Public Comment Report

Project Title:

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

Dates:

The Call for Public Comment ran from November 15, 2017 to December 15, 2017.
The Public Comment Summary was made on January 17, 2018.

Project Overview:

The Centers for Medicare and Medicaid Services (CMS) has contracted with Econometrica, Inc., to adapt, implement, and maintain quality measures for PACE nationwide. 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. The contract was awarded for a one (1)-year base period (or Base Year), with an option for three (3) additional years.

As part of the measure development process, CMS requested interested parties to submit comments on the draft measures that may be suitable for this project. This comment request included the following three (3) measures.

- PACE Participant Influenza Immunization;
- PACE Staff Influenza Immunization; and
- PACE Participant Emergency Department (ED) Utilization Without Hospitalization.

In addition to general comments regarding these three (3) measures and their specifications, we requested feedback on the four (4) specific issues below that became apparent during the validity testing phase.

<u>For Participant and Staff Influenza Immunization Measures:</u>

Issue #1: Definition of reporting influenza season. The experts thought that defining the influenza immunization season as beginning on October 1st and ending on March 31st would not capture participants getting vaccinated before October 1st, although vaccines are available early in August-September. Most experts recommended beginning on September 1st, and the measures were revised to reflect this recommendation. However, some other experts suggested August 1st as the start date or stating "begin with vaccine availability." We are seeking additional comments on the definition of "**reporting influenza season."**

Issue #2: Denominator of the Participant Influenza measure. CMS received several comments on the inclusion criteria for the denominator of the Participant Influenza measure – "including participants enrolled in PACE for **at least one (1) day** during the reporting flu season." The experts thought that one (1) day was not sufficient to ensure

assessment and screening by PACE Organizations. The experts recommended including participants enrolled at least two days (48 hours) or 14 days. We are seeking additional comments on the denominator for this measure.

Issue #3: Definition of Contraindications. In the measure description, we propose to have a separate percentage calculated on this measure for PACE participants that are ineligible to receive immunizations base on contraindications. The experts thought that it would be better to describe **well-defined medically contraindicated conditions**. The Centers for Disease Control (CDC) webpage (https://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm) cited in the instructions combines true contraindications (like anaphylaxis) with precautions (like a history of Guillian-Barre Syndrome following vaccination), so it would not be clear whether the precautions could or should be treated as contraindications for the measure. We are seeking additional comments on defining contraindications and precautions within the measure versus referencing the CDC webpage because recommendations may change over time.

For the ED Utilization Without Hospitalization Measure:

Issue #4: Observation Stays. Many experts disagreed with excluding observation stays from the numerator, which counts the number of ED visits that do NOT result in a hospitalization (*i.e.;* the experts felt that observation stays should not be counted as a hospitalization). We are seeking additional comments on the treatment of observation stays in this measure of ED Utilization without Hospitalization.

Project Objectives:

The primary objectives of this project are to:

- Analyze existing quality measure sets to determine the extent to which they can be uniquely modified, refined, or enhanced for PACE.
- Focus on new areas of measurement during each year of the project.
- Conduct field tests to assess the feasibility of data collection for proposed measures.

Information About the Comments Received:

- Public comments were solicited by announcements made during stakeholder group meetings, email notifications, and memos distributed to PACE Account Managers and PACE Organizations (POs).
- The Call for Public Comment was posted on the CMS Call for Public Comment Web site: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Currently-Accepting-Comments.html.
- In total, 14 unique email responses were received through the PACEQMcomments@econometricainc.com address provided as part of the Call for Public Comment:
    - Nine (9) email responses were from unique PACE Organizations.
    - One (1) email response was from a family caregiver.

- One (1) email response was from the developer of a related measure.
- One (1) email response was from the National PACE Association (NPA).
- Two (2) email responses were from unique State agencies.

Stakeholder Comments—General

Four (4) email responses expressed support for the measurement topics included in Stream 3. However, four (4) email responses expressed concern over the burden of data collection. Additional concerns were expressed in four (4) email responses regarding overlap with existing reporting that PACE Organizations (POs) participate in. Finally, three (3) email responses requested additional clarification and transparency from CMS regarding the future use and intent of these measures.

TEP Recommendations

The Technical Expert Panel (TEP), which includes staff from multiple POs, was sensitive to the concerns over data collection burden. They suggested elimination or combination of quality measure data elements where possible. The TEP also discussed the need for clear information from CMS regarding the implementation of quality measures and how these new measures will impact current reporting, including HPMS reporting.

Response

We appreciate the general comments in support of the effort to develop quality measures for PACE, and remain sensitive to issues surrounding data reporting burden. We will continue to refine data elements collected for each measure throughout the measure development and testing process, and make specific recommendations for data elements that can be combined or eliminated at this time under the discussion of each measure below. It is important to note that, where possible, eMeasures will be developed for quality measures which pass testing and are approved for implementation by CMS. These eMeasures should reduce overall reporting burden for POs that have electronic medical records. Additionally, in cases where measures selected for implementation overlap with current Level 1 or Level 2 reporting, the new measures will replace the current reporting. That is, there will be no duplication between current and newly reported measures after implementation.

Stakeholder Comments

Responses to Specific Issues Regarding Participant and Staff Influenza Immunization Measures

Issue #1: Definition of reporting influenza season. There was no consensus amongst respondents regarding the definition for the influenza reporting season for the Participant or Staff Influenza Immunization measures. Roughly equal numbers of respondents selected August, September, and October as the start on the influenza season, with additional recommendations to harmonize with other immunization measures, or to collect data on the date vaccine availability as part of the measures.

TEP Recommendations

Previously, the TEP recommended using September 1st as the start of the influenza immunization measure, based on member comments regarding vaccine availability and input from a member pharmacist.

Response

Influenza immunizations and the influenza season begin at different months across the United States. We have retained September 1st as the start date for the influenza immunization season, but have added wording to allow inclusion of participants who were immunized in August for the upcoming flu season to avoid any deterrence to immediate immunization if vaccines are delivered prior to September 1st in certain areas.

Issue #2: Denominator of the Participant Influenza measure. Five (5) respondents recommended that PACE Organizations be given 14 days to immunize new participants for the Participant Influenza Measure. Only one respondent recommended a shorter timeframe.

TEP Recommendations

The TEP agreed that the original inclusion or participants enrolled for at least one (1) day was not long enough to allow immunization of new participants.

Response

We agree that assessment and coordination is needed prior to arranging immunizations for new participants. We concur with the recommendations to include participants enrolled in PACE for at least 14 days, and have revised the measure accordingly. Based on questions received regarding the definitions of contractors, and how to handle short term contract staff, we similarly revised the contractor section of the PACE Staff Influenza Immunization measure to include contractors who work on site at a PO for at least 14 days.

Issue #3: Definition of Contraindications. Only three (3) email responses provided input into the definition of contraindications. Two (2) of those recommended defining contraindications in the measure specifications, while the third recommended linking to the CDC webpage for the most up to date contraindications.

TEP Recommendations

The TEP did not provide specific feedback on this issue.

Response

While we understand that it may be more convenient to determine contraindications by referring to the measure specifications, we remain concerned that there may be a delay between a change in recommendations from the CDC and corresponding revision of the measure specifications. Because providers should be basing their immunization

administration recommendations on the most recent guidance rather than the measure specification, we have decided to continue to reference the CDC's webpage.

Other Influenza Immunization Comments

In addition to responses to the specific issues presented in the call for public comments, four (4) email responses provided recommendations regarding ways to combine or reorganize the data elements for both Influenza Immunization measures. Additionally, two (2) email responses commented on overlap between the proposed measures and other PACE quality indicators. Four (4) email responses also requested clarification regarding the definition of "contractor" for the Staff Influenza Immunization measure.

TEP Recommendations

The TEP members recognized the challenges in defining inclusion criteria for this measure, and raised concerns about the feasibility of 1) collecting immunization data from third-party contractors, and 2) requiring non-employees to be immunized. However, members of the TEP (including testimony provided by a PACE participant and caregiver) continue to place importance on the spirit of this measure: minimizing PACE participant exposure to influenza. Throughout the course of discussion, TEP members agreed the measure should be limited to contractors who provide services on-location at a PACE Center to ease the burden of tracking contractor immunization data. The TEP also recommended defining contractors as any person who does not receive a paycheck directly from the PO, but is instead paid as an independent contractor, or receives their paycheck from another entity which the PO contracts with for services. They also recommended that only contractors who provide a service at the PACE Center should be included in the measure denominator.

The TEP also expressed the need for CMS to clarify how overlapping measures will be handled for PACE reporting.

Response

Based on the recommendations made regarding the data elements for the Influenza Immunization measures, we revised both measures to include one (1) data element, with numeric codes to indicate immunizations received, declined, contraindicated, or not offered. This revision should streamline the data collection process for both measures.

Regarding overlap with current quality indicators, in cases where measures selected for implementation overlap with current Level 1 or Level 2 reporting, the new measures will replace the current reporting. That is, there will be no duplication between current and newly reported measures after implementation.

Because the Staff Influenza Immunization measure calculates immunization rates for employees and contractors separately, we acknowledge the need to clarify the definition of "contractor" for this measure. We have added the following language to the measure specifications to define the term contractor:

An individual, working either independently or for a non-PACE entity, that has a contract with a PACE Organization to provide services onsite in a PACE facility. The definition of contractor for this measure is more restrictive than the definition provided in the PACE manual to meet the specificity necessary for reliable and valid measurement.

- Contractors are not on the payroll of a PACE Organization. They are either on the payroll of another entity which receives payment from the PO, or are paid directly by the PO as an independent contractor who receives a form 1099.
- Include all contractors who have worked onsite at a PACE Organization for a minimum of 14 days for the period between September 1st through March 31st of the following year.
- Short term or temporary contractors (those working for a PACE Organization for less than 14 days) are excluded from this measure.
- Community-based independent healthcare practitioners (doctors, dentists, advanced practice nurses, physician assistants, and therapists) are excluded from this measure.

Stakeholder Comments—Responses to Specific Question Regarding Emergency Department Utilization

Issue #4: Observation Stays. Three (3) email responses stated that observation stays should be included in the numerator, while two (2) email responses felt that observation stays should be excluded. A variety of explanations were provided for these recommendations.

TEP Recommendations

Early TEP discussions and recommendations on this measure focused on determining how to measure whether an ED visit was appropriate, and developing a measure specification that did not discourage POs from utilizing the ED when doing so was clinically necessary. The TEP remains comfortable with the measure specification for the proportion of ED visits that did not result in hospitalization, rather than a specification that would consider ED utilization rates more generally. Further, the TEP agreed that including observation stays as a "hospitalization" under the measure specification will help serve to ensure that the measure does not discourage appropriate ED visits. While the TEP grappled with the challenges of this measure over the course of several prior meetings, the members reached consensus on the importance of measuring ED Utilization in PACE, and noted that PACE typically out performs similar care models in this area.

Response

The wording of the comments and reasoning provided for the recommendations around the inclusion or exclusion of observation stays has lead the development team to believe that there may be some confusion regarding the specifications of this measure. The intent of the measure, as presented for comment, was to treat observation stays the same as hospital admissions, that is, an ED visit resulting in an observation stay would not count against a PO for

this measure. The numerator would only include ED visits that did not result in an additional stay in the hospital, either as an admission or observation stay. The measure has been revised to clarify this issue. Additionally, the data element for this measure has been revised to distinguish ED visits resulting in observation stays from ED visits resulting in hospital admissions. This will allow for alternate rate calculations during reliability testing, and will reduce the impact of any remaining confusion over the exclusion criteria.

Other ED Utilization Comments

In addition to responses to the specific issue presented in the call for public comments, general comments regarding the ED Utilization measure were very similar to those received for other measures in this round of public comment. Two (2) email responses commented on overlap between the proposed ED Utilization measure and other quality indicators, and three (3) email responses also requested clarification regarding the intended use of the measure.

TEP Recommendations

The TEP did not provide specific recommendations on these issues raised in the public comments as they relate to ED Utilization. They did express a general desire for clarity from CMS regarding future plans and how overlapping measures will be handled.

Response

Regarding overlap with current quality indicators, if the ED Utilization measure is implemented by CMS, it will replace any overlapping Level 1 or Level 2 reporting.

Overall Analysis of the Comments and Recommendations

- Given the timing of this Public Comment Period, which was held prior to reliability and feasibility, there were many questions raised regarding burden and data collection feasibility which are currently unknown. Further testing will address these issues and assist with making decisions regarding appropriate revisions to the specifications.
- Specifications should be revised as needed based on the issues and clarifications raised during the Public Comment Period and from the results of upcoming reliability and feasibility testing.
- Based on comments received and TEP discussion, we restructured the data elements for the Influenza Immunization measures to create one data element with numeric codes indicating receipt of immunization, contraindication to immunization, or refusal of immunization.
- We modified the inclusion criteria for the Immunization Measures to participants and contractors either enrolled or working on site at a PACE Organization for more than 14 days.
- Based on comments received, we revised the ED Utilization measure data elements to capture ED visits resulting in admission separately from ED visits resulting in observation stays.

We appreciate the input and feedback received from all commenters and value the public comment process. The comments and feedback received from these stakeholders provided meaningful and useful input into the Stream 3 measure specifications and data collection instructions. The TEP reviewed and discussed all Stream 3 comments received during the 30-day Public Comment Period. Some of the commenters submitted comments that can be responded to by highlighting specific areas of the provided measure specifications. There was general support for the intent of the measures, and concerns regarding the measures generally focused on data collection burden.

Public Comment Verbatim Report

Date Posted	Measure Set or Measure	Text of Comments	Name, Credentials, and Organization	Responses
11/21/17	Participant Influenza	Definition of reporting influenza season. We are ok with the defining the influenza immunization season as beginning on September 1st. -We are moving towards that goal currently as it seems that influenza season begins earlier every year. Our goal for next year is to begin vaccinations in September, in line with the -proposed change. August seems early to us, but we would be willing to begin vaccinations as early as vaccines become available. Denominator of the Participant Influenza measure. -We would prefer a minimum of 48 hours on this measure. It is difficult to get all the necessary assessment criteria completed AND get immunizations performed in a single day so the extra time would be incredibly beneficial. 14 days would be preferred with the size of our organization, the extra time could be critical to remain compliant. Definition of Contraindications. -Having a well-defined medically contraindicated condition would be beneficial. Although, adding separate measures means slightly more work, but it would be more accurate and reduce the need for referencing the CDC webpage with the possibility of changes. Separating contraindications and precautions would improve reporting.	Paige Harrington InnovAge - Lowry	Thank you for your comments. Immunizations and flu season begin at different months across the U.S. We have modified the definition of flu season to begin on September 1st, but to include participants who were immunized in August for the upcoming flu season. Additionally, we have modified the measure description to include participants to be those who were enrolled in PACE for a minimum of 14 days. We agree that having specific conditions or experiences that indicate a contraindication for immunization could be helpful, but we did not make this change. The reasons for contraindications change periodically so we advise looking at the CDC website regularly for recent changes.
11/21/27	ED Use	Observation Stays. -We also agree that the observation stays should not be counted as a hospitalization. We believe it is fair to not include those in that number.	Paige Harrington InnovAge - Lowry	Thank you for your comment. The measure counts observation stays as hospitalizations to align with similar NQF-endorsed quality measures. During pilot-testing, we will examine

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				patterns of observation vs. inpatient stays, as well as issues that PACE Organizations encounter in data collection.
11/22/17	General	Centra PACE continues to appreciate data driven initiatives and the desire by CMS to have consistent definitions. The measures selected here are relevant to our PACE organizations, and are already being tracked in one way or another within our organization. To implement and maintain these measures should not be a financial or time burden to PACE organizations because it will simply be a reorganization of current excel spreadsheets. Again, our PACE organization would appreciate comparison reporting with like size organizations. Two of these measures (Participant Influenza Immunization and Emergency Department Utilization) are already tracked as Level 1 data in HPMS. Once these measures are implemented, we recommend that that the current HPMS Level 1 requirement be removed, because the variables listed in these measures are already being reported, and could be extracted from the current HPMS submissions. Once the measures are finalized, please allow a minimum of six months for PACE organizations to implement the required data collection strategy.	Kimberly Woodley Centra PACE	Thank you for your comment. Input regarding the burden of collecting these measures, and their relationship to measures currently being reported is helpful as we move forward with development.
11/22/17	Participant Influenza	1. Participant Influenza Immunization Again, if this measure is adopted, we expect the current Level 1 measure requirements to be eliminated to prevent duplicate data entry. The numerators of the three sub measures, denominator, and inclusion criteria clearly are defined and reasonable.	Kimberly Woodley Centra PACE	If participant flu immunization is adopted, that it will replace the current Level 1 measure. We have adopted your suggestion to combined the received, offered and declined, ineligible, and not offered-not received into one variable with

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		Auto-Generated Participant Number: This is a reasonable field however, it will require PACE organizations to include a participant identifier column for our internal tracking purpose, which will be removed prior to submission. Based on the current definitions, we would like to combine the received, offered/declined, and ineligible to one column in the spreadsheet. It would streamline the reporting and an analysis could be easily done with a pivot table or other electronic sorting tool. We would like to suggest: Influenza immunization status: 1 = Yes, the participant received an influenza immunization during the reporting influenza season, either in the PACE Organization or outside the PACE Organization. 2 = No, the participant was offered and declined the influenza immunization during the reporting influenza season, either in the PACE Organization or outside the PACE Organization. 3 = No, the participant was ineligible to receive the influenza immunization due to contraindication(s) during the reporting influenza season. 4 = No, although the participant was eligible, the participant was NOT offered and did not receive an influenza immunization. 99= There is no documentation available regarding the participant's influenza immunization status (received, offered and refused, or ineligible.) Received influenza vaccination: If the recommendation to combine all the responses into one column is not accepted, then our organization does not have any additional recommendations with this variable. Offered and declined influenza immunization: If the recommendation to combine all responses into one		each immunization status receiving a different numeric code.

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		column is not accepted, then clarification needs to be provided for those participants who were offered and received the vaccination; are these left blank? Ineligible for influenza immunization: If the recommendation to combine all the responses into one column is not accepted, then our organization does not have any additional recommendations with this variable.		
11/22/17	Staff Influenza	The third measure, Staff Influenza Immunization, is tracked by our Parent Organization's Employee Health Department. We are NOT endorsing the use of this measure due to concerns regarding our employee's right to privacy and that non-managers will have access to individual employee information. Additionally, employee immunization is not a requirement addressed in PACE regulations. 2. Staff Influenza Immunization Measure Again our organization is recommending that this measure not be adopted. If it is adopted: The numerators of the six sub measures, two denominators, and inclusion criteria clearly are defined and reasonable. The elements and inclusion criteria are also clear and reasonable. Number of PACE staff members: This variable is unnecessary and should be removed, because this should be equal to the count of the auto-generated staff number. Additional guidance is needed for this data. Would this be a single integer on Column A of the Spreadsheet or would this be a separate spreadsheet with only the two integers? Number of PACE contractors: This variable is unnecessary and should be removed, because this should be equal to the count of the auto-generated	Kimberly Woodley Centra PACE	We concur with the importance of PACE staff's right to privacy. However, this measure does not require identifiable data. One way to address this concern is to have your Employee Health Department, which is authorized to have access to staff medical data, prepare a deidentified (auto-numbered) list of each staff member's immunization status. They will be able to track staff using existing identification number and thus there would be no need to implement another number. Regarding your comments on measure specifications, asking for the number of staff and contractors is a way for you to double-check data entry to see if you have included all staff; there should be agreement between the auto numbered lists and your count of employees and contractors. We appreciate your suggestion to combine the immunization categories into a single variable and

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		contractor number. Additional guidance is needed for this data. Would this be a single integer on Column B of the Spreadsheet or would this be a separate spreadsheet with only the two integers? Auto-Generated staff number: This is a reasonable field however, it will require PACE organizations to include a staff member identifier column for our internal tracking purpose, which will be removed prior to submission. As commented upon in the previous measure, based on the current definitions, we would like to combine the received, offered/declined, and ineligible into one column in the spreadsheet. It would streamline the reporting and an analysis could be easily done with a pivot table or other electronic sorting tool. We would like to suggest: Influenza immunization status: Staff 1 = Yes, the staff member received an influenza immunization during the reporting influenza season, either in the PACE Organization or outside the PACE Organization. 2 = No, the staff member was offered and declined the influenza immunization during the reporting influenza season. 3 = No, the staff member was ineligible to receive the influenza immunization due to contraindication(s) during the reporting influenza season. 4 = No, although the staff member was eligible, the participant was NOT offered and did not receive an influenza immunization. 99= There is no documentation available regarding the staff member's influenza immunization status (received, offered and refused, or ineligible.) Received influenza vaccination: Staff: If the recommendation to combine all the responses into one column is not accepted, then our organization does not		have modified the instructions and data collection spreadsheet to reflect your suggestions, except for the 4th category (not offered and did not receive) which we have combined with no documentation. We applaud NYS's requirements for healthcare staff and contractors to have influenza immunizations, although this is not the case in every state and, thus, an important measure for all PACE Organizations. Regarding contractors, we do not limit contractors to healthcare professionals. Rather, we include any contractor, regardless of job title, who provides "on-site" services to a PACE Organization.

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		have any additional recommendations with this variable. Offered and declined influenza immunization: Staff: If the recommendation to combine all responses into one column is not accepted, then clarification needs to be provided for those staff who were offered and received the vaccination; are these left blank? Ineligible for influenza immunization: Staff: If the recommendation to combine all the responses into one column is not accepted, then our organization does not have any additional recommendations with this variable. Auto-Generated contractor number: This is a reasonable field however, it will require PACE organizations to include a contractor identifier column for our internal tracking purpose, which will be removed prior to submission. As described in the previous variable, based on the current definitions, we would like to combine the received, offered/declined, and ineligible to one column in the spreadsheet. It would streamline the reporting and an analysis could be easily done with a pivot table or other electronic sorting tool. We would like to suggest: Influenza immunization status: Contractor: 1 = Yes, the contractor received an influenza immunization during the reporting influenza season, either in the PACE Organization or outside the PACE Organization. 2 = No, the contractor was offered and declined the influenza immunization during the reporting influenza season. 3 = No, the contractor was ineligible to receive the influenza immunization due to contraindication(s) during the reporting influenza season. 4 = No, although the contractor was eligible, the contractor was NOT offered and did not receive an influenza immunization.		

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		99= There is no documentation available regarding the contractor's influenza immunization status (received, offered and refused, or ineligible.) Received influenza vaccination: Contractor: If the recommendation to combine all the responses into one column is not accepted, then our organization does not have any additional recommendations with this variable. Offered and declined influenza immunization: Contractor: If the recommendation to combine all responses into one column is not accepted, then clarification needs to be provided for those contractors who were offered and received the vaccination; are these left blank? Ineligible for influenza immunization: Contractor: If the recommendation to combine all the responses into one column is not accepted, then our organization does not have any additional recommendations with this variable.		
11/22/17	ED Use	3. Emergency Department Utilization Measure Again, if this measure is adopted, we recommend the current Level 1 measure requirements to be eliminated to prevent duplicate data entry. The numerator, denominator, definition, exclusion, and inclusion criteria clearly are defined and reasonable. Auto-Generated ED Visit Number: This is a reasonable field however, it will require PACE organizations to include a contractor identifier column for our internal tracking purpose, which will be removed prior to submission. We appreciate the clarification for multiple ED visits in a quarter. Acute Care Hospitalization: This is a reason variable and well defined.	Kimberly Woodley Centra PACE	Thank you for your feedback regarding the measure specifications. The intention of the measure would be to replace a duplicate Level 1 reporting measure.
11/27/17	Participant Influenza	1. Participant Influenza Immunization – in agreement with beginning on September 1st as it is still within the 6-month window for the vaccination. Do not agree with begin with vaccine availability or starting August 1st.	Debra Lee Bateman, LIFE St. Joseph of the Pines	Thank you for your comment. We have modified the definition of flu season to begin on September 1, but to include participants who were

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		2. Denominator should include participants enrolled at least 14 days		immunized in August for the upcoming flu season. We have modified the denominator to include only participants who had been enrolled in PACE for 14 or more days.
11/27/17	ED Use	1. Observation Stays- Observation should not be counted as hospitalizations. The ED utilization measure should be broken into three categories: a) ED treated and released b) Admitted to Observation c) Admitted to Inpatient.	Debra Lee Bateman, LIFE St. Joseph of the Pines	Thank you for your suggestion. We have revised the measure to pilot test collecting those three variables - i.e., Yes, the participant was admitted for acute care hospitalization because of the ED visit; Yes, the patient was admitted as observation status because of the ED visit; No, the participant did NOT have an acute care hospitalization or observation stay because of the ED visit.
11/28/17	ED Use	Thank you for the opportunity to provide comments on three draft Quality Measures for the Programs of All-Inclusive Care for the Elderly (PACE). The National Committee for Quality Assurance (NCQA) is writing to comment on observation stay treatment in the proposed "Emergency Department Utilization without Hospitalization" measure. This measure closely parallels our own "Emergency Department Utilization" HEDIS' measure. We believe this measure should group inpatient and observation stays and that it should consider the percent of ED visits that do not result in inpatient OR observation stays. We base our recommendation on our own research which found substantial variation in use of observation stays. In many settings, we saw that observation stays are indistinguishable from hospital	Mary Barton, MD NCQA	Thank you for your input and suggestions. The full measure name is "PACE Participant Emergency Department Utilization Without Hospitalization" to indicate that it is only applicable to PACE participants and PACE Organizations.

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		stays. Our expert panel on this measure therefore felt strongly that the measure should include observation stays with inpatient stays. We also urge you to consider a different name for the PACE measure to avoid any potential confusion with the related HEDIS measure.		
11/30/17	Participant Influenza	• Definition of reporting influenza season. NJ DoAS concurs with the August 1 date. • Denominator of the Participant Influenza measure. NJ DoAS recommends enrollment of at least 14 days with possible consideration for up to 30 days.. • Definition of contraindications. NJ DoAS recommends defined contraindications and precautions.	Paul S. Sullivan Kevin Murphy Division of Aging Services New Jersey Department of Human Services	Thank you for your comment. We have modified the definition of flu season to begin on September 1, but to include participants who were immunized in August for the upcoming flu season. We have modified the denominator to include only participants who had been enrolled in PACE for 14 or more days. We will retain the advice to check the CDC flu website for specific contraindications as your clinicians will check this regularly.
11/30/17	ED Use	• Observation Stays. NJ DoAS recommends including observation stays in the numerator.	Paul S. Sullivan Kevin Murphy Division of Aging Services New Jersey Department of Human Services	The measure counts observation stays as hospitalizations to align with similar NQF-endorsed quality measures. During pilot-testing, we will examine patterns of observation vs. inpatient stays, as well as issues that PACE Organizations encounter in data collection.
12/7/17	General	In review, our organization does not see one quality measure that is suggested as increasing the quality of care of any of our participants. Since we know our participants very well and already have an active, quality review and tracking program, we do not see any benefit	Susan Searl, RN, LNC, SANE-A Total Senior Care	Thank you for your comments. We understand your concerns regarding measurement burden, and the ultimate use of measure data. During reliability and feasibility

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		to the health and well-being of our participants. This is busy work. What entity is going to begin to be able to "plow" through this massive amount of data for at least 5+ years down the road? If the data is not reviewed and shared within the year of collection, it does not benefit the organization or the participant. If no quality issues are identified by CMS at audit, then why require additional material? Maybe this is a tool that could be required of those organizations that are not following data reporting or doing so on a minimal basis. These organizations could be identified & reported for further review based on their most recent audit results until their next audit cycle. We can report data endlessly but our time may be better used intervening and educating and providing quality care for our frail elderly participants.		testing, we will assess the burden of each measure, and use this information to modify measures if needed.
12/7/17	Staff Influenza	PACE Contractors' Influenza Immunization This proposed quality measure is unwieldy, time-consuming, does not indicate added value to the overall care and management of the PACE participant. Due to the large spectrum of services required of and provided by PACE plans, there is a large contingent of contractors who technically fall into the category of HCP who never have direct participant contact. In order for this to be a viable and manageable quality measure, the scope of contracted providers would need to be narrowed considerably. PACE participants live in, and participate in activities in the community, thus potentially exposing themselves to a broad range of persons who may or may not have received an influenza vaccination. The very nature of PACE indicates more of a need to assure participant vaccination than that of contractors.	Susan Searl, RN, LNC, SANE-A Total Senior Care	Thank you for your comments. The influenza immunization of PACE staff and on-site contractors has a significant effect on the health status of vulnerable PACE participants, yet data from the Centers for Disease Control indicates that immunization rate of healthcare workers is quite low. Tracking the immunization status of staff and on-site contractors is fundamental to improving awareness of this issue and to support improvement activities to promote immunization of staff and lessen the risk of flu among not only participants, but among caregivers, PACE staff and contractors as well. We agree that this is not the only risk of

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		It is our understanding all medical professionals are required to follow NYS law. This is a duplication of this process and does not increase the health and safety of participants. All PACE contracts indicate the necessity of following all Public Health Laws and Regulations, making this an additional, unnecessary step. 1. Influenza – NYS law requires all medical staff to have the influenza vaccine or wear a mask. This is already tracked by our human resources department and reported. This is a duplicate requirement. The inclusion criteria breakdown required unnecessarily increases the work load and does not increase the health and safety of the participant. 2. Influenza – Contractors to PACE program – if all medical professionals are required to follow NYS law, then why duplicate this process? Being the police for other professionals is again duplication and does not increase the health and safety of participants. We already require verification or proof of compliance in our record keeping. This is an additional, unnecessary step.		participants contracting flu, but it is a recommended precaution. We applaud NYS's requirements for healthcare staff and contractors to have influenza immunizations, although this is not the case in every state and, thus, an important measure for all PACE organizations. With regard to contractors, we do not limit the measure to contractors who are healthcare professionals. Rather, we will include any contractor, regardless of job title, who provides "on-site" services to a PACE organization.
12/7/17	Participant Influenza	1. Regarding the “Percentage of PACE participants who received an influenza immunization” measure; how is this measure going to be quantified? Through self-measurement by the PACE plan or via some other method of documentation?	Keith Greiner Fallon Health	Data for the Participant Influenza Immunization measure will be extracted from clinical records by each PACE Organization.
12/7/17	Staff Influenza	2. Regarding the “Percentage of PACE staff members who received an influenza immunization’ measure; how is this information for this measure going to be collected and validated? 3. Regarding the “Number of PACE contractors who were offered and declined the seasonal influenza	Keith Greiner Fallon Health	There are two data sources for staff immunization--PACE records for staff members or contractors who are immunized on site -- or -- written or electronic attestation by providers of immunizations to staff members. Validation will parallel steps you take

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		immunization during the reporting influenza season" measure; how is this information for this measure going to be collected and validated?		to provide CMS validation of other reporting metrics.
12/7/17	ED Use	4. We recommend that CMS provide more information on what the "percentage of PACE participant Emergency Department (ED) visits that did not result in being admitted to the hospital" measure will be used for?	Keith Greiner Fallon Health	Currently, the measure will be pilot-tested in selected PACE Organizations. The ultimate use of the measure depends on how it performs in pilot testing.
12/12/17	Staff Influenza	When contractors consist of personnel that are temporary/registry sent for a short assignment (i.e. sent for a 2 day assignment) do we account for them or are they part of the exclusion criteria? Please clarify at what point do we need to account for the temporary/short term assignment personnel.	Gisela Gómez Cuéllar CalOptima PACE	Many short-term personnel will be excluded from the measure unless the work on-site at a PACE organization for more than 14 days. If the short-term staff on on-site for longer than 14 days, they will need to provide you with written or electronic attestation of immunization status.
12/13/17	Participant Flu	Recommend 1 to be coded as 3 Yes for offered and declined Recommend 2 to be defined the same as above - did NOT receive an influenza immunization as in the first "received influenza immunization" box Recommend 1 to be coded as 4 Yes for contraindicated Recommend 2 to be defined the same as above - did NOT receive an influenza immunization as in the first box. Current computer system pulls the data on one report. This would save additional sorting and modifying the data prior to uploading it to CMS.	Wendy Stanton Rocky Mountain PACE	We have modified the immunization status variable to include a category for "offered and declined". The categories are defined to be: Yes, received an immunization; no, ineligible to receive an immunization; No, offered and declined; No, ineligible to receive an immunization; and No, not offered and not received.

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12/13/17	Staff Influenza	Please list examples. Unclear if this includes for example, dentist offices contracted to provide services at dental offices (off-site of PACE). Would this include all of their staff or just the specific doctor that sees PACE participants. Please specify exclusions such as if this includes any staff at ALFs and SNFs that see participants, example a therapy staff providing services at a facility not owned by PACE. The flu immunization is not something that is spelled out specifically in written contracts with outside businesses. I recommend measurement to only include those contracted HCPs that step on-site at a PACE facility to deliver services and receive a direct paycheck for his/her services and actively working for PACE site for business14 days. Recommend 5 standard measurement categories to match the PACE participant measurement categories 1 - received immunization 2 - did not receive (exclude contraindication) 3 - declined/refused/deferred 4 - did not receive due to med contraindicated 99 - no documentation available Participant active 1 day is fine to include in statistics. Staff or contractor on-site to include those actively employed for at least 14 business days. This allows time for hiring and training and collecting the data and also receiving the immunization. One day is not	Wendy Stanton Rocky Mountain PACE	The definition of PACE contractors is limited to personnel who work at a PACE site for more than 14 days. All other contractors are excluded. Regarding examples, the definition of a PACE contractor includes both healthcare professionals, such as physicians, dentists, nurses, and therapists, as well as other contracted personal, such as administrative assistants, data entry personnel, and kitchen staff. We recognize that written contracts with outside businesses may need to be amended at some point to obtain these data. We have revised the categories of immunization status to include (1) Yes, immunization received, (2) No, immunization offered and declined, (3) No, ineligible to receive immunization, (99) No documentation. We have amended participant, staff and contractor immunization data to be restricted to persons enrolled in PACE for more than 14 days, for staff that are employed for more than 14 days, and contractors who are on-site for 14 or more days.

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		recommended. 1 day - first day on job is orientation period.		
12/14/17	General	Overall, Providence ElderPlace supports the move toward Quality measurements for PACE organizations and the general categories of measures proposed. Providence ElderPlace appreciates CMS' efforts to update PACE data elements and measures with the intention to better serve our PACE participants. However, we are deeply concerned these proposals are an additional administrative burden on our PACE staff without increasing the value of care we provide to our participants. In addition, we are concerned some of these proposals are ambiguous with difficult to understand intent. Providence ElderPlace asks CMS to provide more clarity and guidance on how the data will be reported, such as participant specific data versus aggregate data. In an effort to reduce administrative burden, Providence ElderPlace suggests CMS use aggregate data elements and functional upload capabilities. We respectfully request that CMS: · Clarify if the PACE quality measures are in addition to or a replacement for the current HPMS Level 1 quarterly data reporting. There are several areas of redundancy between the current reporting system and the streams of proposed Quality measures, such as falls and immunizations. Providence ElderPlace urges CMS to provide more information on the PACE Quality Data measures and clarity on how CMS intends to implement these measures without unnecessary duplication by PACE organizations to report events as both Level I and PACE Quality Data. Thank you for clarifying the overall plan for data collection for PACE. Clarify if data will be collected by PACE contract number	Ellen Garcia, MPH Providence ElderPlace Oregon Susan Tuller, MHA Providence ElderPlace Washington	Thank you for your comments. We understand your concerns regarding measurement burden, and the ultimate use of measure data. During reliability and feasibility testing, we will assess the burden of each measure, and use this information to modify measures if needed. New measures implemented by CMS for PACE will replace any overlapping Level 1 or 2 indicators. We also anticipate that data will be reported collected at the contract number level, and not at the level of the individual PACE Center when a contract operates more than one (1) center.

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		or by PACE center. We recommend data submission by contract number.		
12/14/17	Participant Influenza	1. PACE participant influenza immunization. The draft guidance defines the flu season as Sept. 1 to March 31. We strongly recommend changing this to Oct. 1 to March 31. The vaccine is rarely available in our region until October. Including the full September participant population (who would not have access to the vaccine) would skew the results for many programs. We also request clarification between the proposed quality measure and the current HPMS reporting of participant flu vaccinations. The measures are similarly defined but not exactly the same in definition. We request this measure replace the current HPMS reporting, so PACE organizations are not required to provide duplicative data to CMS in two different reporting systems.	Ellen Garcia, MPH Providence ElderPlace Oregon Susan Tuller, MHA Providence ElderPlace Washington	In accordance with CDC practice, we have defined the immunization season to begin on September 1st. Further participants immunized in August for the upcoming season will be included. Because this measure is an annual measure, not monthly, offering immunizations beginning in October will not affect your rate. If adopted, the proposed measure would replace the current Level I measure.
12/14/17	Staff Influenza	PACE staff influenza immunization. The draft guidance defines the flu season as Sept. 1 to March 31. We recommend changing this to Oct. 1 to March 31. As stated above, the vaccine is rarely available in our region until October. Including the September staff members (who would not have access to the vaccine) would skew the results for many programs. For the portion of this measure that addresses contractors, we request clarification about the contracted staff that would be included. Based on the following inclusion criteria, we would interpret the proposed measure to include any Licensed Health Care Professional who provides services at the PACE center: Include PACE contractors who provided contracted	Ellen Garcia, MPH Providence ElderPlace Oregon Susan Tuller, MHA Providence ElderPlace Washington	Thank you for your comments. The beginning of the influenza season does vary by region with some commenters requesting August 1st and others requesting October 1st. Others requested that we use a "date certain" so that the season is aligned across all PACE organizations. These are all valid points of view. We have determined to follow CDC guidance by having the influenza season begin on September 1st. The measure specification has been amended to define "contractor" and to include several limitations:

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		services at a PACE Organization for at least one (1) day during the reporting influenza season, regardless of contractual employment status at the end of the reporting period) and the definition of PACE contracted HCPs (Licensed independent practitioners include physicians, dentists, advanced practice nurses, physician assistants, and therapists who are affiliated with the reporting organization but do not receive a direct paycheck from the organization). Please confirm this is the correct interpretation of the intent of this measure. Collecting data for each independently licensed contractor who serves PACE participants from their own clinic location would result in considerable administrative burden for PACE staff with limited benefit. We strongly feel PACE staff time should not be utilized to collect this data since all contracted providers sign attestation of immunization and maintain their own clinical and business licenses.		Contracted personnel must be on site at a PACE Organization for 14 or more days, all job titles of on-site contractors are to be included. A contractor need not be a licensed healthcare professional. The definition of contractor does not include persons who provide services to PACE participants off-site.
12/14/17	ED Use	3. PACE participant emergency department utilization without hospitalization. For this measure, we again request clarification between the proposed quality measure and the current HPMS reporting of emergency department visits. The measures are similarly defined but not the same in definition. We request this measure replace the current HPMS reporting so PACE organizations are not required to provide duplicative data to CMS in two different reporting systems.	Ellen Garcia, MPH Providence ElderPlace Oregon Susan Tuller, MHA Providence ElderPlace Washington	Thank you for your comment. Where there is significant overlap, any new measures that are implemented will replace current Level 1 reporting.
12/15/17	General	Siouxland PACE is extremely supportive of initiatives to provide and track quality care. The rationale for the Stream 3 concepts appear appropriate and relevant for a PACE population; although the measures themselves should be revisited. We have two general concerns: (1) administrative burden; and (2) overall scope. In terms of burden, we are concerned about the time and effort	Randy Ehlers, MSW Siouxland PACE Cathy Simmons, JD, MPP UnityPoint Health	Thank you for your comments and general support. We understand your concerns regarding measurement burden, and the varying capacities of POs to gather and report the data required. The next step in our measure

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		needed to track and report these new measures as it is unlikely that capitation rates will increase to reflect this added burden. While we track these efforts, we do not track in the manner specified by these measures. For the most part, this will involve manual collection until we can eventually convert some to an electronic platform (at added expense). Prior to any measure adoption, we encourage piloting these measures with several PACE organizations at varying degrees of EHR integration / adoption to determine level of effort and providing an additional comment period related to testing efforts and resulting time and effort studies. Second, it is difficult to comment on individual measures without understanding the totality of this quality measure project. We do not know how many total measures will ultimately be included within the final measure set nor how they are intended to be risk adjusted and impact our rates. While we are pleased that CMS is aligning these measures within the "Meaningful Measures" constructs, we lack an overall understanding of the final collection and reporting ask. We urge more transparency in the overall process so that we have better context in which to comment. In response to your specific questions, we urge a balance between administrative burden and definition accuracy. We also encourage measure standardization with existing CMS measures in other settings, including Medicare Advantage measures. The more that PACE measures deviate from similar quality measures, the less likely that PACE will be able to be compared holistically and the greater the administrative expense that will be borne by relatively small PACE Provider Organizations to create customized reporting.	Government & External Affairs	development process includes testing the measures with at a sample of PACE Organizations. This reliability and feasibility testing will assess the burden of each measure and help us to identify particularly troublesome data elements. This information will be used to modify measures if needed. We agree that harmonization amongst similar measures is important, both to avoid confusion and to allow comparisons between programs. Where there are existing measures in use in other settings, we have tried to harmonize where possible. In the case of existing PACE measures, including Level 1 and 2 reporting, when new measures are implemented, they will replace any measures they overlap with.

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		On behalf of our PACE Participants, Siouxland PACE and UnityPoint Health appreciates the opportunity to provide comments to the Stream 3 proposed measures. In addition, Siouxland PACE is a member of the National PACE Association (NPA). We generally support the comments submitted by NPA and are committed to participating with the NPA to further strengthen services and supports for the PACE population. Siouxland PACE and UnityPoint Health look forward to participating in future PACE measure development and other stakeholder forums.		
12/15/17	Participant Influenza	Applying the above general concerns to the proposed measures, we will specifically discuss the Participant Influenza Immunization measure (e.g., a process measure) as an example. While we appreciate the efforts to attempt to control or recognize various exclusionary criteria, we question whether the added reporting burden results in meaningful quality distinctions and reiterate our need to understand the quality context for this measure. In support of this, we point to the recent revisions of a similar immunization measure within the Home Health setting.1 For home health, this measure is simplified - percentage of home health episodes of care during which patients received influenza immunization for the current flu season. Rather than revising the measure to take into account each exclusion, the measure was simply removed from the Quality of Patient Care STAR rating methodology, but not from Home Health Compare reporting. As proposed, we are concerned with the multi-level reporting, whether these results provide meaningful differentiation among programs, and that the ultimate purpose of, and audience for, the reporting is unclear.	Randy Ehlers, MSW Siouxland PACE Cathy Simmons, JD, MPP UnityPoint Health Government & External Affairs	We appreciate your concern about reporting burden. It is important to collect all categories of immunization status, as this level of detail will show each PACE Organization might improve their immunization process. Additionally, the detail leads to a correct assessment of Percent of PACE Participant Immunized. For example, having a high number of participants for whom immunization is contraindicated as a category will not be misinterpreted as poor performance.

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12/15/17	Participant and Staff Influenza	For Participant and Staff Influenza Immunization Measures: 1. Definition of “reporting influenza season” to expand the date range or substitute a date reference with a start date to “begin with vaccine availability.” We encourage the adoption of language common to other CMS immunization measures. For a tracking perspective, it is easier to monitor a date certain than a fluctuating date. 2. Denominator of the Participant Influenza measure to expand the trigger date from 1 day to 2 days or 14 days. Again, we encourage the use of common requirements. For a tracking perspective, it is easier to run reports with a single date trigger than a date range trigger. 3. Definition of Contraindications to identify exclusionary criteria. As mentioned above, we question whether this level of specificity it needed, without truly understanding how CMS intends to use this measure.	Randy Ehlers, MSW Siouxland PACE Cathy Simmons, JD, MPP UnityPoint Health Government & External Affairs	The beginning of the influenza season does vary by region with some commenters requesting August 1st and others requesting October 1st. Others requested that we use a "date certain" so that the season is aligned across all PACE organizations. These are all valid points of view. We have determined to follow CDC guidance by having the influenza season begin on September 1st. We have restricted the participant immunization measure to apply to participants who had been enrolled for a minimum of 14 days.
12/15/17	ED Use	For the ED Utilization Without Hospitalization Measure: 4. Observation Stays counted as a hospitalization. While we generally agree that ED visits are distinguishable from observation stays and should be excluded, the proposed ED utilization measure itself does not necessarily equate to avoidable/preventable/unnecessary ED use, which is the rationale for this measure. The fact that an inpatient stay or observation stay followed the ED visit should not be confused with situations where ED care is medically necessary. With a frail elderly population, the ED should not be de-legitimized as a necessary level of care. In addition, this measure seems to fly in the face of patient and caregiver care preference. While Siouxland PACE has initiatives to address misutilization and/or overutilization of ED services, these efforts should be	Randy Ehlers, MSW Siouxland PACE Cathy Simmons, JD, MPP UnityPoint Health Government & External Affairs	The measure was modeled from other NQF-endorsed ED Utilization quality measures used in CMS programs. As part of pilot-testing we will survey participating PACE Organizations about the usefulness of the ED Utilization measure for internal Quality Improvement, as well as external benchmarking. Those factors will be strongly considered when determining whether the measure is adopted.

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		targeted interventions and not applied to the PACE population as a whole to discourage medically necessary care. This deference to patient/caregiver preferences was referenced by CMS as part of the rationale for excluding this measure from the Home Health Quality of Patient Care STAR rating methodology.		
12/15/17	General	NPA appreciates CMS' efforts to develop, adapt, and implement quality measures for PACE. Effective utilization of performance indicators is a critical component of continuous performance measurement. We anticipate that the implementation of PACE quality measures will support initiatives specifically targeted to improve patient outcomes. We encourage CMS to share trend data and PO-specific performance results that may be used to evaluate the performance of POs against recognized quality standards, with a recognition that measuring the quality of health care is a necessary step in the process of improving health care quality. CMS has previously indicated its plan to publish data benchmarks and overall quality and potentially publicly report PACE data. While NPA supports the use of data and quality measurement to improve participant care across programs and over time, and to educate consumers, calculation and publication of benchmarks and release of overall quality data must be done carefully to ensure these data are meaningful and accurately represent PACE performance. We request that CMS be transparent in communicating the purpose of measure reporting (e.g., quality improvement; accountability; public reporting). We request that CMS share its plans for release of all quality data and provide NPA, POs, and other stakeholders ample opportunity to comment on these plans well in advance of making data	Shawn Bloom National PACE Association	Thank you for your comments. We will continue to consider how to construct useful measures that serves the needs of PACE Organizations, their participants, and CMS, while allowing comparison to other settings. We anticipate that CMS will provide additional information regarding implementation and intended use of PACE quality measures as we move closer to the implementation phase. We do anticipate that any new quality measures which are implemented will replace their overlapping Level 1 and 2 indicators to avoid confusion and duplication of effort.

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		publicly available. CMS has also referenced the potential to compare PO's performance with that of "other like services and programs". One challenge in this regard is to appropriately adjust quality measures for key differences between populations served by PACE and other plans/providers. For example, comparisons between PACE participants and other managed care organization enrollees' health outcomes and service utilization must account for differences in these populations' characteristics (e.g., age, health and functional status, and social determinants of health). As indicated in CMS' information collection request published in the Federal Register (FR) on June 13, 2016 and December 2, 2016 [CMS-10525 (OMB control number: 0938-1264): Program of all-Inclusive Care for the Elderly (PACE) Quality Data Entry in CMS Health Plan Monitoring System (HPMS)], it is our understanding that CMS intends to establish PACE quality measures adopted from the National Quality Forum (NQF), modify them for PACE, and use the modified PACE quarterly measures in place of existing Level I and Level II data reporting elements. The FR notices and supporting materials state that CMS' intent is to "update and implement previously collected PACE data elements known as Level I and Level II into PACE Quality Data". Our understanding of this is that current Level I and Level II data elements will be referred to as PACE Quality Data moving forward, but it remains unclear if additional updates to Level I and Level II reporting requirements are being implemented. Specifically, we request clarification on whether CMS plans to replace existing Level I data reporting elements		

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		for influenza immunizations and emergency room visits with the proposed Participant Influenza Immunization and Participant Emergency Department (ED) Utilization Without Hospitalization quality measures. We recommend that CMS minimize any redundancies in reporting requirements. We also request that CMS provide clarification on whether data will be collected by PACE contract number or by PACE center. It is recommended that data be collected and reported by PACE contract number.		
12/15/17	Participant Influenza	Measure Intent NPA supports the intent of the Percent of Participants with Influenza Immunization measure. We also support the intent of the three (3) sub-measures associated with the measure. It has been recognized for many years that people 65 years and older are at greater risk of serious complications from the flu, leading to both hospitalizations and deaths. We therefore agree that measuring participant influenza immunization is an appropriate quality indicator for PACE. Measure Definitions While NPA recognizes the benefit in evaluating if a participant received the influenza vaccine during the reporting influenza season, if the participant was offered and declined the influenza vaccine, and if the participant was ineligible to receive the influenza vaccine due to contraindications, we recommend that the participant-level data entry requirements be consolidated to streamline the data reporting requirements and reduce undue administrative burden, without compromising the integrity and intent of the three associated sub-measures. Individual-level Data Entry	Shawn Bloom National PACE Association	We appreciate your comments on the proposed participant flu immunization measure. We agree with your concern for reporting burden. For pilot testing, we will retain the four categories of immunization status to that an assessment of reliability of each category can be assessed. Post testing, we will be able to determine if some immunization statuses may be combined. You are correct that the numerator includes participants who received their influenza immunization outside the PACE Organization, including those who received the immunization prior to enrollment in PACE, assuming receipt of this immunization is documented. Thank you for your other helpful comments regarding the measure specifications.

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		Based on the proposed measure definitions and associated data reporting requirements, we recommend that the data entry requirements for “received influenza immunization”, “offered and declined influenza immunization” and “ineligible for influenza vaccination” be reported as one data element, “received influenza immunization”, with the following responses: ▪ 1 = Yes, the participant received an influenza immunization during the reporting influenza season, either in the PACE Organization or outside the PACE Organization. ▪ 2 = Yes, the participant was offered and declined the influenza immunization during the reporting influenza season, either in the PACE Organization or outside the PACE Organization. ▪ 3 = No, the participant was NOT offered and did not receive an influenza immunization. ▪ 4 = Yes, the participant was ineligible to receive the influenza immunization due to contraindication(s) during the reporting influenza season. ▪ 99 = There is no documentation available regarding the participant’s influenza immunization status (received, offered and refused, or ineligible.) Additionally, it is our understanding the numerator for this measure includes PACE participants who received an influenza immunization during the reporting influenza season, either in the PACE Organization or outside the PACE Organization, inclusive of participants who received the influenza vaccination prior to enrolling in the PO and within the reporting influenza season. We request confirmation of our interpretation. NPA offers the following comments specifically regarding the Definition of reporting influenza season, Participant		We understand that there is variation amongst PACE Organizations in terms of PO and participant characteristics. As a first step, we will provide risk stratification at the Organizational level, to examine differences among types of PACE Organizations. Preliminary stratification variables include caseload size, metropolitan status, years in operation and academic affiliation. Additional options for risk stratification or adjustment will continue to be explored.

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		inclusion criteria for the denominator of the Participant Influenza measure, and Definition of contraindications. Definition of reporting influenza season Given the uncertainty and inconsistency in which the influenza vaccine first becomes available, which often varies across geographic regions, we recommend that the influenza vaccination season be defined as beginning on October 1 and ending on March 31 of the following year. This is consistent with current Level I data reporting requirements and existing NQF endorsed quality measures for other healthcare settings. Extending the reporting season prior to October 1 could lead to inaccurate reporting by the POs due to an inability to assess and appropriately give the influenza vaccine because of the unavailability of the vaccine. If the decision is made to expand the reporting season prior to October 1, we recommend that "vaccine availability" be considered as a required data element for this measure. This would allow POs the opportunity to align reporting requirements with vaccine availability. Participant inclusion criteria for the denominator of the Participant Influenza measure Regarding the inclusion of participants enrolled in PACE for at least one (1) day during the reporting flu season in the denominator for this measure, NPA agrees with expert comments that one (1) day is not sufficient to ensure adequate assessment and screening by POs. NPA recommends that CMS consider excluding participants enrolled less than 14 days during the reporting season, as recommended by experts during measure validity testing, allowing POs adequate time to assess and screen new enrollees.		

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		Definition of contraindications We recommend that CMS reference the Centers for Disease Control (CDC) webpage (https://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm), as opposed to detailing specific medically contraindicated conditions within the measure. Requiring the POs to directly access CDC's website would assure that current guidelines are referenced and accommodate for any modifications to contraindication definitions over time. This would also be consistent with measure specifications of existing NQF endorsed quality measures applicable to other healthcare settings. Feasibility of Data Collection We have no comments regarding the feasibility of data collection for this measure. Calculation Methodology Regarding stratification, we request insight on how CMS will utilize PACE Organization characteristics for stratification purposes. As CMS/Econometrica finalizes the stratification variables, we recommend that consideration be given to participant characteristics, as well as POs access to influenza vaccines, which may be limited due to geographic area or other uncontrollable factors.		
12/15/17	Staff Influenza	Measure Intent NPA recognizes that the CDC, the Advisory Committee on Immunization Practices (ACIP), and the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommend that all health care workers get vaccinated annually against influenza to potentially reduce infection transmission of influenza to individuals at high risk for influenza- related complications, leading to	Shawn Bloom National PACE Association	Thank you for your thoughtful comments. The reasons for not having an immunization (declined, ineligible, no documentation) will provide each PACE Organization with baseline information that can be used to inform outreach to staff on the importance of immunizations.

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		hospitalizations and death. While CMS has communicated its intent of the Percent of PACE Healthcare Personnel with Influenza Immunization measure, we are concerned about the adoption of this measure to PACE, specifically with the expectation that the measure will provide POs with information necessary to improve staff influenza rates. Given the variability of applicable laws and regulations governing healthcare worker influenza immunization requirements across states, we suggest that this measure may not adequately reflect POs' efforts toward improving staff influenza immunization rates. Measure Definitions We recommend that if adopted, the measure specifications be limited to PACE staff who were employed by and received a direct paycheck from the PACE organization. If the decision is made to include "PACE-contracted HCPs" in this measure, we request additional clarification on how CMS will define "contractors" and /or "licensed independent practitioners" for inclusion is this measure. We recommend that only contracted practitioners that provide services at the PACE center be included and that community-based licensed independent practitioners be excluded from this measure. We also recommend that individuals that provide services through contractual relationships with community-based organizations (i.e., home care agencies) also be excluded from this measure. Individual-level Data Entry Based on the proposed measure definitions and associated data reporting requirements, we recommend		We agree that because of state and regional variation, that the primary use of the measure by PACE Organizations is to set improvement goals. National data can be used by CMS, CDC, or infection prevention professionals to develop new messaging for immunization outreach. The immunization measures in accordance with your points. (1) staff is defined to be persons receiving a direct paycheck from the PACE Organization. (2) the definition of PACE contractors has been limited to persons who provide on-site services at PACE Organizations for more than 14 days. However, contractors are not limited to healthcare personnel but includes any person providing services on-site at a PACE Organization who does not receive a direct paycheck from a PACE. All other community-based contracted practitioners are excluded from the measure. We have modified the categories of immunization status to (1) Yes, received an immunization; (2) No, was offered and declined an immunization; (3) No, was ineligible to receive an immunization, and (99)

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		that the data entry requirements for “received influenza immunization”, “offered and declined influenza immunization” and “ineligible for influenza vaccination” for staff and contractors, if included in measure, be reported as two data elements, “received influenza immunization: staff” and “received influenza immunization: contractors”, with the following responses to streamline the data reporting requirements and reduce undue administrative burden, without compromising the integrity and intent of the associated sub-measures: ▪ 1 = Yes, the staff member (contractor) received an influenza immunization during the reporting influenza season, either in the PACE Organization or from an external provider. ▪ 2 = Yes, the staff member (contractor) was offered and declined the influenza immunization during the reporting influenza season. ▪ 3 = No, the staff member (contractor) was NOT offered and did not receive an influenza immunization. ▪ 4 = Yes, the staff member (contractor) was ineligible to receive the influenza immunization due to contraindication(s) during the reporting influenza season. 5 ▪ 99 = There is no documentation available regarding the staff (contractor’s) influenza immunization status (received, offered and refused, or ineligible.) NPA offers the following comments specifically regarding the Definition of reporting influenza season, PACE staff/contractor inclusion criteria for the denominator of the Staff Influenza measure, and Definition of contraindications.		no documentation which included "not offered and received".

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		Definition of reporting influenza season We recommended that the influenza vaccination season be defined as beginning on October 1 and end on March 31 of the following year, for the same reasons previously noted. Staff/contractor inclusion criteria for the denominator of the Staff Influenza measure NPA recommends that CMS consider excluding staff/contractors who worked less than 14 days during the reporting season, allowing POs adequate time to assess and screen new staff/contractors. It is also suggested that staff who are on extended leave and work less than 14 days during the reporting season be excluded from the measure. Definition of contraindications As previously noted, we recommend that CMS reference the Centers for Disease Control (CDC) webpage (https://www.cdc.gov/flu/professionals/vaccination/vax-summary.htm), as opposed to detailing specific medically contraindicated conditions within the measure. Feasibility of Data Collection NPA's only concerns with the feasibility of data collection for the measure is specifically related to a PO's ability to collect data related to contractors, if included in the measure as proposed. Calculation Methodology Regarding stratification, we request insight on how CMS will utilize PACE Organization characteristics for stratification purposes. As CMS/Econometrica finalizes the stratification variables, we recommend that consideration be given to POs' access to influenza		

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		vaccines during the reporting season, which may be limited due to geographic area or other uncontrollable factors.		
12/15/17	ED Use	Measure Intent NPA supports the intent of the PACE Participant Emergency Department Utilization Without Hospitalization, which is aligned with national quality improvement efforts. Measure Definitions NPA has no significant concerns with the definitions outlined for the PACE Participant Emergency Department Utilization Without Hospitalization measure. Furthermore, we agree with the recommendations to exclude ED visits that resulted in an observation stay, as defined. Feasibility of Data Collection We have no comments regarding the feasibility of data collection for this measure. Calculation Methodology Regarding stratification, we request insight on how CMS will utilize PACE Organization characteristics for stratification purposes. As CMS/Econometrica finalizes the stratification variables, we recommend stratifying the measure results by variables, including participant characteristics, that may directly influence measure results.	Shawn Bloom National PACE Association	We appreciate NPA's comments on the measure. During pilot testing, we will examine meaningful risk stratification strategies that do not impose a high data collection burden on PACE Organizations.
12/15/17	General	The New Mexico Human Services Department (NMHSD) has reviewed the PACE Quality Measures pertaining to: PACE participant influenza immunization rates; PACE employee influenza immunization rates; PACE ER use without hospitalizations.	Jennifer Mondragon New Mexico Human Services Department	Thank you for taking the time to review the proposed measures.

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		NMHSD does not have any comments or proposed edits to the performance measures presented and thanks CMS for their consideration in allowing the NMHSD to review.		
12/15/17	Participant Influenza	Flu vaccine in elderly PARTICIPANT INFLUENZA IMMUNIZATION Flu vaccine is very important for all Pace Participants provided that they have not had adverse reactions in the past or been advised by medical professionals to NOT get vaccine. It is equally important to teach participants proper hand-washing and reasonable exposure to public places and people who may expose them to flu virus, due to effectiveness of the annual vaccine limiting protection due to virus mutation.	Jennifer Dingman Family caregiver/advocate	Thank you for your comments regarding the importance of the flu vaccine for PACE participants.
12/15/17	Staff Influenza	2. PACE STAFF INFLUENZA IMMUNIZATION PARTICIPANT All staff, including contractors, should be vaccinated against flu and kept away from frail participants for the time frame following vaccine where they could still expose the participant to the flu virus. Proper hand-washing and hygiene are also very important as to protect participants from exposure to the flu.	Jennifer Dingman Family caregiver/advocate	Thank you for your comments regarding the importance of the influenza vaccine as well as other infection prevention procedures in the PACE setting.
12/15/17	ED Use	3. EMERGENCY DEPARTMENT UTILIZATION WITHOUT HOSPITALIZATION Due to "Although significant progress has made in preventing some infection types, there is much more work to be done. On any given day, about one in 25 hospital patients has at least one healthcare-associated infection." It is my opinion that every prudent effort be made by PACE Centers to manage and treat all patients without having to send them to hospitals. As there have been discussions regarding not using ED enough, I feel that conservative use of the ED is in the best interest of	Jennifer Dingman Family caregiver/advocate	Thank you for your comment. The aim of the measure is to aid PACE Organizations in assessing and improving ED use.

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		the participants in all reasonable situations. https://www.cdc.gov/hai/surveillance/index.html		