need to be assessed as implemented, even if not charted out by the caregiver. The answer is yes. If your data show that the plan was implemented, we would assume that it was implemented unless there was information that it was not. If an implementation was documented in the clinical record, we assume that it was implemented even if the participant was not using the prevention element.</p>
85.	8/14/2015	Pressure Ulcers	<p>XXXX would offer that measuring the number of participants who are at risk for Pressure ulcer (Braden score 16 or less) who have a prevention plan in place may be a valuable quality measure to report although manual chart reviews to determine this would be an onerous undertaking for PACE organizations.</p>	<p>Thank you for your comment. While it is possible to capture the tool used for risk assessment, and the Braden Risk Assessment tool is the most commonly used, identification of a threshold score for the determination of "at risk" status may vary legitimately across PACE populations. This might be considered as the PACE measure for pressure ulcers is refined.</p>
86.	8/17/2015	Pressure Ulcers	<p>Pressure Ulcer Prevention Rate</p> <ul style="list-style-type: none"> We feel a PU incidence rate may be a more appropriate measure than prevalence rate. 	<p>Thank you for your comments. 1) We appreciate the consideration of an incident rate vs. prevalence. The two (2)</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			<ul style="list-style-type: none"> • We do not feel it is feasible to collect this information as suggested; we have read and agree with XXXX's position on this measure. • We feel there has been some misunderstanding in the development of the measure concerning Pressure Ulcer risk assessments. PACE participants are not mandated by regulation to conduct monthly assessments like a nursing home. We do not feel it is appropriate to conduct a risk assessment monthly – these should follow a scheduled re-assessment at 6 month intervals (some POs will do more often if they have this as a care plan intervention but would be hard to tease this information out for measurement across all POs) • The Braden scale is a valid and reliable tool for hospitals and nursing homes. There is currently no valid tool for frail elders living in the community. Many pressure ulcers that occur in the community have causes so widely and varied (caregiver not following recommended plan of care, footwear, sitting surfaces, etc.) • We would support a measure of participant's who scored high risk on Braden scale (etc.) having a care plan but otherwise this would be hard to measure 	<p>rates answer different questions. The incident rate, including pressure ulcers that worsen, reflects current quality of care, assuming that pressure ulcers are preventable. The prevalence measure reflects the ongoing demand for care of pressure ulcers and reflects one aspect of the health status of participant populations.</p> <p>2) We appreciate your consideration and feedback.</p> <p>3) Thank you for your comments on the pressure ulcer prevention rate. We understand that PACE sites are mandated to conduct health assessments of PACE participants at 6-month intervals. We will take your comment into consideration when we prepare the final measure specifications.</p> <p>4) Thank you for pointing out that a validated pressure ulcer risk assessment tool for the PACE population is not available. However, the Braden Scale is used both in long-term care and in home-care patients.</p> <p>5) We understand your concern about capturing assessment and prevention activities in the medical record. The feasibility study demonstrated that currently it would be difficult for all PACE organizations to report on these measures.</p> <p>4). Thank you for this feedback as well. One of the important parts of testing is identifying the need for clarification, and the testing will also determine which measures will be implemented.</p>
87.	8/17/2015	Pressure Ulcers	<p>Measure Intent XXXX supports the intent of the Pressure Ulcer (PU) Prevalence Rate measure to determine the number of PACE participants with the presence of a PU.</p>	<p>Thank for your comment and support of the intent of this important draft measure.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
88.	8/17/2015	Pressure Ulcers	<p>Measure Definitions</p> <p>We are unable to determine the target population of this measure due to the ambiguity of the numerator and denominator statements. We request that CMS/Econometrica clarify the denominator. In the denominator, which participants comprise the population available for review? Does the denominator include “all the participants” or “participants whose time it is to be reviewed in the month based on some pre-determined criteria”? Lastly, we seek clarity regarding the criteria on which the number of participants is selected each month for review (e.g., PU risk assessment, problem list, clinical visit). The measure’s lack of specificity regarding frequency/method of assessment limits POs ability to consistently collect and report the necessary data elements.</p>	<p>Thank you for your comments and questions on the Pressure Ulcer Prevalence Rate and defining the denominator. The study collected data that would support a variety of pressure ulcer rate calculations, as we wanted to see how the different measures performed and the feasibility of data collection for the different data elements. We understand that this has led to some confusion about the pressure ulcer measure specification. The final pressure ulcer rate specification will provide the clarity that you request.</p>
89.	8/17/2015	Pressure Ulcers	<p>The Measure Evaluation Report notes that the PU definitions of numerator and denominator had content validity indices of .44 and .57, respectively. We recognize Econometrica’s efforts to revise the definitions; however, it is our recommendation that CMS/Econometrica perform additional steps to clarify the numerator and denominator statements.</p>	<p>Thank you for your comments and for submitting your request for clarification of the numerator and denominator of the pressure ulcer rate. We understand that this has led to some confusion about the pressure ulcer measure specification. The final pressure ulcer rate specification will provide the clarity that you request.</p>
90.	8/17/2015	Pressure Ulcers	<p>Feasibility of Data Collection</p> <p>XXXX suggests that POs also report the location of the PU on the body as this will aid POs in delivering optimal participant care and improving quality of life.</p>	<p>Thank you for your comment. We will consider your suggestion of reporting the location of the pressure ulcer on the body to ensure better participant care.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses										
91.	8/17/2015	Pressure Ulcers	<p>We request that CMS/Econometrica consider including the following PU anatomic location codes.</p> <p>Table 2. Pressure Ulcer Location Codes</p> <table border="1" data-bbox="569 418 1188 743"> <thead> <tr> <th data-bbox="569 418 1188 456">Pressure Ulcer Location Codes</th> </tr> </thead> <tbody> <tr> <td data-bbox="569 456 1188 488">Unspecified</td> </tr> <tr> <td data-bbox="569 488 1188 521">Elbow</td> </tr> <tr> <td data-bbox="569 521 1188 553">Upper Back</td> </tr> <tr> <td data-bbox="569 553 1188 586">Lower Back</td> </tr> <tr> <td data-bbox="569 586 1188 618">Hip</td> </tr> <tr> <td data-bbox="569 618 1188 651">Buttock</td> </tr> <tr> <td data-bbox="569 651 1188 683">Ankle</td> </tr> <tr> <td data-bbox="569 683 1188 716">Heel</td> </tr> <tr> <td data-bbox="569 716 1188 743">Other Site</td> </tr> </tbody> </table>	Pressure Ulcer Location Codes	Unspecified	Elbow	Upper Back	Lower Back	Hip	Buttock	Ankle	Heel	Other Site	<p>Thank you for your comment and for submitting your suggestion that the pressure ulcer measure include data on the anatomical location of the ulcer. We will take your request under consideration as we develop the final measure specifications.</p>
Pressure Ulcer Location Codes														
Unspecified														
Elbow														
Upper Back														
Lower Back														
Hip														
Buttock														
Ankle														
Heel														
Other Site														
92.	8/17/2015	Pressure Ulcers	<p>Calculation Methodology Given the ambiguity of the numerator and denominator statements, we do not understand the logic of the calculation algorithm.</p>	<p>Thank you for your question on the calculation methodology for the pressure ulcer rate. The logic of the calculation follows that for many quality measures: the number of participants with one (1) or more pressure ulcers divided by the number of participants during the period.</p>										
93.	8/17/2015	Pressure Ulcers	<p>There is an apparent discrepancy between the measure formula and the denominator statement. The measure formula states (<i>Average number of PACE participants</i>) whereas the denominator statement indicates <i>Number of PACE participants whose medical records were reviewed for evidence of PU at the end of the month</i>. It is unclear if the denominator is counting average number of participants active during the month or total number of participants whose charts were reviewed.</p>	<p>Thank you for your question regarding the denominator of the Pressure Ulcer Rate. The definition of the denominator used in the study was the number of participants whose records were reviewed. We limited the test to this count in response to comments from pilot sites about the burden of reviewing all participant records in the short amount of time allowed for pilot data collection. The final specification will reflect a longer reporting period, and the denominator will be all PACE participants during the reporting period.</p>										

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
94.	8/17/2015	Pressure Ulcers	The proposed measure does not exclude pressure ulcers that were acquired prior to enrollment, that are recurring in nature, or that were acquired in settings including inpatient hospital, emergency department, and SNF. These exclusion criteria help create a measure that better identifies PU's that developed while the participant was in the care of PACE staff.	Thank you for your comments. One of the important parts of testing is identifying the need for clarification. Pressure ulcers reported should be acquired while enrolled in PACE (i.e., PACE acquired).
95.	8/17/2015	Pressure Ulcers	It is not clear if "medical record reviewed for evidence of PU" requires chart abstraction or if data from any tracking method may be used (i.e. wound log or electronic medical record report).	Thank you for your comment. One of the important parts of testing is identifying the need for clarification. Consideration for wound log, etc., will be given as the measures are finalized.
96.	8/17/2015	Pressure Ulcers	XXXX supports XXXX's position on the intent of the <i>Pressure Ulcer (PU) Prevalence Rate</i> measure to determine the number of PACE participants with the presence of a PU. However, we also seek clarity regarding the criteria, on which the number of participants are selected each month for review and given the ambiguity of the numerator and denominator statements, we do not understand the logic of the calculation algorithm. We also concur with XXXX regarding what is the purpose conducting a risk assessment on participants who already have a pressure ulcer. The use of a specific pressure ulcer assessment tool (Braden, etc.) is essential in providing consistency across plans for reporting on risk. Further, we request clarity on the calculation algorithm and measure logic.	Thank for your comments and support of the intent of this important draft measure. The intent of the measure was to show the completeness of global prevention activities for participants who had developed a pressure ulcer. This measure is about preventing primary pressure ulcers, not about preventing the worsening of a pressure ulcer. We excluded Kennedy Terminal Ulcers in the pressure ulcer measure, as they are not a pressure ulcer stage recognized by the National Pressure Ulcer Advisory Panel (NPUAP). The primary etiology of Kennedy Ulcers is that the participant is at the end of life, rather than primarily the result of pressure. The prevalence or incidence of Kennedy Terminal Ulcers could be developed as a separate measure from Pressure Ulcers. Thank you for your important comment. Thank you; while it is possible to capture the tool used for risk assessment, not all providers have the same cut point (for any tool) to determine that a participant is at risk.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
				Both data on the tool used and the cut point used by the PACE site would need to be recorded. This might be considered at a future date but is out of scope for the purposes of the current measure.
97.	8/17/2015	Pressure Ulcers	<u>Measure Intent</u> As written, the denominator appears to represent participants with pressure ulcers after the exclusions are factored. What is the purpose of conducting a pressure ulcer risk assessment on participants who already have a pressure ulcer?	This was a limitation on the data we asked PACE organizations to collect during the feasibility study. We will take your comment into consideration during the final specification of the measure.
98.	8/17/2015	Pressure Ulcers	<u>Measure Definitions</u> To ensure the consistency of the measure results, XXXX recommends that a structured, systematic pressure ulcer risk assessment tool be specified (e.g. Braden risk assessment tool, Waterlow risk assessment tool, Ramstadius risk screening tool).	Thank you for your comment. While it is possible to capture the tool used for risk assessment, not all providers have the same cut point (for any tool) to determine that a participant is at risk. Both data on the tool used and the cut point used by the PACE site would need to be recorded. This might be considered at a future date.
99.	8/17/2015	Pressure Ulcers	<p>We offer the following measurement approach for CMS' consideration:</p> <p>Measure: Percent of participants at risk with preventative skin care plan</p> <p>Numerator: Number participants at risk for developing a pressure ulcer that have a documented preventative skin care plan.</p> <p>Denominator: Number of participants at risk (determined by Braden score <16).</p> <p>Data frequency: Quarterly</p> <p>To lower the administrative burden, it is recommend that only the most recent assessment be captured if a participant has more than one Braden score during the course of the quarter.</p>	Thank you for your comment. We will take this into consideration for the final measure specification. While a Braden score of 16 is the typical cut point for risk, some PACE organizations use other risk assessment tools and perhaps other cut points for Braden. Because most if not all participants are at risk for pressure ulcers, it might be more useful to limit the measure to prevention processes. One of the important parts of testing is identifying the need for clarification.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
100.	8/17/2015	Pressure Ulcers	<u>Feasibility of Data Collection</u> No comments.	Thank you for your comment. We interpret “no comments” to mean there are no perceived issues.
101.	8/17/2015	Pressure Ulcers	<u>Calculation Methodology</u> In the <i>PU Prevalence Rate</i> measure, the review is conducted on a monthly basis from which the numerator is derived. Assuming that the numerator from the previous measure forms the denominator in the current measure, the time period of the numerator is out of sync as it accounts for assessments conducted in the current or preceding month. We request clarity on the calculation algorithm/measure logic.	Thank you for your comment on the calculation methodology for pressure ulcer assessment. The study collected data for one (1) month, whereas the potential implementation of a pressure ulcer measure will cover a longer period. We will address your concern in the final measure specifications.
102.	8/17/2015	Pressure Ulcers	<u>Measure Definitions</u> To ensure the consistency of the measure results, XXXX recommends that a structured, systematic pressure ulcer risk assessment tool be specified (e.g. Braden risk assessment tool, Waterlow risk assessment tool, Ramstadius risk screening tool). XXXX comment: If this is done effectively with affiliated preventative interventions then the PU Stage 1 is a redundant measure.	Thank you for your comments. While it is possible to capture the tool used for risk assessment, not all providers have the same cut point (for any tool) to determine that a participant is at risk. Both data on the tool used and the cut point used by the PACE site would need to be recorded. This might be considered at a future date.
103.	8/17/2015	Pressure Ulcers	<u>Measure Intent</u> As written, the denominator appears to represent participants with pressure ulcers after the exclusions are factored. What is the purpose of conducting a pressure ulcer risk assessment on participants who already have a pressure ulcer?	Thank you for your question. The intent is to reduce the denominator size by looking retrospectively to determine whether there was a risk assessment before the incident Pressure Ulcer, which reduces the level of burden if it were all participants. We will take your comment into consideration.
104.	8/17/2015	Pressure Ulcers	<u>Measure Definitions</u> To ensure the consistency of the measure results, XXXX recommends that a structured, systematic pressure ulcer risk assessment tool be specified (e.g. Braden risk assessment tool, Waterlow risk assessment tool, Ramstadius risk screening tool).	Thank you for your comment. While it is possible to capture the tool used for risk assessment, not all providers have the same cut point (for any tool) to determine that a participant is at risk. Both data on the tool used and the cut point used by the PACE site would need to be recorded. This might be considered at a future date.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
105.	8/17/2015	Pressure Ulcers	<p>We offer the following measurement approach for CMS' consideration:</p> <p>Measure: Percent of participants at risk with preventative skin care plan</p> <p>Numerator: Number participants at risk for developing a pressure ulcer that have a documented preventative skin care plan.</p> <p>Denominator: Number of participants at risk (determined by Braden score <16).</p> <p>Data frequency: Quarterly</p> <p>To lower the administrative burden, it is recommend that only the most recent assessment be captured if a participant has more than one Braden score during the course of the quarter.</p>	<p>Thank you for your comment. We will take this into consideration for the final measure specification. While a Braden score of 16 is the typical cut point for risk, some PACE organizations use other risk assessment tools and perhaps other cut points for Braden. Because most if not all participants are at risk for pressure ulcers, it might be more useful to limit the measure to prevention processes. One of the important parts of testing is identifying the need for clarification.</p>
106.	8/17/2015	Pressure Ulcers	<p>Feasibility of Data Collection</p> <p>No comment.</p>	<p>Thank you for your comment. We interpret "no comments" to mean there are no perceived issues.</p>
107.	8/17/2015	Pressure Ulcers	<p>Calculation Methodology</p> <p>In the PU Prevalence Rate measure, the review is conducted on a monthly basis from which the numerator is derived. Assuming that the numerator from the previous measure forms the denominator in the current measure, the time period of the numerator is out of sync as it accounts for assessments conducted in the current or preceding month.</p> <p>We request clarity on the calculation algorithm/measure logic.</p>	<p>Thank you for your comment on the calculation methodology for pressure ulcer assessment. The study collected data for one (1) month, whereas the implementation of a pressure ulcer measure will cover a longer period. The calculation of the rate will be, for example, the number of participants with one (1) or more pressure ulcers in a quarter (or a year) divided by the number of participants during the period. We will address your concern in the final measure specifications.</p>
108.	8/17/2015	Pressure Ulcers	<p>Measure Definitions</p> <p>We are unable to determine the target population of this measure due to the ambiguity of the numerator and denominator statements. We request that CMS/Econometrica clarify the denominator. In the denominator, which participants comprise the population available for review? Does the denominator include "all the participants" or</p>	<p>Thank you for your questions on the calculation of the pressure ulcer rate and on the inclusion and exclusion criteria. For the reporting period (at least quarterly), the numerator would be all participants who had one (1) or more pressure ulcers.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			<p>“participants whose time it is to be reviewed in the month based on some pre-determined criteria”? Lastly, we seek clarity regarding the criteria on which the number of participants is selected each month for review (e.g., PU risk assessment, problem list, clinical visit). The measure’s lack of specificity regarding frequency/method of assessment limits POs ability to consistently collect and report the necessary data elements.</p> <p>XXXX Comment: Inclusion of participants with PU prior to PACE admission?</p> <p>Also, on the numerator my experience has been an underreporting of PU Stage 1. At this time unable to collect information through our EHR system. Please demonstrate the reasoning behind the PU Stage 1 reporting. The other concern is differentiating the hospice/end of life participant subset from the functional/longevity/palliative groups.</p>	<p>For the test, pressure ulcers were to be identified as present on enrollment or PACE acquired. We had heard from stakeholders that both the demand for care of pressure ulcers (all participants with pressure ulcers, no matter whether acquired before enrollment in PACE or after enrollment) and the quality of care for PACE participants (PACE-acquired pressure ulcers) were important concepts to capture. The denominator for both rates is the number of PACE participants during the reporting period.</p> <p>We did not ask PACE organizations to collect a sample for pressure ulcer data collection (e.g., those on a problem list), but to report on all participants.</p> <p>You are correct that Stage 1 pressure ulcers are less reliably identified than those of Stage 2 or greater. We will take this into account in our specification of the final measure.</p> <p>Finally, you ask about differentiating the hospice/end of life participants from those in the functional/longevity/palliative groups. We would be concerned about pressure ulcers in all of these groups, although, as specified in the instructions, we excluded Kennedy Terminal Ulcers from the pressure ulcer measure, as they are not a pressure ulcer stage recognized by the NPUAP. The primary etiology of Kennedy Ulcers is that the participant is at the end of life, rather than primarily the result of pressure.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses										
109.	8/17/2015	Pressure Ulcers	<p>We request that CMS/Econometrica consider including the following PU anatomic location codes. XXXX sees the need for Coccyx to be added.</p> <p>Table 2. Pressure Ulcer Location Codes</p> <table border="1" data-bbox="569 451 1192 771"> <thead> <tr> <th data-bbox="569 451 1192 488">Pressure Ulcer Location Codes</th> </tr> </thead> <tbody> <tr><td data-bbox="569 488 1192 521">Unspecified</td></tr> <tr><td data-bbox="569 521 1192 553">Elbow</td></tr> <tr><td data-bbox="569 553 1192 586">Upper Back</td></tr> <tr><td data-bbox="569 586 1192 618">Lower Back</td></tr> <tr><td data-bbox="569 618 1192 651">Hip</td></tr> <tr><td data-bbox="569 651 1192 683">Buttock</td></tr> <tr><td data-bbox="569 683 1192 716">Ankle</td></tr> <tr><td data-bbox="569 716 1192 748">Heel</td></tr> <tr><td data-bbox="569 748 1192 771">Other Site</td></tr> </tbody> </table>	Pressure Ulcer Location Codes	Unspecified	Elbow	Upper Back	Lower Back	Hip	Buttock	Ankle	Heel	Other Site	<p>Thank you for your comment that the pressure ulcer measure should include data on the anatomical location of the ulcer, including the coccyx. We will take your request under consideration as we develop the final measure specifications.</p>
Pressure Ulcer Location Codes														
Unspecified														
Elbow														
Upper Back														
Lower Back														
Hip														
Buttock														
Ankle														
Heel														
Other Site														
110.	8/17/2015	Pressure Ulcers	<p><u>Measure Intent</u> XXXX supports the intent of the <i>Pressure Ulcer (PU) Prevalence Rate</i> measure to determine the number of PACE participants with the presence of a PU.</p>	<p>Thank for your comment regarding the intent of this important draft measure.</p>										
111.	8/17/2015	Pressure Ulcers	<p><u>Measure Definitions</u> We are unable to determine the target population of this measure due to the ambiguity of the numerator and denominator statements. We request that CMS/Econometrica clarify the denominator. In the denominator, which participants comprise the population available for review? Does the denominator include “all the participants” or “participants whose time it is to be reviewed in the month based on some pre-determined criteria”? Lastly, we seek clarity regarding the criteria on which the number of participants is selected each month for review (e.g., PU risk assessment, problem list, clinical visit). The measure’s lack of specificity regarding frequency/method of assessment limits POs ability to consistently collect and report the necessary data elements.</p>	<p>Thank you for your comments and questions on the Pressure Ulcer Prevalence Rate and defining the denominator. The study collected data that would support a variety of pressure ulcer rate calculations, as we wanted to see how the different measures performed and the feasibility of data collection for the different data elements. We understand that this has led to some confusion about the pressure ulcer measure specification. The final pressure ulcer rate specification will provide the clarity that you request.</p>										

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses										
112.	8/17/2015	Pressure Ulcers	The <i>Measure Evaluation Report</i> notes that the PU definitions of numerator and denominator had content validity indices of .44 and .57, respectively. We recognize Econometrica's efforts to revise the definitions; however, it is our recommendation that CMS/Econometrica perform additional steps to clarify the numerator and denominator statements.	Thank you for your comment regarding the clarification of the numerator and denominator of the pressure ulcer rate. The final measure specifications will take into account information from all sources: the environmental scan, validity study, reliability study, and feasibility study.										
113.	8/17/2015	Pressure Ulcers	<i>Feasibility of Data Collection</i> XXXX suggests that POs also report the location of the PU on the body as this will aid POs in delivering optimal participant care and improving quality of life.	Thank you for your comment. We will consider your suggestion of reporting the location of the Pressure Ulcer on the body to ensure better participant care.										
114.	8/17/2015	Pressure Ulcers	We request that CMS/Econometrica consider including the following PU anatomic location codes. Table 2. Pressure Ulcer Location Codes <table border="1" data-bbox="569 760 1188 1084"> <thead> <tr> <th data-bbox="569 760 1188 797">Pressure Ulcer Location Codes</th> </tr> </thead> <tbody> <tr><td data-bbox="569 797 1188 829">Unspecified</td></tr> <tr><td data-bbox="569 829 1188 862">Elbow</td></tr> <tr><td data-bbox="569 862 1188 894">Upper Back</td></tr> <tr><td data-bbox="569 894 1188 927">Lower Back</td></tr> <tr><td data-bbox="569 927 1188 959">Hip</td></tr> <tr><td data-bbox="569 959 1188 992">Buttock</td></tr> <tr><td data-bbox="569 992 1188 1024">Ankle</td></tr> <tr><td data-bbox="569 1024 1188 1057">Heel</td></tr> <tr><td data-bbox="569 1057 1188 1084">Other Site</td></tr> </tbody> </table>	Pressure Ulcer Location Codes	Unspecified	Elbow	Upper Back	Lower Back	Hip	Buttock	Ankle	Heel	Other Site	Thank you for your comment that the pressure ulcer measure should include data on the anatomical location of the ulcer. We will take your request under consideration as we develop the final measure specifications.
Pressure Ulcer Location Codes														
Unspecified														
Elbow														
Upper Back														
Lower Back														
Hip														
Buttock														
Ankle														
Heel														
Other Site														
115.	8/17/2015	Pressure Ulcers	<i>Calculation Methodology</i> Given the ambiguity of the numerator and denominator statements, we do not understand the logic of the calculation algorithm.	Thank you for your comment on the calculation methodology for the pressure ulcer rate. The logic of the calculation follows that for many quality measures: the number of participants with one (1) or more pressure ulcers divided by the number of participants during the period.										

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
116.	8/17/2015	Pressure Ulcer Prevention	<p><u>Measure Intent</u> Please indicate the intent of the <i>Pressure Ulcer Prevention Plan of Care</i> measure. Is the denominator defined as all participants enrolled with the additional criteria or a subset of the previous measure? Is measure intended to prevent the development of a PU among participants at risk or prevent worsening and/or recurrence of a PU among participants with an existing PU? As Kennedy Terminal Ulcers are highly prevalent among PACE participants, we request that CMS/Econometrica consider how to account for this type of pressure ulcer.</p>	<p>Thank you for your questions regarding the intent of the pressure ulcer prevention measure. In response to your questions, the intent of the measure was to show the completeness of global prevention activities for participants who had developed a pressure ulcer. This measure is about preventing primary pressure ulcers, not about preventing the worsening of a pressure ulcer.</p> <p>We excluded Kennedy Terminal Ulcers in the pressure ulcer measure, as they are not a pressure ulcer stage recognized by the NPUAP. The primary etiology of Kennedy Ulcers is that the participant is at the end of life, rather than primarily the result of pressure. The prevalence or incidence of Kennedy Terminal Ulcers could be developed as a separate measure from Pressure Ulcers. Thank you for your important comment.</p>
117.	8/17/2015	Pressure Ulcer Prevention	<p><u>Measure Definitions</u> No comment.</p>	<p>Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.</p>
118.	8/17/2015	Pressure Ulcer Prevention	<p><u>Feasibility of Data Collection</u> No comment.</p>	<p>Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
119.	8/17/2015	Pressure Ulcer Prevention	<p><u>Calculation Methodology</u> We request clarity on the calculation algorithm/measure logic.</p>	<p>Thank you for your question on the pressure ulcer prevention algorithm. The measure is a composite measure intended to determine if the participant had undergone a complete prevention protocol. The measure combines information from four (4) questions for participants who had pressure ulcers: (1) Was the participant assessed for the risk of pressure ulcers? (2) Was the participant assessed as “at risk”? (3) Did at-risk participants have a prevention plan ordered? (4) Was the plan implemented for at-risk participants who had a prevention plan ordered? The denominator is all participants with one (1) or more pressure ulcers.</p>
120.	8/17/2015	Pressure Ulcer Prevention	<p><u>Measure Intent</u> The intent of this is clear. As this measure is a subset of the preceding measures, it our sense that the process to compute this measure will become clear once the aforementioned issues are resolved.</p>	<p>Thank you for your comments. One of the important parts of testing is identifying the need for clarification.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
121.	8/17/2015	Pressure Ulcer Prevention	<p>Measure Intent Please indicate the intent of the Pressure Ulcer Prevention Plan of Care measure. Is the denominator defined as all participants enrolled with the additional criteria or a subset of the previous measure? Are measure intended to prevent the development of a PU among participants at risk or prevent worsening and/or recurrence of a PU among participants with an existing PU? As Kennedy Terminal Ulcers are highly prevalent among PACE participants, we request that CMS/Econometrica consider how to account for this type of pressure ulcer.</p>	<p>Thank you for your comment regarding the intent of the pressure ulcer prevention measure. In response to your questions, the intent of the measure was to show the completeness of global prevention activities for participants who had developed a pressure ulcer. This measure is about preventing primary pressure ulcers, not about preventing the worsening of a pressure ulcer.</p> <p>We excluded Kennedy Terminal Ulcers in the pressure ulcer measure, as they are not a pressure ulcer stage recognized by the NPUAP. The primary etiology of Kennedy Ulcers is that the participant is at the end of life, rather than primarily the result of pressure. The prevalence or incidence of Kennedy Terminal Ulcers could be developed as a separate measure from Pressure Ulcers. Thank you for your important comment.</p>
122.	8/17/2015	Pressure Ulcer Prevention	<p>Measure Definitions No comment.</p>	<p>Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.</p>
123.	8/17/2015	Pressure Ulcer Prevention	<p>Feasibility of Data Collection No comment.</p>	<p>Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
124.	8/17/2015	Pressure Ulcer Prevention	<p>Calculation Methodology We request clarity on the calculation algorithm/measure logic.</p>	<p>Thank you for your question on the pressure ulcer prevention algorithm. The measure is a composite measure intended to determine if the participant had undergone a complete prevention protocol. The measure combines information from four (4) questions for participants who had pressure ulcers: (1) Was the participant assessed for the risk of pressure ulcers? (2) Was the participant assessed as “at risk”? (3) Did at-risk participants have a prevention plan ordered? (4) Was the plan implemented for at-risk participants who had a prevention plan ordered? The denominator is all participants with one (1) or more pressure ulcers.</p>
125.	8/17/2015	Pressure Ulcer Prevention	<p>Measure Intent The intent of this is clear. As this measure is a subset of the preceding measures, it our sense that the process to compute this measure will become clear once the aforementioned issues are resolved.</p>	<p>Thank you for your comments. One of the important parts of testing is identifying the need for clarification.</p>
126.	8/17/2015	Pressure Ulcer Prevention	<p>The pressure ulcer risk assessment window is too narrow. The minimum required assessment interval for PACE participants is every 6 months. Participants with an existing pressure ulcer may have had a risk assessment performed within the last 6 months but not within the last 60 days.</p>	<p>Thank you for your comment that pressure ulcer risk assessments are conducted every 60 days in home care but only every six (6) months in PACE programs. We will consider your comment as we finalize the PACE quality measures.</p>
127.	8/17/2015	Pressure Ulcer Prevention	<p>The guidance indicates that the target population is “all participants in the PACE site census during the month”. This denominator conflicts with the denominator for the PACE- acquired pressure ulcer rate because it requires a record review of all PACE participants to establish the presence of an ulcer.</p>	<p>Thank you for your comment related to census, which has been made by others. Through feedback given by our TEP and other stakeholders, it has been recommended that census be used going forward.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
128.	8/3/2015	Readmission Rate	In the Environmental Scan, page 18 has the following definition: The Final Rule defines readmissions for the PACE program as “PACE participants readmitted to an acute care hospital within 31 days.” This rule includes emergency (unscheduled) care, defined as “PACE participants seen in the hospital emergency room (including care from a PACE physician in a hospital emergency department) or an outpatient department/clinic emergency” (CMS PACE User’s Guide, 2008). However, that is not correct. PACE participants seen in an emergency setting within 30 days of hospital discharge are not considered readmissions.	Thank you for your comments. This is a correct interpretation, as an Emergency Department visit that does not result in an admission (or results in an observation stay only) would not count as a readmission. We will review the Environmental Scan and make any necessary corrections.
129.	8/14/2015	Readmission Rate	Measure Intent XXXX supports the intent of the <i>30-day All-Cause Readmission Rate</i> measure to examine avoidable 30-day hospital readmissions among PACE participants.	Thank you for your comment and support.
130.	8/14/2015	Readmission Rate	Measure Definitions: XXXX also supports the defined exclusion criteria.	Thank you for your comment and support.
131.	8/14/2015	Readmission Rate	We do request clarification of the exclusion criteria, “Admission to one acute hospital directly after discharge from another acute hospital” as a hospital to hospital transfer.	Thank you for your comment. As presented, this does read as an exclusion from the draft Readmissions Measure (i.e., hospital-to-hospital transfer).
132.	8/14/2015	Readmission Rate	Feasibility of Data Collection No comment.	Thank you for your comment.
133.	8/17/2015	Readmission Rate	30 Day All Cause Readmission Rates <ul style="list-style-type: none"> We support this measure as is. 	Thank you for your comment and support of the current draft measure.
134.	8/17/2015	Readmission Rate	Measure Intent XXXX supports the intent of the <i>30-day All-Cause Readmission Rate</i> measure to examine avoidable 30-day hospital readmissions among PACE participants. XXXX also supports the Technical Expert Panel’s recommendation to consider a future measure which examines “days in the community” as such a measure can assess changes in setting from home to SNF, acute care, emergency department, etc.	Thank you for your comment and suggestion. The “Days in the Community” measure will be considered in the future.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
135.	8/17/2015	Readmission Rate	<p><u>Measure Definitions</u> Examining 30-day all-cause readmission in isolation may not provide an accurate indication of quality. For example, a “high-performing” PACE program may have a low admission rate, and their readmission rate (calculated as proposed) may well be high, because the only participants being admitted to hospitals are individuals for whom hospitals actually offer substantial gains and whose health is fragile and finding stability is challenging. On the other hand, a “low-performing” PACE program might have a high hospital admission rate due to the number of elders who could have been served in other settings, but their readmission rate may be low since its admission rate is so high. We recommend that CMS consider examining the 30-day all-cause readmission rate in conjunction with the hospital admission rate.</p>	<p>Thank you for your comment and this important consideration of the impact on the readmissions rate of reducing the denominator that would impact the rate (e.g., avoidance of inappropriate admissions). This was also discussed among the TEP. We will take your recommendation into consideration.</p>
136.	8/17/2015	Readmission Rate	<p>There is a lack of clarity on how admissions will be captured in these measures. We have created the following scenario to understand how the measure will be computed. Please confirm whether our understanding is correct. Scenario – the following admits are for the same patient after all exclusion/inclusion criteria have been factored.</p> <ul style="list-style-type: none"> • Admit 2/15 – Discharge 2/22 • Admit 3/10 – Discharge 3/15 • Admit 3/20 – Discharge 3/24 • Admit 3/27 – Discharge 3/31 <p>The following depicts our understanding of how the measure will be compute for the month of February.</p> <ul style="list-style-type: none"> • The 1st discharge associated with the Admit 2/15 – Discharge 2/22 constitutes the index discharge. • The 2nd discharge associated with the Admit 3/10 – Discharge 3/15 is counted as a re-admit for <u>February</u> because the discharge date of 3/15 is within 30 days of the prior discharge (which occurred in February). <p>And, the following depicts our understanding of how the measure</p>	<p>Thank you for your comments and illustration. One of the important parts of testing is identifying the need for clarification. As defined in the testing instructions, there would be one (1) 30-day readmission for the 2/22 discharge (i.e., index discharge), which occurs on 3/10. Because it was a review of March data, only February discharges are eligible for readmissions. Consideration will be given to the revised denominator statement following the testing phase.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			<p>will be computed for the month of March.</p> <ul style="list-style-type: none"> • The 2nd discharge associated with the Admit 3/10 – Discharge 3/15 above becomes the index discharge (therefore the same occurrence which is counted as a re-admit for the prior month is now the index for the current month). • The 3rd discharge associated with the Admit 3/20 – Discharge 3/24 is counted as a re-admit for the month of March because it is within 30 days of the index discharge of 3/15. • The 4th discharge associated with the Admit 3/27 – Discharge 3/31 is also counted as a re-admit for the month of March because it is also within 30 days of the index discharge of 3/15. <p>Therefore in the scenario above, there will be one (1) re-admit for February and two (2) for March. To ensure consist interpretation and implementation of the measure, we request that CMS consider revising the denominator statement as follows: Denominator statement: <i>Number of PACE participants admitted to an acute care hospital during the reporting month.</i></p>	
137.	8/17/2015	Readmission Rate	<p><u>Feasibility of Data Collection</u> No comment.</p>	Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.
138.	8/17/2015	Readmission Rate	<p><u>Calculation Methodology</u> No comment.</p>	Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.
139.	8/17/2015	Readmission Rate	<p><u>Calculation Methodology</u> No comment. XXXX has no further comments on this quality measure.</p>	Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
140.	8/17/2015	Readmission Rate	<p>Measure Intent XXXX supports the intent of the 30-day All-Cause Readmission Rate measure to examine avoidable 30-day hospital readmissions among PACE participants. XXXX also supports the Technical Expert Panel's recommendation to consider a future measure which examines "days in the community" as such a measure can assess changes in setting from home to SNF, acute care, emergency department, etc.</p>	<p>Thank you for your comment and suggestion. The "Days in the Community" measure will be considered in the future.</p>
141.	8/17/2015	Readmission Rate	<p>Measure Definitions Examining 30-day all-cause readmission in isolation may not provide an accurate indication of quality. For example, a "high-performing" PACE program may have a low admission rate, and their readmission rate (calculated as proposed) may well be high, because the only participants being admitted to hospitals are individuals for whom hospitals actually offer substantial gains and whose health is fragile and finding stability is challenging. On the other hand, a "low-performing" PACE program might have a high hospital admission rate due to the number of elders who could have been served in other settings, but their readmission rate may be low since its admission rate is so high. We recommend that CMS consider examining the 30-day all-cause readmission rate in conjunction with the hospital admission rate.</p>	<p>Thank you for your comment regarding the impact on the readmissions rate by reducing the denominator that would impact the rate (e.g., avoidance of inappropriate admissions). This was also discussed among the TEP. We will take your recommendation into consideration.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
142.	8/17/2015	Readmission Rate	<p>There is a lack of clarity on how admissions will be captured in this measure. We have created the following scenario to understand how the measure will be computed. Please confirm whether our understanding is correct.</p> <p>Scenario – the following admits are for the same patient after all exclusion/inclusion criteria have been factored.</p> <p>Admit 2/15 – Discharge 2/22</p> <ul style="list-style-type: none"> • Admit 3/10 – Discharge 3/15 • Admit 3/20 – Discharge 3/24 • Admit 3/27 – Discharge 3/31 <p>The following depicts our understanding of how the measure will be compute for the month of February.</p> <p>The first discharge associated with the Admit 2/15 – Discharge 2/22 constitutes the index discharge.</p> <ul style="list-style-type: none"> • The second discharge associated with the Admit 3/10 – Discharge 3/15 is counted as a re-admit for February because the discharge date of 3/15 is within 30 days of the prior discharge (which occurred in February). <p>And, the following depicts our understanding of how the measure will be computed for the month of March.</p> <ul style="list-style-type: none"> • The second discharge associated with the Admit 3/10 – Discharge 3/15 above becomes the index discharge (therefore the same occurrence which is counted as a re-admit for the prior month is now the index for the current month). • The third discharge associated with the Admit 3/20 – Discharge 3/24 is counted as a re-admit for the month of March because it is within 30 days of the index discharge of 3/15. • The fourth discharge associated with the Admit 3/27 – Discharge 3/31 is also counted as a re-admit for the month of March because it is also within 30 days of the index discharge of 3/15. <p>Therefore in the scenario above, there will be one (1) re-admit for February and two (2) for March.</p> <p>To ensure consist interpretation and implementation of the measure, we request that CMS consider revising the denominator statement as follows:</p> <p>Denominator statement: Number of PACE participants admitted to an acute care hospital during the reporting month.</p>	<p>Thank you for your comment and illustration. One of the important parts of testing is identifying the need for clarification. As defined in the testing instructions, there would be one (1) 30-day readmission for the 2/22 discharge (i.e., index discharge), which occurs on 3/10. Because it was a review of March data, only February discharges are eligible for readmissions. Consideration will be given to the revised denominator statement following the testing phase.</p>

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
			Therefore in the scenario above, there will be one (1) re-admit for February and two (2) for March. To ensure consist interpretation and implementation of the measure, we request that CMS consider revising the denominator statement as follows: Denominator statement: <i>Number of PACE participants admitted to an acute care hospital during the reporting month.</i>	
143.	8/17/2015	Readmission Rate	Feasibility of Data Collection No comment.	Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.
144.	8/17/2015	Readmission Rate	Calculation Methodology No comment.	Thank you for your comment. We interpret “no comment” to mean there are no perceived issues.
145.	8/17/2015	Readmission Rate	The proposed measure methodology may understate the volume of readmissions. The numerator is based on <i>distinct participants</i> instead of <i>distinct admissions</i> . It is possible that one participant may have more than one readmission within the 30-day window.	Thank you for your comments. Yes, you are correct in that one (1) participant could have more than one (1) readmission within 30 days. But, for this testing period, we were only interested in whether there was one (1) readmission within 30 days. However, once the testing is finalized, that could prompt changes to the measure specifications.
146.	8/17/2015	Readmission Rate	The denominator may be overstated using the proposed methodology. The denominator includes all discharges for the prior month including those for participants who were not readmitted within 30 days. Measure performance could vary widely based on fluctuations in discharges from month to month.	Thank you for your comments. The testing could result in changes to the specifications. Your comments will be considered as we go through the remaining measure development process.
147.	8/17/2015	Readmission Rate	PACE programs may find it challenging to collect data related to the exclusion criteria, as they contain non-standard data points that are not typically seen on hospital discharge aggregate reports (i.e. left against medical advice).	Thank you for your comment. Clarification on exclusion criteria may be required going forward.

No.	Date Posted	Measure Set or Measure	Text of Comments	Responses
148.	8/17/2015	Readmission Rate	XXXX supports the intent of the <i>30-day All-Cause Readmission Rate</i> measure to examine avoidable 30-day hospital readmissions among PACE participants; however, as XXXX points out in their comments, examining this in isolation may not provide an accurate indication of quality. There is a lack of clarity on how admissions will be captured in this measure. XXXX agrees with XXXX in ensuring consistent interpretation and implementation of the measure, we request that CMS consider revising the denominator statement as follows: Denominator statement: <i>Number of PACE participants admitted to an acute care hospital during the reporting month.</i>	Thank you for your comments. One of the important parts of testing is identifying the need for clarification. Consideration will be given to the revised denominator statement following the testing phase.

Appendix B

Public Comment Verbatim Report

Second Round Questions

No.	Comments Public/TEP	Date Posted	Verbatim Comments
Question 1. CMS and Econometrica are considering an acuity methodology, which would include a geographic and participant health status component. Should a substitute measure include acuity adjustment? Recognizing there is no standard measure of acuity, please suggest acuity assessment specific to PACE Organizations.			
149.	Public	9/24/2015	CMS has a risk adjustment and frailty score for all PACE participants. We get the risk score from CMS, but not the frailty score. The risk score changes every 6 months. The challenge would be to match neither the event to be reported with the risk score as it is not stored in the EHR nor the event reporting software. Please consider impact on staff time for additional data gathering.
150.	Public	9/24/2015	The measure should include an acuity adjustment. Although we are not completely clear on the use of the geographical component, the state does think it would be beneficial to include residential setting as part of the acuity methodology as well.
151.	Public	9/24/2015	<ul style="list-style-type: none">• Yes, we should acknowledge the need for acuity risk adjustment. It should be a well-established methodology specifically geared towards this population. You need a risk adjustment tool that is incredibly specific/sensitive at the upper end. The methodology needs to be tested to ensure it accounts for the differences between a more mature PACE site and a newly established one.• An acuity assessment specific to this population must be incredibly sensitive at the upper end given the overall frailty of the population. Such an assessment tool, should be tested to ensure it accounts for variance among more mature PACE Organizations and newly established ones.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
152.	Public	9/24/2015	<p>The question seems to suggest that Econometrica found significant variations in PACE participant's status that warranted consideration of applying risk adjustment to the measures. In order to address the question accurately, it would be important to know whether the variation was based on observed differences in one or more of PACE participant's functional, medical, or cognitive status.</p> <p>While there is abundance of diagnostic data for use in risk adjustment models based on disease state, PACE organizations lacks a common assessment instrument and data standard to consistently and validly apply an adjustment model to the PACE population to identify differences in functional and cognitive status. To address this data gap, XXXX has developed a common data platform across all PACE organizations referred to as the Common Data Set (CDS). The CDS contains a standardized dictionary of definitions for data elements to collected – demographics/assessments (CDS I) and services (CDS II). The creation of this standardized participant specific data set will allow for better defining the PACE population; create opportunities to measure the value and performance of PACE; support improved and more efficient benchmarking; distinguish PACE from emerging delivery models; and foster the evolution and adoption of electronic health records for PACE. With that said, XXXX has just initiated the rollout process of the CDS and will need some time to train/educate all the PACE organizations.</p> <p>In absence of the CDS, two data sources are currently available to determine the functional, medical, and cognitive characteristics of the PACE population – CMS frailty adjuster and CMS-HCC risk adjustment methodology. With respect to the frailty adjuster, there are inherent limitations to using this data source for measuring functional status: 1) CMS uses the number of functional limitations represented by the Activities of Daily Living (ADL) scale to calibrate the frailty model and then determines the relative organization-level frailty of those in the community that are 55 years of age and older; 2) frailty scores are calculated using results from the Health Outcomes Survey – Modified (HOS-M), which is an anonymous self-reported survey; and, 3) given that it is self-reported, response rates among PACE participants are far from universal.</p> <p>Secondly, the Medicare HCC risk score is a description of each PACE enrollees' diagnostic characteristics, including the presence of cognitive disease. However, the risk score itself does, not alone, reflect the presence of cognitive status. Further, the data source does not take into account participants' functional limitations.</p> <p>While we are generally inclined to support the use of some risk adjustment model to adjust the measures, we would need to better understand the degree and nature of participants' differences, the risk adjustment methodology to be applied, and the data sources used to calculate the risk scores.</p>
153.	TEP	9/13/2015	<p>It would be great to have acuity adjustment for the falls and PU metrics. Severity adjustment can be included to factor in patient acuity levels. Geography and participant health status can act as coefficients for risk adjustment. Participant health status can be included in clinical co-morbidities and socioeconomic variables to consider are age, gender, race, and social support.</p>

No.	Comments Public/TEP	Date Posted	Verbatim Comments
154.	TEP	9/15/2015	I agree that we should have an acuity adjustment specific to each measure that compares PACE to a PACE like population. Other than HCC plus Frailty there are no measures that have applied to PACE and such measures would need to be developed specific to the quality measure. There is no one measure that risk adjusts across all quality measures.
155.	TEP	9/15/2015	The risk score would be one measure, otherwise there is no standard acuity measure in PACE.
156.	TEP	9/16/2015	Please refer to email message sent that references variables that effectively predict a participants risk for falls. There are other valid tools that predict a patients risk for developing pressure ulcers and can be used to objectively capture acuity around a given measure.
157.	TEP	9/16/2015	We do not see the value in this measure. We have no control over acuity and already have frailty and risk adjustment measures.
158.	TEP	9/21/2015	Not aware of any other acuity measure.
<p>Question 2: Our testing results suggest that a monthly reporting timeframe for the Falls and Falls With Injury measures is not sufficient in order to produce meaningful results. CMS and Econometrica believe that a larger “look-back” data reporting period would produce reliable, valid data across the PACE organizations. Currently, our intent is to shift the reporting period from monthly to quarterly. Is quarterly reporting an appropriate timeframe for reporting falls? Do you believe that a different reporting period should be used?</p>			
159.	Public	9/17/2015	Quarterly would be appropriate.
160.	Public	9/24/2015	YES; No
161.	Public	9/24/2015	A quarterly measure is preferred over a monthly measure in order to see trends. An increased frequency of falls is often related to health decline. XXXX recommends trending the last 6 months and a focus on 2 or more falls in less than 30 days.
162.	Public	9/24/2015	<ul style="list-style-type: none"> Quarterly reporting should be the default. Quarterly reporting is a sufficient frequency that should produce meaningful results.
163.	Public	9/24/2015	XXXX appreciates that CMS recognizes that implementing a sound data collection methodology is imperative to ensuring meaningful and valid results. We also agree that a longer reporting period would not only reduce data reporting burden, but provide a greater longitudinal period across which to measures changes. To that end, we recommend that falls be reported quarterly.
164.	TEP	9/13/2015	Quarterly reporting is an appropriate timeframe for reporting falls. The larger time period will be more reliable and should have increased validity.
165.	TEP	9/15/2015	Quarterly reporting is appropriate.
166.	TEP	9/15/2015	Quarterly is an appropriate timeframe – but recommend pilot testing first to be sure reliability and validity.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
167.	TEP	9/16/2015	My experience with quality reporting and performance reporting has been that the reporting needs to be as close to the performance time frame in order for that measure to be used in a meaningful manner. If a month's data is not conducive to reliable, valid data and a quarter is the smallest time frame to achieve this, then I would recommend a quarter as opposed to a larger time frame. If two months of data can be grouped to achieve this, I would recommend a two month time frame- this would allow the measure to be reported for comparison six times a year as opposed to four times a year with a quarterly schedule. While a two month time frame is not used in other quality reporting programs, it does not preclude the PACE program from using this time frame.
168.	TEP	9/16/2015	We agree that quarterly reporting is appropriate.
169.	TEP	9/21/2015	Quarterly data will provide us with better statistical analysis.
<p>Question 3: Based on some of the comments we received, it seems like PACE stakeholders have an interest to see a paired measure for falls. Would a paired (or composite) measure combining falls and falls with injury be more appropriate? How could a paired or composite measure be accomplished?</p>			
170.	Public	9/17/2015	Would prefer a simple statistic, i.e. 15 falls, 7 with serious injury, as defined by NDNQI. To list each fall and its outcome would be burdensome, and a duplication of QAPI efforts that are already in place.
171.	Public	9/22/2015	Preventing injuries from falls seems to be the most critical area of focus. Would like emphasis on this measure (and subsequent reduction in number and severity of injuries when possible).
172.	Public	9/24/2015	Yes; We use one set of measures for all falls, one data point being the injury level.
173.	Public	9/24/2015	It is important to separate out falls that did not result in injury from falls that resulted in injury. An often underreported area of falls is ER visits related to falls, XXXX would like to see this included. Another area of interest may be to report calls to EMS that do not result in ER visits. This is an area that is frequently discussed as a means to reach older adults who have fallen without injury. It is a great opportunity to provide an intervention. As part of this measure, the strata of injuries related to falls should include sudden/transient change in mentation at the moderate level. Mentation change is not addressed until medical treatment is sought which may miss mild head injuries where the participant refuses medical care.
174.	Public	9/24/2015	<ul style="list-style-type: none"> • Both the individual scores and the composite would be relevant. You need to be able to distinguish the falls with injury because of CMS's criteria with Serious Reportable Events (SREs). • XXXX recommends utilization of both individual scores, as well as a composite measure combining falls and falls with injury. Falls with injury must use the same parameters used in reporting Serious Reportable Events or Level II events to ensure these events are also included in the data reporting.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
175.	Public	9/24/2015	<p>To promote parsimony within the measure set, we recommend that the data elements required for the Falls Rate and Falls with Injury measures be combined and that the results be reported as a single measure - Falls with Injury. XXXX suggests that CMS report the cumulative overall fall rate, as well as, stratify the results by injury level.</p> <p>XXXX agrees that the numerator inclusion criteria should be expanded to account for an injury to the head that may otherwise be reported. We recommend that inclusion be revised as follows: "Incident involved an observed, reported, noticeable or suspected trauma or impact to the head" (regardless of CT findings within 24 hours of injury and an Injury Level of None=1).</p>
176.	TEP	9/13/2015	<p>If consideration is given to paired measure, it sounds like that the combination of measures will result in one measure "Falls with injury". Both Falls and falls with injury measures have high usability because Quality improvement activities will arise from both measures. The combination of the measure should not give the message that the focus is only in preventing falls with injuries but to prevent falls in general. Development of the falls prevention measure in combination with falls with injury measure should lead to appropriate QI activities to prevent falls.</p>
177.	TEP	9/15/2015	<p>I think we should not track falls and only track falls with injury; that is the measure that is actionable.</p>
178.	TEP	9/16/2015	<p>My recommendation would be to pair a measure with another measure that provides a context to the primary measure's performance. Thus a suitable pair for the Fall measure would be the likelihood for a patient to fall (i.e. the risk a patient would fall). So a validated tool that predicts a patients fall when paired with the outcome (a fall) would be one meaningful way to pair the measure. Similarly, a tool like the Branden Scale that predicts risk of developing a pressure ulcer can be paired with the pressure ulcer measure. This will ensure that the acuity of a patient related to the factors that can affect a measure rate are captured and can provide a context to interpret the performance of a given measure. A readmission measure can be paired with a validated tool that assesses the risk of readmissions.</p>
179.	TEP	9/16/2015	<p>We do not think "all falls" data would be consistently accurate. The number of fall reported for our participants who reside in residential care or assisted living facilities is higher than the number received from participants living in their own home.</p> <p>We support a measure of falls with injury (3 – 5 level) as a numerator and participants served in the quarter as the denominator.</p>
180.	TEP	9/21/2015	<p>I would recommend collecting the data separately to analyze and then provide a composite.</p>

No.	Comments Public/TEP	Date Posted	Verbatim Comments
<p>Question 4: Some comments received during the initial public comment period suggest that many falls go unreported. CMS and Econometrica are considering ways of involving PACE participants or their caregivers in order to promote effective data reporting. For example, we could develop and implement a form-like process to document falls in the home by the PACE participant or caregiver. What are the benefits of developing a form-like process for PACE participants to track falls that would assist with recall/reporting? Are there other more effective ways of involving PACE participants and their caregivers on reporting falls?</p>			
181.	Public	9/17/2015	A form like process, would not improve compliance. It is an additional sheet of paper that the participant or caregiver must complete.
182.	Public	9/22/2015	Although I feel it is important to collect data on falls, I am concerned the focus on collection will be considered: 1) Punitive and 2) Futile. In the former case, patients and staff maybe reluctant to collect data in fear it may cause a patient to be discharged (not the case but a perception) or the staff/family member may consider it “their fault” and thus promote under reporting. For this reason reporting (and required forms) should be brief and concise and quarterly. In the latter case, futility, the real question I have is what will we do with the data? Yes knowing incidence of falls and “frequent fallers” is of great value in developing preventive programs, but what happens when all preventive measures are instituted and the patient continues to fall? The goal of keeping patients at home then becomes counter to recording falls in the frequent faller - the only remaining options are greater supervision, bed alarms, one-on-one nursing assistance- all which would require nursing home placement. What if the patient and family want to remain at home and recognize the risk fall but decide to stay at home? Will falls be reported? Will it impede patient/provider trust?
183.	Public	9/24/2015	Given the population served, it is highly unlikely that they will accurately report falls if given a form to fill out. We would rather keep their focus on taking medications, checking blood sugars, etc.
184.	Public	9/24/2015	Self-reporting results in under reporting. Participant and caregiver reporting of falls would help capture the numerous falls that go unreported and increase accuracy of reporting, especially where the participant and caregiver did not seek medical intervention. It would also be helpful to have the caregiver involved in the reporting to ensure that the participant remembers to report the fall. A form could be useful but could easily be misplaced by the participant. Could a phone app be a useful tool for the caregiver to report real time? Another option to ensure the reporting of falls is to have the participant’s medical practitioner (during routine medical visits) ask the participant if they have had any falls recently (similar to the use of depression tools that physicians use with patients during their visits).

No.	Comments Public/TEP	Date Posted	Verbatim Comments
185.	Public	9/24/2015	<ul style="list-style-type: none"> • We should leverage existing patient touch points. We could use a modified approach because there are already other surveys in use. Given the broad definitions of falls (falls in any location; fall back/sink into a bed, chair, etc.; participants assisted to the floor; etc.), false-negatives are a concern. Members/caregivers may not be aware of the various definitions. • XXXX recommends CMS continue to use the existing patient touch points for the reporting of falls. Any concerns regarding underreporting maybe related already to patient and/or caregiver recall issues. Utilizing the current broad definition of falls for self-reporting by caregivers may result in an increase in false negatives.
186.	Public	9/24/2015	<p>Given the number of participants living alone in the community, it is likely that incidental falls will be underreported due to participant concern of relinquishing independence and potential placement in an institutional setting of care. A participant's autonomy and self-determination to make choices for himself or herself are paramount to the PACE model. The concept means that all adults have the right to make their own choices about their health and care, even if healthcare professionals believe these choices endanger the person's health or longevity. This point is offered to emphasize the need for a measure which focuses on minimizing fall risk and risk of fall-related injuries while maximizing individual dignity, freedom, and quality of life.</p> <p>XXXX applauds CMS' consideration of how to effectively promote PACE participant- and caregiver-reported falls; something we strongly support. And, while PACE organizations can work to increase education on fall prevention and encourage reporting of falls at home, there is no mandate and/or authority in place to enforce participant/caregiver to reports falls in the home. As a result, and based on experience, there will likely be significant variation in family reporting on falls, both in terms of accuracy, completeness, and overall willingness. As noted above, participants may underreport falls, and related injuries, out of concern that this would jeopardize their ability to remain at home. For family caregivers, they may be unlikely to report falls, and related injuries, out of concern that this would reflect poorly on their role as a caregiver. If a form-like process is established, CMS will need to ensure the validity of the instrument and consider the impact of response bias on the performance results.</p>
187.	TEP	9/13/2015	<p>A form like process is a good idea to help with reporting falls from patients/caregivers. Education level, language barriers and compliance in filling the form might be some of the barriers in accomplishing this. Not sure if another way could be that the patient/caregiver calls the PACE site and reports fall in a suggested format which is then documented in patient's record. It might not be very feasible or reliable but ultimately the data is collected and reported by that PACE site. Also, another thing to discuss would be as to how the patient filled forms are submitted to the PACE sites timely to include the data in the quarterly reporting.</p>
188.	TEP	9/15/2015	<p>It would be difficult if not possible to have systematic and consistent reporting and no effort should be placed on the development of this tracking.</p>

No.	Comments Public/TEP	Date Posted	Verbatim Comments
189.	TEP	9/15/2015	This is most effectively left to the PACE programs to develop and implement systems to promote reporting of falls. PACE teams tend to believe that primarily participants know and remember they fell, but do not want to report (for a variety of reasons). Adding a form would not improve this situation – and would add tremendous administrative burden on the program. On a case by case basis, which is what PACE does best, the PACE programs need to develop processes that promote the reporting of falls. However, with the lack of data in general, it may be impossible to know what the real number of falls is and therefore how many go unreported. This is a very complicated issue – creating and adding a form is not the answer.
190.	TEP	9/16/2015	I would recommend that this answer is best captured by a facilitated group discussion with stakeholders. The challenge here is that the data will be used to make decisions about value. This may be a big disincentive for participants or caregivers in a non-clinical setting to self- report a fall for fear of the consequences that they perceive will be result from this reporting. It would also be very difficult to validate if the form is being used consistently and thus if some reporters are more diligent in completing the form, they may end up being perceived as having a higher rate of falls that those individuals who do not report this consistently.
191.	TEP	9/16/2015	Our PO has developed a fax form for fall reporting. We don't think a standardized form across all PACE sites is necessary. We also ask participants and caregivers to call if there are any injuries associated with the fall, in addition to faxing the form.
192.	TEP	9/21/2015	PACE participants/caregiver could answer this better.
<p>Question 5: Based on some of the comments received and our testing results, CMS and Econometrica are considering the development of a fall prevention measure in future contract years. What factors should CMS consider in developing a prevention measure for falls within PACE?</p>			
193.	Public	9/17/2015	Each time a person falls, they are seen in our clinic and our therapy does a review of the fall. From that fall, interventions are put in place. Perhaps a list of interventions that is in place at the time of the fall.
194.	Public	9/24/2015	The impact on staff time is very important to us. Any measure should minimize additional data gathering, and have a clear purpose.
195.	Public	9/24/2015	CMS and Econometric should consider factors that contribute to falls or increase the risk of falls, including the participant's diagnoses (including balance issues), vision, the participant's living environment (e.g., tripping hazards like rugs), participant history of falls, participant and caregiver education about reducing the risk of falls, etc. Research shows the most effective intervention is consistent participation over time in evidence based falls prevention exercise programs. Some programs also have a wellness component which includes the other risks for falls (home safety, vision, medications, diet rich in calcium). Falls prevention measures also include Vitamin D, calcium and other bone strengthening supplements. New study shows this is an effective approach in falls reduction.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
196.	Public	9/24/2015	<ul style="list-style-type: none"> It would need to be some process metric. If PACE programs are held accountable to this, are we going to see any progress? We should look at falls/second falls – secondary prevention of falls. Focusing on secondary and not primary fall prevention might yield better results. XXXX would recommend measures that focus on secondary rather than primary prevention of falls. CMS must consider the prevalence of falls in the population especially as individual's age in place in more mature PACE Organizations.
197.	Public	9/24/2015	While measuring fall rates is extremely important, fall rates are limited in that they do not describe how to improve care. To know where to focus improvement efforts, it is important to measure whether key practices to reduce falls are actually happening. To that end, a fall prevention measure should include screening for fall risk, care plan for falls documented, and execution of care plan. For that reason, we strongly support the development of a fall risk screening measure.
198.	TEP	9/13/2015	The metric can comprise of documentation of fall risk assessment/ fall score (a consistent fall prevention scale that can be used amongst all PACE sites will be helpful), developing clinical pathways for falls prevention, fall prevention activities. Consideration should also be given to risk/acuity adjustment.
199.	TEP	9/15/2015	Ultimately the measure of success with falls prevention would be the rate of falls with injury, making this measure redundant and prone to all kinds of biased reporting.
200.	TEP	9/15/2015	Medication management reviews, home safety assessments done annually.
201.	TEP	9/16/2015	<p>CMS should consider two main factors that will affect the reliability and validity of the data that are unique to the PACE program:</p> <ol style="list-style-type: none"> Who will be collecting and reporting this data- in the clinical setting the caregivers can be trained and tested to ensure that the data they collect and report is consistent with the measure specifications. For PACE participants in the community, since there may be an unwitnessed fall that does not get reported, what can be done to ensure that the data does not get biased as a result of self-reporting? How will CMS validate the data that are reported? Experience from the IP setting demonstrates that a strong validation process is necessary to ensure that the measure specifications are followed to collect and report data. This ensures that differences in performance rates can be attributed to meaningful differences in performance and are not a reflection of differences in how data are collected and reported.
202.	TEP	9/16/2015	Please consider the burden of reporting and what would constitute a prevention measure.
203.	TEP	9/21/2015	Indicators should include: day of week, time of day, medications and time meds administered with a focus on specific medication if possible, gender, age, functionality (w/c bound, ambulatory).

No.	Comments Public/TEP	Date Posted	Verbatim Comments
<p>Question 6: CMS and Econometrica believe that preventative measures are vital to ensuring quality of care for PACE participants. Through our testing and the public comments, we understand that current processes are prohibitive in terms of capturing data for a pressure ulcer prevention measure. CMS and Econometrica would like to invite feedback on how we can direct and/or incorporate processes in order to promote effective reporting on such a measure. Should CMS adapt a pressure ulcer scoring system (e.g., Braden) and/or a bundling pressure ulcer prevention system to capture data effectively and consistently across PACE organizations?</p>			
204.	Public	9/17/2015	100% of participants have a skin risk assessment, and based on the risk assessment interventions are put in place. Braden does not adequately address PACE participants; it is designed for an acute care setting. It would be expensive for CMS to develop a comparable tool.
205.	Public	9/17/2015	<p>Having worked many years in nursing homes and short-term skilled rehabs as a social worker and discharge planner, I'm in full support of standardized measuring tools used throughout healthcare systems. I think a wound care measuring tool such as the Braden scale would be ideal for PACE as it's been proven effective in long-term care for many years.</p> <p>As a PACE analyst I have found that many centers have created their own specific tools which are not compatible with other PACE organizations. A scoring system such as the Braden scale would capture data effectively and consistently across PACE organizations.</p>
206.	Public	9/22/2015	Pressure ulcer reporting is very important - how do we handle "Kennedy ulcers, or ulcers associated with malignancy and end of life reporting (should it be a separate category as development and management are different than other pressure ulcers.)
207.	Public	9/24/2015	Yes, we have incorporated the Braden into our EHR nursing assessment.
208.	Public	9/24/2015	The Braden score is considered an evidenced based tool for identifying risks of pressure ulcer not prevention measures. The National Pressure Ulcer Advisory Panel recognizes the need to measure preventions of PU.
209.	Public	9/24/2015	<ul style="list-style-type: none"> • It could be part of a bundling system where the scoring could determine if an individual is high risk. Interventions may not be enough. We should look at measuring interventions in order to address preventions. The methodology for determining risk should be standard. Right now, it is uncertain whether it's the type of intervention or whether the intervention was implemented. Another thing to look at is how involved is the caregiver. Caregivers can have a direct impact on quality. You need to account for what the caregiver does and does not do. Caregiver support should be addressed. • Developing measures related to pressure ulcers should be done in consideration for both risk factors, as well as the implementation of appropriate interventions. PACE Organization's should be required to utilize industry accepted assessment tools such as those used by nursing facilities. Measures should also include the appropriate emphasis on caregiver driven interventions.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
210.	Public	9/24/2015	A measure that assesses the number of participants who are at risk for Pressure ulcer (Braden score 18 or less) who have a prevention plan in place may be a valuable quality measure. To lower the administrative burden, it is recommended that only the most recent assessment be captured if a participant has more than one Braden score during the 6-month reporting period. It also is important to capture incident cases of PACE-acquired PUs, as well as, assess worsening of PUs.
211.	TEP	9/13/2015	Yes. Braden scale is a valid tool used in hospitals and nursing homes. If this or another valid tool would be suitable for the PACE population which might have more frail elderly, it should be used. This will help in consistency in data collection and comparison at the same level across all PACE sites.
212.	TEP	9/15/2015	Many POs do use pressure ulcer scoring like Braden in the applicable subpopulation with significant mobility limitations.
213.	TEP	9/15/2015	Braden is widely utilized and applicable to the PACE population – standardizing its use would be reasonable.
214.	TEP	9/16/2015	Yes. It would be the only way to ensure that the results of the Fall and Pressure measure rates are interpreted in a meaningful way and that programs with a higher ulcer rate with a higher percentage of participants at risk for ulcers are not perceived as providing lower quality care when compared to programs with a lower ulcer rate and lower percentage of patients with a risk for developing pressure ulcers.
215.	TEP	9/16/2015	We do think a standardized validated tool should be used. Because there is more than one tool, it might be helpful for CMS to recommend two or three that could be used. Requiring every PO to use the same one would place a burden on those with EHRs to make changes to their current systems. A bundled prevention system that is outpatient based, specific to the PACE population (aged with chronic conditions and multiple co-morbidities) that could be personalized and encompass goals of care would be welcome.
216.	TEP	9/21/2015	We should capture pressure ulcers based upon the severity of pressure ulcer and the presence of such ulcer on admission to the program.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
<p>Question 7: Several comments from the public were related to the performance of PACE organizations and low admission rates are well considered and appreciated. Given the current focus on readmissions as an area of quality improvement (e.g., Hospital Compare), there are conversations regarding whether the focus should be on reduced admissions, or index stays, which would reduce the rate since the denominator is not as large. Is admission a more appropriate quality measure for PACE than 30-day Readmissions, or is there a more appropriate measure for use in the context of PACE?</p>			
217.	Public	9/17/2015	30 day readmission rates would be appropriate for PACE.
218.	Public	9/22/2014	With respect to All-Cause re-admissions: The more effective a program is at reducing preventable hospitalizations, the less likely it will be that it can eliminate or make significant reductions in its re-admission rate. In a two year period following UM review and care transitions redesign, we reduced our admissions per member, per year by 30% but our re-admission rate did not change significantly. Instead of or in addition to using the index admissions or total admissions as a denominator, I would suggest examining the validity of looking at the re-admissions as a percentage of the population as a whole. This could be compared to the nursing-home eligible community-dwelling and nursing home dwelling participants of other plans. I also agree with the suggestion that this be paired with a hospital admissions (both index and non-index) rate.
219.	Public	9/23/2015	I share the concern regarding low denominators of hospital admissions from PACE Organizations to falsely represent readmission rates when reported as a % of discharges. While recognizing that preventing avoidable readmissions is still something to focus on for all providers across the continuum it may be more helpful to develop an alternative rate for PACE. Reducing index admissions would be a beneficial additional measure that could also align with ACO metrics for ambulatory sensitive conditions.
220.	Public	9/24/2015	We believe the most important measure, more so than the number of admissions or re-admissions, is whether or not it was preventable. This is a process requiring intensive review, and goes beyond a simple count. Appropriate admissions are not a problem, but those that could have been prevented are – a simple count will not be very revealing, and could be subject to misinterpretation.
221.	Public	9/24/2015	Please consider that many elderly participants may not be admitted to the hospital; they may be treated and release or held over for observation without admission. I would recommend a focus on admissions with the exclusion of participants on hospice status and Emergency Department visits stratified as less than X hours or more than X hours (possibly the dividing point be 6-8 hours). CMS and Econometrica may also want to give consideration to a utilization measure of different levels of medical service including ER visits without admission.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
222.	Public	9/24/2015	<ul style="list-style-type: none"> • It is best to measure readmissions. We need to clearly define “unplanned” readmissions. The current list of exclusions is appropriate. Readmissions are something that could potentially be prevented with proper discharge planning and prevention strategies being implemented. Solving the readmission problem is a necessary prerequisite for solving admissions. • The 30-day readmission rate is a more appropriate measure for PACE Organization given the frailty of its members. Prevention measures can be leveraged to help reduce the number of unplanned readmissions.
223.	Public	9/24/2015	Examining 30-day all-cause readmission in isolation may not provide an accurate indication of quality. For example, a “high-performing” PACE program may have a low admission rate, and their readmission rate (calculated as proposed) may well be high, because the only participants being admitted to hospitals are individuals for whom hospitals actually offer substantial gains and whose health is fragile and finding stability is challenging. On the other hand, a “low-performing” PACE program might have a high hospital admission rate due to the number of elders who could have been served in other settings, but their readmission rate may be low since its admission rate is so high. We recommend that CMS consider examining the 30-day all-cause readmission rate in conjunction with the hospital admission rate.
224.	TEP	9/13/2015	It is recommended that the current focus on readmission applies and stays consistent with many of the CMS reporting programs but due to the uniqueness of the PACE population and the questions on reliability of this measure where a low performing site can falsely have a lower readmission rate, Hospital admission rate will not have this disadvantage. Another metric to consider can be days in the community.
225.	TEP	9/15/2015	It would be appropriate to track ambulatory sensitive hospitalization rates and ambulatory sensitive ED rates.
226.	TEP	9/15/2015	I would recommend both be measured – admissions PMPM and readmissions.
227.	TEP	9/16/2015	I would defer to the experts on the TEP that are in PACE programs about this. From my experience with measure reporting and quality measurement, I would urge that whatever measure is used, that it utilizes some level of risk adjustment to allow for comparisons across different populations and that attention is paid that the measure as specified does not create perverse incentives to withhold care for a PACE participants in order to control the rates being reported.
228.	TEP	9/16/2015	We agree with the 30 day readmission measure. An overall hospital admissions measure could dissuade POs from utilizing appropriate and necessary inpatient care.
229.	TEP	9/21/2015	After listening to the webinar yesterday, I understand this indicator will possibly be “dropped”. This is a significant indicator for acute care hospitals and can provide PACE programs with an outcome measure.

No.	Comments Public/TEP	Date Posted	Verbatim Comments
General comments:			
230.	Public	9/17/2015	<p>Regardless of the measures, please do not increase the burden of reporting with detailed participant specific information, for example participant AC had a fall on 9/1/15 at 7pm and with no injury. Participant AC had a fall on 9/1/15 at 8pm and had minor injury, bruise to right hand which was evaluated in clinic. This type of detail is done in a healthy QAPI program which should be in place and reviewed quarterly by the CMS Account Manager.</p> <p>Another burden would be a 100% chart review quarterly to assure that each Participant has been risk assessed and what that assessment is. Again this type of information is an “expectation” of the semi-annual/annual assessment, and should be part of the chart review done by CMS at their survey.</p>
231.	Public	9/22/2015	<p>Additional measures: Referring to the HHS website on patients with multiple chronic medical conditions (http://www.hhs.gov/ash/initiatives/mcc/goals/framework-goals.html), future measures to be considered would be: Outcomes measures across multiple co-morbidities (i.e., COPD, CHF, Diabetes - preventing ER visits, hospitalization, 30 day readmissions), patient self-management, Quality of life, functional Independence, prevention of medication errors.</p>
232.	Public	9/23/2015	<p>We received the email from CMS inviting us to comment on the 7 additional questions on Sept 16, 2015. The comments are due September 24. Given that 2 days were lost to the weekend, which is not enough time to read the document, let alone respond.</p> <p>Please bear in mind that we are still gathering enormous amounts of information for CMS every day – HPMS data and Level II events, and using very awkward tools for data submission to CMS. We had to read through all the materials, prepare a presentation for our QI Committee, and then try to get feedback – can’t be done, or at least be done well.</p> <p>The timeframe for response needs to be extended, please. Thank you, <i>(Note: This commenter later supplied answers to the questions and are included in this report)</i></p>
233.	Public	9/24/2015	<p>Overall XXXX recommends that CMS develop quality measures in conjunction with current discussions for quality measurement approach for Medicare-Medicaid Plans given the similarities in goals and issues related to risk adjustments.</p>

No.	Comments Public/TEP	Date Posted	Verbatim Comments
234.	Public	9/24/2015	<p>In January 2014, CMS issued the final rule outlining requirements for home and community-based service (HCBS) settings. The rule supports enhanced quality in HCBS programs and adds protections for individuals receiving services. The rule reflects CMS' intent to ensure that individuals receiving services and supports through Medicaid's HCBS programs have full access to the benefits of community living and are able to receive services in the most integrated setting. In addition, CMS specifies that service planning for participants in Medicaid HCBS programs must be developed through a person-centered planning process that addresses health and long-term services and support needs in a manner that reflects individual preferences and goals. This planning process, and the resulting person-centered service plan, will assist the individual in achieving personally defined outcomes in the most integrated community setting, ensure delivery of services in a manner that reflects personal preferences and choices, and contribute to the assurance of health and welfare.</p> <p>The four measures selected (falls, falls with injury, pressure ulcers and 30-day readmissions) rely solely on clinical measures and fail to capture the very essence of CMS's own definition of home and community based services. While the current measures are important clinical measures, they are silent on other critical quality aspects such as the individual's experience of care; the person centered planning process and community integration. PACE programs across the country would be well served to include quality measures beyond standard clinical quality measures. Failure to include these non-clinical measures places PACE program participants at risk of receiving care that is not in line with key components of the home and community based service setting rule.</p>