Preliminary Review Team Findings on

The COPD and Asthma Monitoring Project
Submitted by Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group, Inc.

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April 11, 2017
Presentation Overview

• Preliminary Review Team (PRT) Composition and Role
• Proposal Overview
• Summary of the PRT Review
• Key Issues Identified by the PRT
• PRT Evaluation Using the Secretary’s Criteria
Preliminary Review Team Composition and Role

- The PTAC Chair/Vice Chair assigns two to three PTAC members, including at least one physician, to each complete proposal to serve as the PRT. One PRT member is tapped to serve as the Lead Reviewer.

- The PRT identifies additional information needed from the submitter and determines to what extent any additional resources and/or analyses are needed for the review. ASPE staff and contractors support the PRT in obtaining these additional materials.

- After reviewing the proposal, additional materials gathered, and public comments received, the PRT prepares a report of its findings to the full PTAC. The report is posted to the PTAC website at least two weeks prior to public deliberation by the full Committee.

- The PRT report is not binding on PTAC; PTAC may reach different conclusions and a different recommendation from that contained in the PRT report.
Proposal Overview

- **Intervention:** Participating COPD and asthma beneficiaries would receive a Bluetooth peak flow meter and software tools to permit data transmission to a central server which – through monitoring and management – could trigger clinical interventions to reduce early exacerbation and respond quickly to infection detection.

- **Payment:** The proposal calls for the Centers for Medicare & Medicaid Services (CMS) to pay for the Bluetooth peak flow meters, pay an inflation-adjusted per beneficiary per month (PBPM) remote monitoring and management fee, waive copays for beneficiary access to the monitoring services, and allow collaborating pharmaceutical and device companies to provide beneficiaries with discount pricing and coupons for drugs or equipment prescribed to control their pulmonary conditions.

- **Quality and Performance:** The proposal aims to improve the health of patients and reduce avoidable emergency department (ED) and inpatient utilization. Reductions in ED and inpatient utilization are expected to offset the costs of the intervention and thereby lower total cost of care. The submitter expects to reduce mortality, as well.
## Summary of the PRT Review

<table>
<thead>
<tr>
<th>Criteria Specified by the Secretary (at 42 CFR §414.1465)</th>
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**PRT Recommendation**

Do not recommend proposed payment model to the Secretary
Key Issues Identified by the PRT

• Improvement in the management of Medicare patients with COPD, asthma, and other chronic lung diseases should be a high priority for CMS. While the framework the submitter proposed has merit, the proposal needs further development.

• The PRT has concerns with the details of the proposed PFPM’s payment methodology, notably:
  – There are no quality performance requirements to earn shared savings.
  – The model does not count some real costs such as Part D spending.
  – Risk adjustment is based on the number of chronic conditions a patient has; this method has not been tested.

• The PRT found the model lacking in terms of how integration would be achieved:
  – Primary care providers would not share in the financial risks and incentives of the program.
  – Other providers beyond the pulmonary subspecialists are not clearly integrated.
The proposal aims to
– Address payment for care management for COPD and asthma, two well-defined and clinically important conditions (nationwide, there are ~5.4 Million Medicare fee-for-service beneficiaries with COPD, asthma, or both);
– Cover daily monitoring utilizing new technology and introducing two-sided risk; and
– Broaden CMS’ Alternative Payment Model (APM) portfolio by including pulmonary physicians, whose opportunities to participate in APMs have been limited.

While the proposal is for an initial 2,000-beneficiary pilot, the submitter intends to scale up following validation.
## Criterion 2. Quality and Cost (High Priority)

**Criterion Description**
The proposal is anticipated to (1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

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- The proposal minimally meets this criterion.
- There is considerable literature that investment in programs that enroll well-selected patients with chronic conditions characterized by frequent exacerbations resulting in hospitalizations can effectively improve quality and reduce costs.
- There appears to be limited data for the specific intervention included in the proposal. Many details of the planned approach (e.g. software development) remain to be worked out.
Criterion 3. Payment Methodology (High Priority)

**Criterion Description**
Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

**PRT Conclusion**
Does not meet criterion

**Unanimous or Majority Conclusion**
Unanimous

- The basic approach – a PBPM payment and a shared two-sided risk arrangement – seems appropriate for the clinical innovation the submitter proposes, but there are too many unspecified or questionable features:
  - There are no quality performance requirements to earn shared savings.
  - The model does not count some real costs such as Part D spending.
  - Risk adjustment is based on the number of chronic conditions a patient has; this method has not been tested.
  - The PBPM amount is not based on the cost to provide the proposed services.
  - The cost structure assumed device prices that were based on European pricing.
## Criterion 4. Value over Volume

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- Remote patient monitoring via Bluetooth technology and software would seem to enable clinicians to efficiently monitor and manage a patient population.
- The early detection of disease exacerbation or infection, coupled with early intervention, is meant to lead to fewer ED visits and hospitalizations.
Criterion 5. Flexibility

Criterion Description
Provide the flexibility needed for practitioners to deliver high-quality health care.

PRT Conclusion
Meets criterion

Unanimous or Majority Conclusion
Majority

- The proposal is simultaneously rigid and somewhat vague:
  - The proposal appears to rely largely on one specific device and data transmission method.
  - The exact clinical protocols have not been worked out.
  - The enrollment process and coordination with other local providers is unclear.

- All PRT members agreed that the proposal lacks sufficient detail regarding the clinical protocols and coordination with other providers. Nonetheless, the PRT members were split on whether or not greater specificity should be required in order to meet this criterion.
Criterion 6. Ability to be Evaluated

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- The proposed PFPM aims to
  - Reduce ED visits,
  - Reduce hospitalizations,
  - Reduce mortality, and
  - Achieve Medicare cost savings.

- The data to evaluate the degree to which CAMP achieves these goals should be obtainable from existing sources.

- The monitoring technology proposed in this model should present opportunities for the incorporation of novel data into program evaluation.

- However, it is important for this model, as well as other PFPMs, to include validated quality measures.
Criterion 7. Integration and Care Coordination

**Criterion Description**  
Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

**PRT Conclusion**  
Does not meet criterion

**Unanimous or Majority Conclusion**  
Unanimous

- The proposed PFPM is likely to encourage greater care coordination but is lacking in terms of how integration would be achieved.
- The care of patients with chronic pulmonary disease almost always requires multiple different types of physicians coordinating their care efforts. The proposal does not describe in sufficient detail how coordination will be assured or what the financial or contractual relationship of CAMP physicians will be with the other physicians involved in enrolled patients’ care. It is not clear how these other physicians will be identified or contacted.
- Primary care providers would not share in the financial risks and incentives of the program.
- A significant proportion of clinical resource use for patients with COPD is not related to their COPD, so explicit plans for coordination with other providers would seem to be beneficial.
## Criterion 8. Patient Choice

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- Patient enrollment is optional.
- The model is driven largely by patient compliance in providing Bluetooth peak flow meter and self-assessment data.
- The services described in this proposal are meant to be a “value-add” rather than supplant existing patient-provider relationships.
- The proposal explicitly takes into account patients’ comorbidities and plans to offer participating beneficiaries relevant educational opportunities.
Criterion 9. Patient Safety

Criterion Description
How well does the proposal aim to maintain or improve standards of patient safety?

PRT Conclusion
Meets criterion

Unanimous or Majority Conclusion
Unanimous

• The proposal would improve the standards of patient safety by creating an early warning system for disease exacerbation and infection detection.

• The proposal incorporates various goals, such as achieving a statistically significant decrease in mortality, to guard against patient harm.
  – It will be important for the submitter to connect quality to financial incentives.
Criterion 10. Health Information Technology

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- Health information technology is a key element of this proposal (e.g. Bluetooth peak flow meters, smartphone apps, and computer-based algorithms and decision support tools).
- The specific software and device interfaces need to be developed.
- Basic electronic health record (EHR) interoperability challenges are probable, as clinicians are likely to use different EHR systems.
Preliminary Review Team Findings on:

American College of Surgeons–Brandeis Advanced Alternative Payment Model

Submitted by American College of Surgeons (ACS)

Grace Terrell, MD (Lead Reviewer)
Harold D. Miller
Bruce Steinwald

April 11, 2017
Presentation Overview

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• PRT identifies additional information needed from the submitter and determines to what extent any additional resources and/or analyses are needed for the review. ASPE staff and contractors support the PRT in obtaining these additional materials.

• After reviewing the proposal, additional information provided by the submitter, information from other materials gathered, and public comments received, the PRT rates the proposal on each of the Secretary’s criteria and prepares a report of its findings to the full PTAC. The report is posted to the PTAC website at least two weeks prior to public deliberation by the full Committee.

• The PRT report is not binding on the PTAC; PTAC may reach different conclusions and a different recommendation from that contained in the PRT report.
• **Intervention:** Episode-based Payment Model. Episodes defined by updated version of episode grouper (EGM) developed for CMS by Brandeis University.

• **Targeted Procedures/Conditions:** > 100 procedures / conditions (payment episodes) identified for potential focus; e.g., upper respiratory infection; appendectomy; colonoscopy; cataract surgery; acute simple, benign fibrocystic / dysplastic breast disease; other/not otherwise specified juvenile idiopathic arthritis; lung resection; coronary artery bypass grafting; open heart valve surgery; liver transplant; heart failure; and breast neoplasm (malignant). Initial implementation proposed to focus on 75 procedures in 10 clinical areas involving 75 separate medical specialties.

• **Advanced APM Entities enter into risk-based contracts with Medicare and take accountability for quality and cost of episodes of care.** Entities could be “single-specialty practices, multispecialty practices or convenor groups of small provider practices with or without ties to particular facilities... as long as the entity is able to perform its management and fiduciary responsibilities.” Contract with CMS would involve Medicare payments for every instance of the procedure/condition episodes defined in the contract during a performance period for which the entity’s affiliated Qualified Participants (QPs) provide a service paid for by Medicare. Each entity participating in the model CMS will identify its affiliated QPs who will participate under business agreements.

• **Physicians** participate by contracting with APM entity.
• **Physician payment** continues through the Medicare Physician Fee Schedule, but the APM Entity is at financial risk based on participating physicians’ “attributed role” in providing care.

• **Attributed roles** are determined by clinical algorithms that retrospectively identify all clinicians who participated in the care of a patient for each type of episode and infer the nature of each clinician’s role. Savings or losses attributed to each participating QP are based on the episodes he/she is involved in and his/her specific role in that care.

• **Retrospective bonus payments and penalties** are paid to the APM Entity based on the difference between observed and expected spending for the episode.

  “The APM entity would engage in gainsharing with affiliated QPs as agreed upon in their business agreements, and guided at its discretion by the team-based fiscal attribution framework.”

• **When spending exceeds expected amount**, participating providers may be required to contribute to repayments to CMS, and the model will build in stop-loss provisions to protect against catastrophic losses.
• **Improvements in quality and efficiency** expected to result from financial incentives and use of Clinical Affinity Groups (CAGs). CAGs are sets of clinicians who regularly participate together in episodes of a given type. CAG decisions and services are intended to influence the way in which patients are treated for a type of episode.

• **Quality measurement** is focused on two categories of measures: episode-based quality measures and all-patient based quality measures, but measures are not specified.

• **In the early transition period of the model,** accountability would be focused on reporting of quality measures to allow participants to transition into the model and set a baseline for performance based payment adjustment in later years.

• **Over time,** the Secretary would set a minimum threshold of performance on quality measures.
### Summary of the PRT Review

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#### PRT Recommendation

Do not recommend proposed payment model to the Secretary
Criterion 1. Scope of Proposed PFPM (High Priority)

The proposal aims to broaden or expand CMS’ APM portfolio by either: (1) addressing an issue in payment policy in a new way, or (2) including APM Entities whose opportunities to participate in APMs have been limited.

PRT Conclusion: Proposal Meets the Criterion

• Broad-scope model that would provide a payment mechanism for large number of clinicians covering a broad range of services, from time-limited procedures to ongoing management of patients with chronic conditions, in in-patient, ambulatory, and outpatient facilities.

• Initial implementation proposed to focus on 75 procedures in 10 clinical areas involving 75 separate medical specialties. Expansion into acute and chronic conditions would increase the scope of the model with potential for over half of all clinicians in the country to have greater than 75% of their professional fees covered by this methodology.

• However, details missing on how model would impact provider payments and patient care in specific areas. Information lacking about how the APM would function for the majority of the episodes described.

• Support for model has been indicated by physicians involved with surgery, but an episode payment model for many hospital procedures (i.e., the Bundled Payment for Care Improvement Initiative) is already being tested by CMS.
Criterion 2. Quality and Cost (High Priority)
The proposal is anticipated to (1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

PRT Conclusion: Proposal Does Not Meet the Criterion

- Current MIPS quality measures identified as the starting point for quality reporting, but proposal states current MIPS reporting data sets “unlikely to produce clinically meaningful improvement in outcomes of care when rigorously evaluated.”
- No penalties for reductions in quality; and quality primarily based on reporting on processes rather than outcomes; moreover, initial requirements are for reporting, not performance on measures.
- Insufficient assurance of adequate quality protections to offset the financial incentives for lower spending. Spending could be reduced in ways that would not be beneficial to patients.
- Proposal asserts that new grouper software takes into account all spending in an episode of care, but does not describe how physicians would control costs of services they do not deliver directly, such as post-acute care costs, and does not explain whether the risk adjustment methodology adequately addresses differences in patient needs that can affect costs.
- Because participation is optional, less than full participation would leave Medicare at risk for the portion of spending attributed to physicians not participating in the clinical affinity group.
- Overall: insufficient information describing the ways in which care delivery would change in order to improve quality and/or reduce costs and the reasons those changes could not occur under current payment systems.
Criterion 3. Payment Methodology (High Priority)

Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

PRT Conclusion: Proposal Meets the Criterion

• Payment methodology is described in sufficient detail with respect to its general principles, and specific examples were provided in response to follow-up questions.
• However:
  – Payment methodology dependent on CMS updating the episode definitions in the EGM over time. The methodology is asserted to be applicable within other payment models such as ACOs, for most types of providers, in most settings, and for both procedures and chronic conditions, but no specific examples were provided describing how the model might be successfully implemented in such a broad range of settings. Because the same basic methodology is intended to be customized to each of a large number of conditions, procedures, and settings, additional details will need to be developed before it can be implemented for all of those conditions, procedures, and settings.
  – Model proposes to assign each clinician involved in a patient’s care one of several designated clinical roles (e.g., primary provider, principal provider, episodic provider, supporting provider, and ancillary provider). Each clinical role a priori would be assigned a fixed proportion of savings amount determined by “policy.” Yet there is no information supporting the proportions proposed nor is any process defined for how those proportions might be adjusted over time.
Criterion 4. Value over Volume
The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

PRT Conclusion: Proposal Does Not Meet the Criterion

• Proposed model could incentivize efficient provision of services within episodes of care where there are opportunities for greater efficiencies
• However:
  – Quality of care is neither rewarded nor penalized unless savings occur.
  – Insufficient mechanisms to ensure that savings are not achieved at the expense of quality, or to encourage or reward quality even with no change in spending.
  – Use of retrospective episode grouper is intended to provide information and standards for individual providers, episodes, and patients for accountability. However, reducing spending within individual episodes does not necessarily achieve savings in total cost of care, unless accompanied by methods of controlling number of episodes provided or ensuring clinical appropriateness of episodes.
  – Although the proposal indicates that utilization of procedural episodes would be controlled through their nesting within condition-based episodes, the proposal would not restrict the procedural episodes to only be implemented inside condition-based episodes, nor is there any requirement that the physicians who would be accountable for managing utilization under condition-based episodes would actually participate in the model.
Criterion 5. Flexibility
Provide the flexibility needed for practitioners to deliver high-quality health care.

PRT Conclusion: Proposal Meets the Criterion

• Model could be used in inpatient, outpatient, and ambulatory settings for multiple procedures and chronic conditions involving multiple types of providers.

• Model permits flexibility with respect to number and types of physicians who could participate in clinical affinity groups.

• However, some issues need to be resolved:
  – Unclear how independent practices in different specialties with overlapping but not identical service areas could effectively participate, since not all patients in one practice in a clinical affinity group would be in the other practices in the group and vice versa.
  – Proposal asserts that rural, critical access, and small group providers can participate “under the umbrella of a new corporate entity or convener group.” However, the proposal does not describe how to overcome logistical challenges or potential regulatory or monetary hurdles.
  – Model does not appear to provide for direct payment for innovative services not eligible for payment under current payment systems and does not explain how physicians would provide such services without payment.
  – Unclear whether and how physicians would have greater flexibility to control post-acute care costs and other types of non-physician services.
Criterion 6. Ability to be Evaluated
Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

PRT Conclusion: Proposal Meets the Criterion

• An evaluation could be performed by comparing changes in spending under the EGM for participating vs. non-participating practices.

• However, the model would be very complex to evaluate because:
  – Not all clinicians in a clinical team are required to participate and there may be many different combinations of physicians participating in clinical affinity groups. While creating flexibility in implementation, this increases the complexity of evaluation because of the potential for multiple configurations of clinical affinity groups and for interactions between the variations in care delivery and variations in the clinical affinity group composition.

  – Model depends upon the ability to identify members of the care teams accurately with respect to role (primary provider, principal provider, etc.) and their contributions across settings and the ability to report quality measures of greater specificity than is currently required by payers.
Criterion 7. Integration and Care Coordination
Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

PRT Conclusion: Proposal Meets the Criterion

• Model includes innovative way to support multiple clinicians working together as part of clinical affinity groups.

• Model aims to increase integration across specialties by identifying clinicians who regularly participate in a given type of episode for measuring and reporting utilization and quality data.

• However:
  – No apparent minimum threshold for the level of integration required, nor any way to encourage or require support by, and coordination with, the physicians who are not part of the alternative payment model entity.
  – Voluntary nature of the involvement of members of the care team may result in less integration and care coordination than desirable or necessary to successfully reduce spending and ensure quality.
Criterion 8. Patient Choice
Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

PRT Conclusion: Proposal Meets the Criterion

• Patients are not limited in which physicians and other providers they can choose for the different components of care included in episodes.

• No requirement for gatekeeper arrangements or narrowed networks that would limit patient choice.

• Model may improve attention to individual differences in patient characteristics (including social needs, conditions, and health-related preferences) by incentivizing attention to the social determinants of health outcomes as a driver of adverse variances in cost and quality. However, not clear whether the risk adjustment methodology will adequately protect against participants avoiding high-need patients.

• If the model allows a wider range of clinicians to participate in advanced alternative payment models than what exists in the current CMS models, then expansion by demographical, clinical, or geographic diversity may be incentivized.
Criterion 9. Patient Safety
How well does the proposal aim to maintain or improve standards of patient safety?

PRT Conclusion: Proposal Meets the Criterion

• Model aims to address patient safety by ensuring that episode spending measures include costs resulting from excessive, delayed or avoided care, and poor outcomes of care.
• Because episode definitions would include costs of treatment of complications, there are implicit penalties for an increase in patient safety problems.
• Process measures used for the quality component would also help ensure patient safety.

• However:
  – Initial quality measures only provide incentives for improvement if there are savings.
  – Model does not describe how disruptions in care transitions and care continuity would be addressed if all clinicians involved in services prior to and after the transition were not participating.
PRT Conclusion: Proposal Meets the Criterion

• Model requires “at least 50% of eligible clinicians in each APM entity to use CEHRT for clinical documentation, communication, and patient care,” similar to requirement for advanced APMs.

• Model does not restrict current health information integration efforts and may incentivize use of technology that promotes improved care coordination and monitoring of factors affecting rates of complications.

• Model requires identification of providers as either primary, principal, episodic, supporting, or ancillary; and its required reporting of quality measures may require enhancements of current coding practices for claims reporting.

• However, the need for technology to identify high risk patients or technology-enhanced care innovations is not directly addressed in the proposal.
Key Issues Identified by the PRT

Overall PRT Conclusion:

• Proposed model should not be recommended because:
  – It does not meet the high priority criterion pertaining to quality and cost of care
  – It does not meet the criterion for “value over volume.”

• The broad scope of the proposal and the limited detail on how it would affect individual conditions and procedures make it difficult to determine whether it would meet the criteria for physician-focused payment models in all cases.

• PRT does not “recommend limited scale testing” because the proposal did not identify a small number of specific clinical areas, episode types, and venues that would be appropriate for limited scale testing.

• PRT believes model could have considerable impact if these concerns were adequately addressed in a revised proposal.