

Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

Len Nichols, PhD (Lead Reviewer)

Tim Ferris, MD

Grace Terrell, MD

March 22, 2017

In accordance with the Physician-Focused Payment Model Technical Advisory Committee's (PTAC's) *Processes for Reviewing and Evaluating Proposed Physician-Focused Payment Models and Making Recommendations to the Secretary of the Department of Health and Human Services*, proposals for Physician-Focused Payment Models (PFPMs) that contain the information requested by PTAC's Request for Proposals will be assigned to a Preliminary Review Team (PRT). The PRT will draft a report containing findings regarding the proposal for discussion by the full PTAC. This PRT report is preparatory work for the full PTAC and is not binding on the PTAC. This report is provided by the PRT to the full Committee for the proposal identified below.

A. Proposal Information

1. **Proposal Name:** The COPD and Asthma Monitoring Project (CAMP)
2. **Submitting Organization or Individual:** Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group, Inc. (PMA)
3. **Submitter's Abstract:**

"The COPD and Asthma Monitoring Project (CAMP) is a proposed payment model designed to treat a population of high-risk Medicare beneficiaries with COPD and other chronic lung conditions. Care of this high-risk population is provided through remote interactive monitoring that brings all the resources to leverage the expertise of a large telemedicine, pulmonary and allergy practice in the acute and chronic management of large populations of patients with COPD, asthma and other chronic lung diseases. Novel data presentation formats, computerized decision support, and smart alarms are used to enhance patient safety, patient education, patient compliance, increase effectiveness, and standardize clinical and operating processes. In addition, the technology infrastructure facilitates performance improvement by providing an automated means to measure outcomes, track performance, and monitor resource utilization. The program is designed to support an integrated healthcare delivery system

as well as the independent practicing physician. If approved, CAMP will improved quality, decreased mortality while producing large cost savings for CMS.”

B. Summary of the PRT Review

Criteria Specified by the Secretary (at 42 CFR §414.1465)	PRT Conclusion	Unanimous or Majority Conclusion
1. Scope of Proposed PFPM (High Priority)	Meets criterion	Unanimous
2. Quality and Cost (High Priority)	Meets criterion	Unanimous
3. Payment Methodology (High Priority)	Does not meet criterion	Unanimous
4. Value over Volume	Meets criterion	Unanimous
5. Flexibility	Meets criterion	Majority
6. Ability to be Evaluated	Meets criterion	Unanimous
7. Integration and Care Coordination	Does not meet criterion	Unanimous
8. Patient Choice	Meets criterion	Unanimous
9. Patient Safety	Meets criterion	Unanimous
10. Health Information Technology	Meets criterion	Unanimous
PRT Recommendation (check one): <input checked="" type="checkbox"/> Do not recommend proposed payment model to the Secretary. <input type="checkbox"/> Recommend proposed payment model to the Secretary for: <input type="checkbox"/> limited-scale testing of the proposed payment model; <input type="checkbox"/> Implementation of the proposed payment model; or <input type="checkbox"/> Implementation of the proposed payment model as a high priority.		

C. Information Reviewed by the PRT

1. Proposal (Proposal available on the PTAC [website](#))

Proposal Overview: The CAMP proposal is to use telemonitoring and pulmonology specialist management of COPD and asthma patients 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. The proposal is for a 2,000-patient pilot, which the submitter intends to scale up following validation.

Under the proposed model, 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. The intervention would be collaborative with engaged local providers and an adjuvant to (not a replacement for) existing patient-provider relationships.

The proposal calls for CMS to pay for the Bluetooth peak flow meters, pay an inflation-adjusted per beneficiary per month (PBPM) remote monitoring and management fee, and waive co-pays 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. The proposal also requests a safe harbor designation from federal self-referral laws, to protect the collaborative clinical relationships that are necessary to make the model work. The proposed two-sided risk arrangement would permit CMS to recoup up-front costs first, use number of chronic conditions as a risk adjuster to find the target spending level, and then remaining savings from total Part A and B costs of care above the cost to CMS of the technology and of the PBPM payments would be shared as well as would losses up to a stop loss percentage amount.

PRT Review: The CAMP proposal was received on December 10, 2016. The PRT met between December 21, 2016 and February 1, 2017. The PRT sent questions to the submitter, and the answers received were very helpful in clarifying the PRT's understanding of some of the details and rationale of the proposal. The PRT received and reviewed three public comment letters. The questions and answers and public comment letters are available on the PTAC [website](#).

2. Data Analyses

The PRT sought additional information regarding costs and utilization associated with COPD and asthma. The Office of the Assistant Secretary for Planning and Evaluation (ASPE), through its contractor, produced data tables that are available on the PTAC [website](#).

3. Literature Review and Environmental Scan

The submitter cites relevant literature in the proposal. ASPE, through its contractor, also conducted an abbreviated environmental scan that included a review of peer-reviewed literature as well as a search for relevant grey literature, such as research reports, white papers, conference proceedings, and government documents. The abbreviated environmental scan is available on the PTAC [website](#).

Documents comprising the environmental scan were primarily identified using Google and PubMed search engines. Key words guiding the environmental scan and literature review were directly identified from the letter of intent (LOI). The key word and combination of key words were utilized to identify documents and material regarding the submitting organization, the proposed model in the LOI, features of the proposed model in the LOI or subject matter identified in the LOI. Key terms used included

“Pulmonary Medicine Associates,” “PMA,” “telemedicine,” “oncology care model,” “remote monitoring,” “remote monitoring asthma,” “remote monitoring chronic obstructive pulmonary disease,” and “telemonitoring outcomes.” This search produced seven documents from the grey literature and five peer-reviewed articles. These documents are not intended to be comprehensive and are limited to documents that meet predetermined research parameters including a five-year look back period, a primary focus on U.S. based literature and documents, and relevancy to the LOI.

D. Evaluation of Proposal Against Criteria

Criterion 1. Scope of Proposed PFPM (High Priority Criterion). The proposal aims to broaden or expand the 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.

The goal of this section of the proposal is to explain the scope of the PFPM by providing PTAC with a sense of the overall potential impact of the proposed model on physicians or other eligible professionals and beneficiary participation. Proposals should describe the scope and span of the payment model and discuss practice-level feasibility of implementing this model as well as clinical and financial risks.

PRT Qualitative Rating:

Meets Criterion

The PRT’s unanimous judgment is that the proposed PFPM meets this criterion. The proposed PFPM aims to address payment for care management for COPD and asthma, two well-defined and clinically important conditions, in new ways, by expanding payment to cover daily monitoring utilizing new technology and introducing two-sided risk. The proposed PFPM also aims to broaden CMS’ Alternative Payment Model (APM) portfolio by including pulmonary physicians, whose opportunities to participate in APMs have been limited.

The PRT notes that while the proposal is for an initial 2,000-beneficiary pilot, the submitter intends to scale up following validation. Nationwide, there are approximately 5.4 million Medicare fee-for-service beneficiaries with COPD, asthma, or both, and the average annual Medicare Part A, B, and D spending for beneficiaries with these conditions is around \$30,000.

Criterion 2. Quality and Cost (High Priority Criterion). 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.

The goal of this section of the proposal is to better understand the “value proposition” that will be addressed by the proposed PFPM. The submitter was asked to describe how the components of the value proposition will be achieved. For example, how will clinical quality,

health outcomes, patient experience, and health care cost management be addressed within the model and how will performance be measured? The submitter was also asked to describe any current barriers to achieving desired value/quality goals and how they would be overcome by the payment model. Finally, the submitter was asked to identify any novel clinical quality and health outcome measures included in the proposed model. In particular, measures related to outcomes and beneficiary experience were to be noted.

PRT Qualitative Rating:	Meets Criterion
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The PRT's unanimous judgment is that the proposed PFPM just barely meets this criterion's goals of being likely to improve or maintain quality at no additional cost or while decreasing cost. Conceptually this proposal makes sense. There is considerable literature supporting the idea that investment in programs that enroll well-selected patients with chronic conditions characterized by frequent exacerbations resulting in hospitalizations (e.g., congestive heart failure) can effectively improve quality and reduce costs. Nonetheless, there appears to be limited data for the specific intervention proposed here. The submitter cited only one study of a similar clinical approach in the literature with sufficient size to be persuasive, and the study was conducted in Germany with quite different payment and cost structures. Nevertheless, the study did show promising improvements in utilization, cost, and quality. Still, many details of the planned approach remain to be worked out by the submitters including construction, software development, training of personnel, the enrollment process, and coordination with local providers. For example, the clinical algorithms are not fully developed at present, but would be developed in the early phase of the model's implementation. Therefore, the PRT's confidence in the likelihood of success on quality and cost is not high, but it is adequate to justify going forward if other criteria are met.

Criterion 3. Payment Methodology (High Priority Criterion). 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.

The goal of this section is to better understand the payment methodology for the proposed model, including how it differs from both existing payment methodologies and current alternative payment models. The submitter is asked to describe how the proposed PFPM will incorporate the performance results in the payment methodology and to describe the role of physicians or other eligible professionals in setting and achieving the PFPM objectives, as well as the financial risk that the entity/physicians will bear in the model. The submitter is asked to differentiate between how services will be reimbursed by Medicare versus how individual physicians or other eligible professionals might be compensated for being a part of this model. Finally, a goal of this section is to better understand any regulatory barriers at local, state, or federal levels that might affect implementation of the proposed model.

While the proposed PFFM's basic approach – a PBPM payment and a shared two-sided risk arrangement – seems appropriate for the clinical innovation the submitter proposes, the PRT's unanimous judgment is that there are too many unspecified or questionable features of the payment methodology to meet this criterion. Major shortcomings in the payment model include the following:

- (a) there appears to be no quality performance requirements to earn shared savings, should sufficient cost savings occur (i.e. there is a lack of accountability);
- (b) the justification for the PBPM amount is weak and not based on actual experience or detailed analysis of the services that need to be provided for these kinds of patients under the monthly fee arrangement;
- (c) the model as proposed would not count some real costs – waived copayments and discounted drug costs for beneficiaries that would likely substantially add to costs if the model was applied nationwide. Neither would it include Part D spending in general, which should be “recouped” by CMS before net savings have actually occurred;
- (d) the proposed risk adjustment to the target spending for the shared savings calculation, based on the number of chronic conditions, while interesting, has not been tested and may impart higher financial risk to clinicians than may be prudent. Stronger use of available Medicare data might improve the initial design of this essential element, but given the inherent uncertainties involved in the impact of the proposed model, developing accurate risk adjustment for this proposal will be a necessary early part of a piloted test of this promising PFFM;
- (e) the key technological device in this model has not been approved by the Food and Drug Administration;
- (f) the cost structure assumed device prices that were obtained in Germany, so cost estimates and savings calculations would need to be adjusted to reflect US pricing; and
- (g) more generally, the PTAC's approach to recommending payment models will, whenever possible, avoid the endorsement of any specific company's product. In this case, there are multiple options for telemonitoring of patients with respiratory conditions and the proposal does not make a compelling argument for this particular technology.

During its review, the PRT discussed “fee-at-risk” arrangements. Such a model could provide a PBPM payment for investment in the medical management infrastructure. The PBPM payment would be the only downside financial risk and would need to be refunded if cost and quality targets were not reached. Participating clinicians would not bear downside risk for total costs of care. Depending on how the payment model was structured, participants could still potentially benefit from shared savings if the savings exceeded a pre-established savings target. An additional benefit would be that it could be applied to numerous other clinical situations, reducing the need for CMS to create multiple different payment programs.

Criterion 4. Value over Volume. The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

The goal of this section of the proposal is to better understand how the model is intended to affect practitioners' behavior to achieve higher value care through the use of payment and other incentives. PTAC acknowledges that a variety of incentives might be used to move care towards value, including financial and nonfinancial ones; the submitter is asked to describe any unique and innovative approaches to promote the pursuit of value including nonfinancial incentives such as unique staffing arrangements, patient incentives, etc.

PRT Qualitative Rating:	Meets Criterion
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The PRT's unanimous judgment is that the proposed PFPM meets this criterion. Remote patient monitoring via Bluetooth technology and software would seem to enable clinicians to efficiently monitor and manage a patient population. Under the proposed PFPM, a care team member would only reach out to patients in need of intervention per clinical algorithms applied to patient-supplied data. The early detection of disease exacerbation or infection, coupled with early intervention, is meant to lead to fewer ED visits and hospitalizations. At the same time, the two-sided risk arrangement would seem to counter incentives to create a clinical algorithm that leads to unnecessary intervention (e.g. unnecessary specialty visits).

Criterion 5. Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care

The goal of this section is to better understand (1) how the proposed payment model could accommodate different types of practice settings and different patient populations, (2) the level of flexibility incorporated into the model to include novel therapies and technologies, and (3) any infrastructure changes that might be necessary for a physician or other eligible professionals to succeed in the proposed model.

PRT Qualitative Rating:	Meets Criterion
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The PRT is split on this criterion; two members conclude that the proposed PFPM does meet this criterion, and one does not. Nonetheless, the PRT was unanimous about what specific issues were relevant to this decision. The proposal is simultaneously rigid – relying largely on one specific device and data transmission method – and somewhat vague, since the exact clinical protocols have not been worked out, and the enrollment process and coordination with other local providers was unclear. While the proposal is for an initial 2,000-beneficiary pilot, the submitter indicates in the proposal, “Once proven, this model can be replicated and scaled to meet demands in different regions of the country...CAMP will have the flexibility to partner with rural provider networks.” Ultimately, the PRT members are split along the lines whether to give the proposed PFPM, “the benefit of the doubt.”

Criterion 6. Ability to be Evaluated. Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

The goal of this section is to describe the extent to which the proposed model or the care changes to be supported by the model can be evaluated and what, if any, evaluations are currently under way that identify evaluable goals for individuals or entities in the model. If there are inherent difficulties in conducting a full evaluation, the submitter is asked to identify such difficulties and how they are being addressed.

PRT Qualitative Rating:	Meets Criterion
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The PRT's unanimous judgment is that the proposed PFPM meets this criterion. The proposed PFPM aims to reduce ED visits, hospitalizations, and mortality and achieve Medicare cost savings. The data to evaluate the degree to which CAMP achieves these goals should be obtainable from existing sources (e.g. Medicare claims). Furthermore, the technology at the heart of this model is expected to generate new/additional data. Nonetheless, it is important for all PFPMs to include validated quality metrics.

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.

The goal of this section is to describe the full range of personnel and institutional resources that would need to be deployed to accomplish the proposed model's objectives. The submitter is asked to describe how such deployment might alter traditional relationships in the delivery system, enhance care integration, and improve care coordination for patients.

PRT Qualitative Rating:	Does Not Meet Criterion
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The PRT holds the unanimous position that the proposed PFPM does not meet this criterion. While the PRT concludes that the proposed PFPM is likely to encourage greater care coordination, the PRT found the proposed PFPM lacking in terms of how integration would be achieved. The proposal describes the sharing of information with primary care providers (PCPs) (e.g. recommendations for medication changes) and making information easily accessible to clinicians. However, the proposal does not seem to describe an integrated care model in which primary care or other providers beyond the pulmonary subspecialists are integrated into the care planning as part of a broader care team. Further, in response to questions asked by the PRT, the submitter indicated that PCPs would not share in the financial risks and incentives of the program. While the submitter's willingness to take on a total cost of care model is laudable, 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. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

The goal of this section is to describe how patient choice and involvement will be integrated into the proposed PFPM. The submitter was asked to describe how differences among patient needs will be accommodated and how any current disparities in outcomes might be reduced. The submitter was asked to describe, as an example, how the demographics of the patient population and social determinants of care may be addressed.

PRT Qualitative Rating:	Meets Criterion
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The PRT's unanimous conclusion is that this proposed PFPM is unlikely to reduce patient choice. Patients will be offered the opportunity to enroll, and the model is driven largely by patient compliance in providing Bluetooth peak flow meter and self-assessment data. In addition, the services described in this proposal are meant to be a "value-add" rather than supplant existing patient-provider relationships. Furthermore, the proposal explicitly takes into account patients' comorbidities and plans to offer participating beneficiaries relevant educational opportunities. It will be important to have clinical protocols that are responsive to changes in patient status as detected through their proposed telemonitoring technology.

Criterion 9. Patient Safety. How well does the proposal aim to maintain or improve standards of patient safety?

The goal of this section is to describe how patients would be protected from potential disruptions in health care delivery brought about by the changes in payment methodology and provider incentives. The submitter is asked to describe how disruptions in care transitions and care continuity will be addressed. Safety in this instance should be interpreted to be all-inclusive and not just facility-based.

PRT Qualitative Rating:	Meets Criterion
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The PRT unanimously concluded that the proposed PFPM meets this criterion. The PRT concludes the proposal would improve the standards of patient safety by creating an early warning system for disease exacerbation and infection detection. While the submitter anticipates Medicare cost savings, those savings are expected to come from avoided ED visits and hospitalizations due to early intervention and better patient management. In addition, the proposal incorporates various goals, such as achieving a statistically significant decrease in mortality, to guard against patient harm. However, it will be important for the submitter to connect quality to financial incentives. As noted above, there appear to be no quality performance requirements to earn shared savings.

Criterion 10. Health Information Technology. Encourage use of health information technology to inform care.

The goal of this section is to understand the role of information technology in the proposed payment model. In this section the submitter is asked to describe how information technology will be utilized to accomplish the model’s objectives with an emphasis on any innovations that improve outcomes, improve the consumer experience and enhance the efficiency of the care delivery process. The submitter is also asked to describe goals for better data sharing, reduced information blocking and overall improved interoperability to facilitate the goals of the payment model.

PRT Qualitative Rating:	Meets Criterion
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The PRT’s unanimous judgment is that the proposed PFPM met this criterion. HIT is a key element of this proposal (e.g. Bluetooth peak flow meters, smartphone apps, and computer-based algorithms and decision support tools). The submitter indicated that the specific software and device interfaces need to be developed. Basic EHR interoperability challenges are probable, as clinicians are likely to use different EHR systems. However, the PRT concludes that what was proposed is feasible.

E. PRT Recommendation

<p>Do not recommend proposed payment model to the Secretary</p>
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F. PRT Comments

Improvement in the management of Medicare patients with COPD, asthma, and other chronic lung diseases should be a high priority for CMS. The innovative care model proposed by this submitter could make a significant contribution to that goal, provided a more robust payment methodology is developed to support this approach, including specific analysis of program cost, potential savings, and detailed protocols for care management.

The PRT applauds the creativity and the effort of the submitter and shares the submitter’s goal of improving care and saving resources now used for less than optimal care for COPD and asthma patients. The PRT concludes that the framework the submitter has proposed – PBPM payments with a two-sided risk arrangement – could benefit the patients, clinicians, and organizations involved as well as the Medicare program. The PRT also finds this kind of PFPM is potentially scalable for these types of patients and providers.

However, several elements of the proposal need to be further developed. In particular, the PRT had concerns with the details of the proposed PFPM's payment methodology, and determined that the proposal did not meet this high priority criterion. The PRT also found that the proposed PFPM did not meet the integration and care coordination criterion. Thus, the PRT's unanimous judgment is that the proposed payment model should not be recommended in its present form and at the present time.

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