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June 11, 2019

Jeffrey Bailet, MD  
Committee Chairperson  
Physician-Focused Payment Model  
Technical Advisory Committee  
Office of the Assistant Secretary  
for Planning and Evaluation  
U.S. Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Dr. Bailet:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide our strong support for the Patient-Centered Asthma Care Payment (PCACP) proposal that was submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) by the American College of Allergy, Asthma, and Immunology (ACAAI). The AMA has been assisting the ACAAI in the development of the PCACP proposal from its inception. Several foundational elements of this model represent significant advances in the design of physician-focused payment models that the AMA has advocated in comments to the PTAC, meetings with the Center for Medicare & Medicaid Innovation, and discussions with stakeholders and policymakers.

First, rather than focusing only on improving management of asthma after the patient has been diagnosed, PCACP is also designed to ensure the diagnosis is accurate. It does this by paying adequately for a complete diagnostic work-up, development of an initial treatment plan, and management of the patient's condition for an initial period of time, and by measuring the effectiveness of the treatment plan in controlling symptoms as a way of ensuring the diagnosis is accurate. This is an important advance, since neither the fee-for-service system nor current alternative payment models (APMs) appropriately support the work involved in accurate diagnosis. By ensuring that a diagnosis is determined as quickly and accurately as possible for patients who have asthma-like symptoms, PCACP can reduce avoidable spending and improve quality both during and after the diagnostic phase. For example, current payment systems pay for tests, but do not pay physicians for the time needed to determine which tests are necessary and appropriate to rule out alternative diagnoses. Moreover, by paying adequately for educating patients about their condition and how they can best manage exacerbations when they occur, PCACP can begin reducing emergency visits and hospitalizations as soon as symptoms are first identified. PCACP includes utilization and quality measures that are specifically designed to ensure quality and efficiency during this phase of care.

PCACP also incorporates an innovative approach to risk stratification based on the severity of the patient's asthma, including their asthma-related or asthma-like symptoms and comorbidities that are known to exacerbate asthma, such as smoking, obesity, and rhinitis or sinusitis. This is preferable to the

risk adjustment systems in other APMs that use data on other health issues that may have no relationship to effective care for the patient's asthma.

Several aspects of PCACP address comments and recommendations made by the PTAC based on its review of an earlier proposal focused on management of asthma and chronic obstructive pulmonary disease (COPD). The ACAAI's proposal is also responsive to comments from the Secretary of Health and Human Services (HHS) when the department reviewed the PTAC report of this previous proposal. At that time, the PTAC stated that "improvement in the management of Medicare patients with COPD, asthma, and other chronic lung diseases should be a high priority for CMS." In its September 2017 response, HHS said it was "keenly interested in ideas for how to improve specialty care for Medicare beneficiaries with complex chronic illnesses such as COPD and asthma," and further stated that "HHS would be interested in CMS testing an APM with more focus on COPD/Asthma, and is generally interested in APMs that address management of chronic conditions." The PCACP proposal does exactly what HHS said it wanted.

Moreover, PCACP explicitly incorporates the approach to asthma care payment that the PTAC has endorsed previously, while also addressing the specific issues and concerns that were raised by PTAC and HHS two years ago:

- PTAC has said that a combination of per-beneficiary per month payments and a two-sided risk arrangement focused on reducing emergency visits and hospitalizations is an appropriate method of paying for care of patients with asthma. PCACP uses this approach for new asthma patients and those with poorly-controlled asthma—asthma care teams would receive a monthly payment for each such patient in place of current visit payments, and the payments would be increased or decreased based on measures of quality and spending.
- HHS said that it was important to define "how payment amounts and spending targets should be set for Medicare patients who are more likely to have multiple health problems and for whom additional time and resources may be needed to support both proactive outreach and coordination with other physicians." PCACP defines several categories of asthma patients based on the severity of their condition and the number and types of comorbidities they have, and establishes different payment amounts, quality targets, and spending targets for each category.
- Both PTAC and HHS have indicated that an APM needs to explicitly tie payment to quality. PCACP does this in two ways. First, an asthma care team would not receive any payment under the model unless specific quality standards described in the proposal are met. Second, even if the minimum quality standards are met, the monthly payment would be reduced if performance on quality measures is significantly below a benchmark level based on quality levels that are known to be achievable for similar patients.
- PTAC has stated that it believes the spending measure in an asthma care APM needs to include Part D spending. The PCACP APM holds the asthma care team accountable for all aspects of asthma-related spending, including medications.
- Both PTAC and HHS, as well as the AMA, repeatedly have emphasized the importance of supporting integration and coordination of care between specialists and primary care physicians. PCACP payments are explicitly designed to support a team care approach between primary care physicians and allergists or pulmonologists. The first category of payments (for Diagnosis and

Initial Treatment) would only be available to specialists for a maximum of three months while they determine a diagnosis and effective treatment plan, and the second category of payments (for Continued Care for Patients with Difficult-to-Control Asthma) would only be available to specialists for patients who cannot be successfully managed using standard treatment approaches. For the majority of asthma patients, the model explicitly assumes they should have their care managed by a primary care physician, not by a specialist, but that the specialist should remain an integral member of the patient's asthma care team.

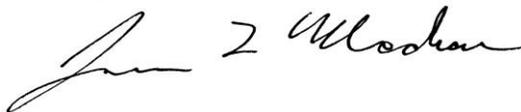
PCACP includes several other important features that are not found in current CMS APMs and that should be tested:

- a separate bundled payment for allergy testing, designed to avoid overuse of multiple separate types of tests without penalizing physicians for using testing when appropriate;
- patient-reported outcome measures;
- accountability elements designed to ensure that small practices are not subjected to large changes in payment due to random variations in patient characteristics or outcomes; and
- instead of a one-size-fits-all approach, there are several options for higher levels of payment "bundling" in PCACP, which parallels the multiple models included in the new Primary Cares Initiative.

Not only will implementation of the proposed payment model support improved care for Medicare patients with asthma and achieve reductions in Medicare spending for these patients, we believe that modified versions of the PCACP design could be used to improve care for patients with other chronic conditions, thereby leading to even greater savings for Medicare and better outcomes for a wide range of patients. Moreover, APMs such as PCACP that support coordinated care by primary care and specialist physicians for patients with difficult-to-manage chronic diseases will complement and help support the success of APMs focused on primary care practices.

The AMA urges you and the other PTAC members to recommend the Patient-Centered Asthma Care Payment model to the Secretary of HHS for priority consideration and rapid implementation. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD

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Physician-Focused Payment Model Technical Advisory Committee  
c/o U.S. Department of Health and Human Services  
Assistant Secretary for Planning and Evaluation, Office of Health Policy  
200 Independence Avenue, SW  
Washington, DC 20201

Submitted electronically via [PTAC@hhs.gov](mailto:PTAC@hhs.gov)

RE: Patient-Centered Asthma Care Payment (PCACP)

Dear Committee Members,

Established in 1943, the AAAAI is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We appreciate the opportunity to provide comments on the Patient-Centered Asthma Care Payment (PCACP), submitted by the American College of Allergy, Asthma & Immunology.

A/I professionals lead in the diagnosis, treatment and ongoing management of asthma, allergy and immunology conditions. By itself, asthma – a chronic disease that affects the airways in the lungs – affects more than 25 million Americans at a total cost of \$56 billion per year. Asthma causes 14.2 million missed days of work and 10.5 million missed days of school, and results in 479, 300 hospitalizations, 1.9 million emergency department visits, and 8.9 million doctor visits. For these and other reasons, we have a strong interest in models that support A/I professionals ability to continue delivering high-quality care at an affordable cost to patients.

We appreciate the tremendous effort that our A/I colleagues have devoted to developing a bundled payment model, which aims to optimize asthma health outcomes, improve beneficiary experience, and reduce utilization of unnecessary services while decreasing Medicare spending. We believe proposals such as this are very important as we transition to value-based healthcare, and anticipate this, and other A/I focused care models, will be proffered in the coming years as emphasis

**(more)**

on value-driven of reimbursement continues to encompass a greater proportion Medicare spending. We look forward to the discussion that ensues as the PTAC deliberates this model.

We appreciate the opportunity to provide comments on the aforementioned model of interest to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

A handwritten signature in black ink that reads "David M. Lang". The signature is written in a cursive style with a large initial "D" and a long, sweeping underline.

David M. Lang, MD FAAAAI  
President

February 28, 2020

Physician-Focused Payment Model Technical Advisory Committee  
c/o Assistant Secretary for Planning and Evaluation  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

RE: Patient-Centered Asthma Care Payment Proposal

Dear Chairman Bailet and Members of the Committee:

At your March 16 meeting, I urge you to recommend that the Secretary of Health and Human Services initiate testing of the Patient-Centered Asthma Care Payment (PCACP) proposal.

PCACP is exactly the kind of “physician-focused payment model” that Congress envisioned when it passed MACRA and created PTAC. PCACP was designed by practicing physicians to (1) address specific opportunities to improve the quality of life for more than a million Medicare beneficiaries who have asthma, in a way that will also (2) reduce Medicare spending on avoidable hospital admissions, Emergency Department visits, medications, and other services both for asthma patients and for patients who have been misdiagnosed as having asthma. It replaces current fees for office visits and other services with bundled payments tied to outcomes and patient needs. This represents true value-based payment, unlike the small bonuses and penalties on top of the current fee-for-service system used in current pay-for-performance and shared savings APMs. The payment methodology is structured in a way that enables small and rural physician practices to participate as well as large health systems, in contrast with the wholesale shifts in insurance risk that are currently being promoted by CMS and other payers.

The desirability of enabling both small and large physician practices to deliver significantly better care at lower costs for such a large subgroup of Medicare beneficiaries is reason enough to support testing of the PCACP APM. But PCACP has a number of additional characteristics that should make it a high priority for both a positive recommendation from PTAC and for prompt testing by CMS:

- PCACP would be the first truly condition-based APM in the Medicare program supporting high-quality ambulatory care for patients with a chronic disease. Unlike the Medicare Bundled Payments for Care Improvement (BPCI) initiatives, PCACP does not require that a patient with a chronic disease be hospitalized in order to be eligible for the APM, since the goal of good chronic disease management is to *avoid* hospital admissions. Moreover, unlike BPCI, PCACP does not limit services for a patient who has been hospitalized to an arbitrary 90-day period after discharge.
- PCACP would be the first APM in the Medicare program that is explicitly designed to support accurate diagnosis of a chronic condition. Eligibility and payments in every other APM in the Medicare program are based on the diagnoses assigned to a patient, but there is no explicit mechanism for ensuring the accuracy of those diagnoses. Asthma is an ideal condition for an APM focused on improving diagnosis because multiple studies have shown that a high proportion of patients with asthma symptoms are misdiagnosed (both diagnosed as having asthma when they do not and diagnosed with other conditions when they actually have asthma), and errors in diagnosis are

particularly likely in the elderly. Moreover, use of the wrong medications for misdiagnosed patients can be deadly.

- PCACP would be the first APM in the Medicare program that ties physician payments to patient-reported outcomes (i.e., improvements in their symptoms), not just process measures, care experience, and hospital utilization.
- PCACP would be the first APM in the Medicare program in which physicians would not be paid at all if they failed to meet minimum standards of quality in the delivery of patient care.
- PCACP would be the first APM in the Medicare program to completely replace visit-based payments with monthly payments tied to quality standards and outcomes, giving physicians full flexibility to deliver services to patients in the most effective way possible. It would also be the first APM to create a bundled payment for diagnostic testing instead of separate fees for individual tests.
- PCACP would be the first APM in the Medicare program to stratify payment amounts based on actual differences in patient-reported symptoms and needs rather than merely on the number of different diagnoses assigned to them in claims data (as is done in the problematic Hierarchical Condition Category (HCC) system CMS routinely uses in its APMs).
- PCACP would be the first APM in the Medicare program that explicitly supports a team-based approach to chronic disease management involving both primary care physicians and specialists, and it would also be the first APM that explicitly focuses specialty expertise where it creates the greatest value, i.e., ensuring an accurate diagnosis and managing the care of patients with difficult-to-control conditions, rather than having repeated office visits with well-managed patients.

It was disappointing that the Preliminary Review Team (PRT) report on PCACP failed to recognize most of these strengths, and even for those it did acknowledge, their importance was not clearly explained. Because of its unique and important characteristics, I believe that PCACP would not only benefit patients with asthma, it could serve as a model for how APMs could be designed for patients who have other chronic diseases.

The PRT report lists over 30 alleged weaknesses in the proposal. Many of these points are vague, others are inaccurate, and some unfairly demand a level of certainty about results or perfection in design that no payment model proposal could be expected to achieve. In many cases, the American College of Allergy, Asthma, and Immunology provided detailed responses explaining why the PRT's concerns were not valid, but the PRT still included the same concerns in its report without explaining why the responses were inadequate. In several cases, the PRT report criticized a component of the proposal without providing any indication that a better alternative exists. For example:

- The PRT report appears to criticize PCACP for focusing on patients who are newly diagnosed or whose asthma is poorly controlled, even though that is exactly the subset of the population where the biggest opportunities for reducing spending and improving quality exist. National Health Interview Survey (NHIS) data for 2017 show that more than 40% of asthma patients over age 65 experience an asthma attack during the year; CMS data show that Medicare beneficiaries with asthma average more than one ED visit every year and that nearly one third of asthma-related ED visits by Medicare beneficiaries result in a hospital admission. Although the PRT report implies that hardly anyone on Medicare would be newly diagnosed with asthma, CMS data show that more than 20% of Medicare beneficiaries with asthma during the year were newly diagnosed with the condition. As noted earlier, a high percentage of patients who are newly diagnosed with asthma are misdiagnosed, which means they will likely receive unnecessary expensive medications and continue making ED visits, so targeting these patients to ensure they are accurately diagnosed and correctly treated will save money as well as helping those patients address their symptoms more successfully.
- The PRT report criticizes the PCACP APM for being “overly complex” because it has three phases of payment and several levels of payments based on differences in patient need. However, the report

fails to acknowledge that this structure replaces 10 current Evaluation & Management (E/M) payment codes (five of which could potentially be billed multiple times each month) as well as separate codes for spirometry and other tests, which means the payments in PCACP are actually far simpler than the current fee schedule. By way of comparison, the CMS Comprehensive Primary Care Plus (CPC+) APM includes a five-level Care Management Fee, a two-part Performance-Based Incentive Payment, and a Comprehensive Primary Care Payment *in addition* to the 10 current E/M payments and separate fees for testing, making it far more complex than PCACP. Moreover, it seems unlikely that the physicians in small practices who developed and submitted the PCACP proposal would have done so if they believed PCACP would be “difficult for providers to implement and manage” or if they believed that the Medicare fee schedule was already adequate to support the improved approach to patient care described in the proposal. The criteria used to assign patients to different payment levels are based on the clinical information that the physician practices would already be collecting in order to manage patients’ care effectively, so there would be less coding burden under PCACP than in the current fee-for-service payment system and other APMs.

- The PRT report claims that the proposed model “does not address the core factors that are most likely to address utilization among Medicare beneficiaries with asthma” and that it is “unlikely to affect spending,” even though the Environmental Scan prepared by PTAC’s staff states that “self-management of asthma through education and treatment compliance are key to controlling severe asthma” and that “well-controlled asthma is associated with reduced use of health care resources and impairment.” The PCACP model explicitly requires participating physicians to develop an Asthma Action Plan for each patient that follows evidence-based guidelines and that is explicitly designed to both prevent asthma exacerbations and quickly intervene when they occur, and the sample Asthma Action Plan included in the proposal explicitly discusses ways patients can control environmental factors and stop smoking. The PRT does not explain why it believes this type of evidence-based care would be ineffective or what it believes physicians should do differently.

I have attached additional comments on each of the points the PRT identified as weaknesses that will hopefully demonstrate that the proposal meets all ten of the criteria established by HHS and that the proposal deserves a strong positive recommendation from PTAC. I also urge that you carefully re-examine the negative statements in the PRT report before incorporating any of them into your formal report on the proposal. As you know, the Department of Health and Human Services has routinely pointed to weaknesses identified by PTAC as reasons not to pursue testing of otherwise desirable APMs. If you do include any of these points, I hope you will also include examples of specific changes in the proposal that would address your concerns so that applicants can better understand what PTAC is seeking.

Thank you in advance for considering my comments. Thank you also for the many hours of time that the members of PTAC and its staff always devote before, during, and after your meetings to ensure a thorough and fair review of proposals. Please let me know if you have any questions or if I can provide any additional information that would be helpful to you during your deliberations.

Sincerely,



Harold D. Miller  
President and CEO

Attachment

**ANALYSIS OF PRELIMINARY REVIEW TEAM REPORT TO PTAC  
ON THE PATIENT-CENTERED ASTHMA CARE PAYMENT PROPOSAL**

	<b>Weakness as Stated by PRT</b>	<b>Comments</b>
<b>Scope</b>		
1	The proposal relies on statistics and evidence of effectiveness pertaining to younger populations, and the validity of extrapolation of these metrics to the Medicare population is not demonstrated.	The physicians who developed PCACP have extensive experience treating asthma patients of all ages, and they have assured PTAC that the results with older populations would be similar. The PRT did not provide any indication as to why it believes the results would be different. Moreover, it is impossible for the applicants to prove that the proposed change in care is effective since they cannot actually deliver the change in care until payments are available to support it.
2	The exclusion criteria in the model could reduce the potential number of Medicare patients who might participate in PCACP.	The PRT has access to Medicare data, so it is not clear why it failed to do any analysis to determine the number of Medicare beneficiaries who could potentially participate. A PTAC analysis performed for a different proposal indicates that even excluding the subset of patients who also have COPD, there are likely as many as one million Medicare beneficiaries who could participate.
3	The proposal does not identify how the Medicare FFS payment system is causing failures in diagnosing and managing Medicare patients with asthma. The proposal also does not clearly articulate how the existing Medicare FFS payments fail to compensate providers for the types of activities described in the proposal.	The many reasons why current fee-for-service payments fail to support good care of patients with chronic disease are so well known that it seems unnecessary for the applicants to recite them in the proposal. For example, current payments are tied to face-to-face visits with physicians, so they do not provide the flexibility for physician practices to deliver care in evidence-based ways. In addition, the amounts of current Medicare payments at best support 15-20 minute visits with patients, which is clearly inadequate to allow accurate diagnosis of a difficult-to-diagnose condition or allow a physician practice to develop a customized plan that could successfully address multiple causes of a patient's problem.
4	It is possible that patients with asthma and their associated providers could participate in existing APMs such as accountable care organizations (ACOs) or Comprehensive Primary Care Plus (CPC+). Such models would enable a broad approach to patient health and directly incorporate allergists, immunologists, or pulmonologists.	It is only possible to participate in ACOs or CPC+ where they exist. Only 30% of Medicare beneficiaries are enrolled in ACOs and the majority of counties in the country do not have enough Medicare beneficiaries to form an ACO. CPC+ is only available to primary care practices in 13 states and 5 metropolitan areas. Moreover, neither CPC+ nor the Medicare Shared Savings Program would support the changes in care delivery described in the proposal, since there is no change in payment

	<b>Weakness as Stated by PRT</b>	<b>Comments</b>
		for either primary care providers or specialists who participate in an MSSP ACO, and CPC+ only includes new payments for primary care providers, not for specialists.
5	The model does not include innovations in care delivery or approach [sic] to improve care for patients with asthma beyond tools already available in Medicare.	It is not clear what kinds of “innovations” the PRT is referring to. The proposal clearly describes using a very different approach to delivering care than what exists today, starting with a focused effort to develop an accurate diagnosis and identify an effective treatment plan, and then focusing additional attention on patients who have more serious problems.
6	Though the prevalence of asthma in the general population is considerable, prevalence decreases with age.	It is not clear what relevance a decrease in prevalence with age has when the prevalence of asthma among older adults is still high.
7	The number of Medicare beneficiaries with asthma who meet the proposed inclusion and exclusion criteria is likely to limit the scope of the proposed model.	The PRT does not explain what threshold it believes is necessary for adequate “scope.” An APM that could improve care for as many as a million Medicare beneficiaries every year clearly surpasses any reasonable minimum threshold.
<b>Quality and Cost</b>		
8	The proposal likely overestimates the potential savings in the Medicare FFS asthma population by assuming that effects of improved asthma care would mirror utilization, spending, and savings reported for the wider asthma population.	The PRT provides no evidence that improved asthma care would have less benefit for older individuals than for younger adults or that the difference would be large enough to justify rejecting the proposed APM. The Environmental Scan produced by PTAC staff states that individuals aged 65 and older have the highest rate of asthma-related hospital stays and that diagnosis of late-onset asthma among the elderly can be challenging and delayed, which suggests that potential savings in the Medicare population could be greater than for younger adults.
9	The proposed model does not contain explicit provisions to address social determinants that are related to asthma control, such as smoking cessation, the patient’s environment, or access to services.	The PCACP APM requires participating physicians to develop a written asthma action plan consistent with evidence-based guidelines for treating asthma. The National Heart, Lung, and Blood Institute (NHLBI) Guidelines for the Diagnosis and Management of Asthma ( <a href="https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma">https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma</a> ) include the need to avoid tobacco smoke and environmental issues that can cause asthma exacerbations. The Asthma Action Plan included in the proposal describes the kinds of actions that could be taken to address environmental factors.

	<b>Weakness as Stated by PRT</b>	<b>Comments</b>
		The PRT report does not indicate what additional provisions it believes would be desirable. Since there will be wide variation in the factors that could be contributing to asthma exacerbations for different patients, and different solutions will be needed for different patients in different communities, the requirement to develop a written plan consistent with the guidelines is the best way to address this. This is similar to the requirement in the CMS Oncology Care Model for oncology practices to develop a written diagnosis and treatment plan for each patient that is consistent with IOM standards.
10	Most of the studies cited in the proposal are observational studies for younger populations that may not appropriately control for the fact that if patients enroll in management programs due to an exacerbation event, their expenditures subsequently decline, regardless of management program effectiveness.	Most of the studies of all healthcare interventions for all types of disease are observational studies and most have the same weaknesses cited by the PRT. There were no randomized control trials that supported current CMS APMs and it is unreasonable to criticize this proposal on that basis.
11	Medicare beneficiaries diagnosed with asthma who meet eligibility criteria are likely to be dispersed across provider practices, making it difficult for providers to achieve sufficient volume of participating patients to support practice transformation and achieve quality improvements.	This is no different than every other Medicare APM, where Medicare beneficiaries are “dispersed across provider practices,” and only a fraction of the patients treated by the practice will be included in the APM. However, unlike most Medicare APMs which further reduce the number of eligible patients through complex attribution rules and only provide small supplemental payments, practices in PCACP will receive significantly different payments for each patient who is eligible, making it much easier for the practice to change the way it delivers care.
12	The quality measures could be improved by adding objective measures of quality to complement the subjective measures that are proposed.	The PRT report does not explain which “objective measures” would improve the proposal. The comment inappropriately implies that the measures of spirometry and frequency of ED and urgent care visits and the minimum standards of care included in the proposal are not “objective” measures of quality.
13	Thresholds for some of the performance measures are not clearly specified (e.g., cut-off for well-controlled versus poorly controlled). Other measures, such as the patient perception of whether they got better, are very subjective.	The National Heart, Lung, and Blood Institute (NHLBI) Guidelines for the Diagnosis and Management of Asthma ( <a href="https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma">https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma</a> ) clearly specify the thresholds for the different levels of control. Contrary to what the PRT report states, the proposal does not include a

	<b>Weakness as Stated by PRT</b>	<b>Comments</b>
		measure of the “patient perception of whether they got better.” PCACP has a measure of whether the frequency and severity of the patient’s symptoms has changed, which is an appropriate outcome-based measure for this disease.
14	The proposed model does not address how care or payment would be coordinated between primary care providers and participating specialists, nor how that relationship might evolve over the course of the model.	The proposal clearly explains how patients with well-controlled asthma would be managed by primary care providers with support from asthma specialists, and how patients with difficult-to-control asthma would be managed by Asthma Care Teams consisting of either specialists or primary care providers with specialist support. It is impossible and inappropriate to be more specific than this, since the exact process for coordination will differ in different communities and for different patients.
15	The model does not clearly identify the factors that would lead to improved asthma control among Medicare beneficiaries to a degree that is sufficient to reduce hospitalizations.	The proposed model is designed to ensure that patients are prescribed the most effective medications and that they use those medications and also self-management techniques to successfully control their symptoms. The Environmental Scan prepared by PTAC’s staff clearly states that “self-management of asthma through education and treatment compliance are key to controlling severe asthma.”
<b>Payment Methodology</b>		
16	The proposed model is overly complex, with multiple tracks assigned by provider assessment within the three main categories. This complexity could make it difficult for providers to participate.	The proposed payments would replace 10 current Evaluation & Management (E/M) payment codes (five of which could potentially be billed multiple times each month) as well as separate codes for spirometry and other tests, which means the payments in PCACP are actually far simpler than the current fee schedule. The CMS Comprehensive Primary Care Plus (CPC+) APM is more complex than PCACP, with a five-level Care Management Fee, a two-part Performance-Based Incentive Payment, and a Comprehensive Primary Care Payment <i>in addition</i> to the 10 current E/M payments and separate fees for testing, and it is being successfully used by small primary care practices. The criteria used to assign patients to different payment levels are based on the clinical information that the providers would already be collecting in order to manage patients’ care effectively, so there would be less coding burden under PCACP than in the current fee-for-service payment system and other APMs. Many of the

	<b>Weakness as Stated by PRT</b>	<b>Comments</b>
		physicians who developed PCACP have small practices and have stated that PCACP would not be difficult for them to implement and manage.
17	There is insufficient justification for the additional payment amounts beyond what the fee schedule already covers.	There is widespread agreement that the current payment amounts in the Medicare fee schedule are inadequate to support high-quality ambulatory care for patients, particularly those with chronic disease, and CMS has announced that it will significantly increase the payment amounts for office visits in 2021. Consequently, there is clear justification for monthly payment amounts in PCACP that are higher than the amounts Medicare currently pays.
18	The proposal does not demonstrate how additional payments will lead to reduced ED visits.	The additional payments in PCACP are designed to enable physician practices to more accurately diagnose patients, ensure that medications are effective, and provide better education and self-management to patients in order to reduce the frequency and severity of asthma exacerbations so that fewer emergency department visits are needed.
19	The payment model lacked specificity regarding important elements such as patient liability/copayment for the APM payments.	The law specifies a standard amount of patient cost-sharing for all services paid for under Medicare. CMS would need to waive this requirement in order for PCACP to have a different cost-sharing amount.
20	Clinically, it is unclear when patients would enter into the model. Providers may be likely to fully work up and diagnose a patient before offering the model to patients. Alternatively, the first category acknowledges that some patients who enter the model may be determined not to have asthma.	The proposal clearly specifies that a patient could enter the model in several different ways; for example, they could either have new or previously unaddressed asthma-like symptoms or they could have been receiving treatment that was failing to address their symptoms. The PRT report does not explain why it believes a provider would be “likely to fully work up and diagnose a patient before offering the model to patients” when the model is specifically designed to better support the process of diagnosis. Moreover, the model appropriately includes patients who have asthma-like symptoms but are determined not to have asthma, since this ensures these patients are not incorrectly given asthma medications, but the payment for these patients would be lower since they would not need to have an asthma action plan developed.
21	The proposed payment models are based on a monthly actuarial risk model, and the participating provider has discretion to determine which patients are included in the risk model. The provider could enroll eligible	PCACP is not a “monthly actuarial risk model.” It provides monthly payments that are stratified by patient need, and the payments are adjusted based on performance on specific measures of quality and spending. Providers have discretion about whether

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	patients after the provider knew whether it would be financially beneficial to the provider for them to participate.	to treat an individual patient in every current Medicare APM as well as in the fee-for-service system; for example, a Medicare beneficiary will not be included in an ACO unless one of the physicians in the ACO bills for a visit with that patient. The PRT report does not explain how a provider “could enroll eligible patients after the provider knew whether it would be financially beneficial to the provider for them to participate,” nor does it explain what changes could avoid this alleged problem. PCACP is designed to provide adequate payments to support care for patients with achievable performance standards, and to provide higher payments for patients with higher needs, in order to minimize any benefit or penalty from choosing particular types of patients. The ability to successfully improve outcomes for a patient would only be known after efforts were made to improve outcomes; under PCACP, a patient can only be enrolled by a provider if the patient has not previously been treated by the provider, so once the provider began treating the patient outside of PCACP, they could no longer enroll the patient in PCACP regardless of whether they determined it would be financially beneficial to do so.
22	The model’s month-to-month approach is confusing.	It appears that the PRT report may be referring to the fact that the category of payment for an individual patient can be changed from one month to the next if the patient’s needs change, rather than being fixed for an entire year. The report does not explain what is confusing about this. For example, if a patient develops a new comorbidity that qualifies for a higher payment category, the practice would document this change and bill the code for the new category during the next month.
23	The proposed model specifies a number of exclusions for patients (e.g., COPD) which limits the financial risk providers would bear.	The goal of an APM should not be to maximize the amount of financial risk that providers bear, it should be to maximize the ability of the participating providers to deliver high-quality care for patients and reduce avoidable spending. PCACP includes a number of exclusions to enable asthma specialists to focus on patients whose needs are primarily driven by their asthma, not by other problems, and to enable the physicians to be held accountable for how effectively they manage asthma care. A separate model could be developed for patients with COPD, and although that model might be similar in structure to PCACP, the quality

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		standards and performance measures would need to be different. Forcing PCACP to include a larger group of patients would certainly increase financial risk for the providers, but it would not mean that the patients would receive better care or that Medicare savings would be greater, and it would likely either deter participation by physicians or force some of the participants out of business.
24	Care quality and outcome measure calculations exclude patients who fail to change behaviors (e.g., failure to stop smoking or obtain prescribed medications). These exclusions would avoid financial penalties for providers who are not able to change these behaviors, but they also cover some important aspects of asthma management. The value of an APM could be lessened considerably if the most vulnerable patients are not included in the model or if the payment model incentives do not encourage behavioral change.	Including patients who fail to stop smoking or obtain prescribed medications in the quality and outcome measures is more likely to force physician practices to avoid treating the patients altogether than to improve the care for the patients. PCACP gives physician practices additional resources and flexibility so that they have greater ability to encourage patient adherence to treatment goals, but there are some barriers that are impossible for a physician practice to address (e.g., if the patient cannot afford the necessary medications, or if the patient simply refuses to take actions that are feasible for them to take). It is likely that these patients will have better outcomes than they would otherwise if they receive the improved care supported by PCACP, but it is inappropriate to expect that a practice will be able to achieve the same outcomes for these patients as those who are able and willing to adhere to their treatment plans. PCACP strikes an appropriate balance between ensuring access for patient and creating accountability for physicians.
25	The performance metrics in the model do not encompass some important components. While the proposal states “the model includes shared risk by physicians and hold them accountable for meeting quality and cost measures,” details of risk sharing are not provided. For example, provider payments do not appear to be directly affected if patients have a high rate of ED visits or hospital stays.	The proposal clearly states that a participating Asthma Care Team would not be paid at all if it fails to meet the minimum quality standards specified in the proposal, and it also clearly states that the payments to the practice could be reduced if its patient have a high rate of ED visits. As stated in the proposal, the payments could be reduced by up to 5% initially and up to 9% eventually, with the specific amount depending on the practice’s performance on the other quality and spending measures included in the APM. This is similar to every other CMS APM, which bases rewards and penalties on a composite measure of quality and spending. However, unlike many other CMS APMs, a practice in PCACP can receive a significant reduction in payment solely based on poor quality care, regardless of whether it has reduced spending or not, so accountability in

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		PCACP is actually greater.
26	The proposed care model could potentially be implemented more simply through a billing code, so a bundled payment may not be necessary.	The PRT report does not explain what type of billing code it means or how it would work. Unlike other CMS “bundled” payment models, PCACP creates new billing codes for bundles of services that replace existing billing codes for individual services, which makes it far simpler to administer for both the practices and CMS. However, it would be impossible to implement PCACP by creating one single billing code, because PCACP is not providing the same set of services to every patient every month.
27	Recent improvements in the MPFS are intended to support the types of care the PCACP proposal adopts. The proposal dismisses the potential value of new Medicare policies for interprofessional consultations implemented in January 2019 without providing evidence of the failure of these policies to improve care.	It seems clear that the changes in the MPFS, while desirable, are not sufficient to support truly high-value care to patients or CMS would not be creating other APMs that replace MPFS payment with new types of monthly payments.
28	Although the model proposes an Asthma Care Team, the group that receives and distributes portions of the payment to other members of the care team is not identified. The monthly payment could work well in some situations such as an integrated health care system, but mechanisms for distributing the monthly payment across settings are not specified.	The proposal clearly states that the Asthma Care Team would receive the payment. The exact nature of the entity would need to differ from community to community, which is why all current Medicare APMs provide flexibility as to how the Alternative Payment Entity is structured. In many cases, the Asthma Care Team would be a single physician practice, and there would be no need to distribute any payments to other organizations.
29	The payment calculations provided by the submitter include an upward adjustment of 30% because of a higher assumed hourly practice cost for delivering the care. Justification for the higher hourly cost is not provided.	As noted earlier, there is widespread agreement that the current payment amounts in the Medicare fee schedule are inadequate to support high-quality ambulatory care for patients, particularly those with chronic disease, and CMS has announced that it will significantly increase the payment amounts for office visits in 2021. The hourly cost that was included in the payment calculations is consistent with many published estimates of what it costs to operate a high-performing physician practice.
30	The complexity of the payment methodology could make it difficult for providers to participate.	As noted earlier, the payment methodology is simpler than both the current fee-for-service system and other APMs, and the physicians who developed the methodology do not believe it would be difficult for them to participate.
31	The month-to-month approach to payments could compound unpredictability for	Monthly payments are far more predictable for a physician practice than fee-for-service payments.

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	providers, especially without a clear method for allocating the monthly payment across members of the Asthma Care Team, and limit provider accountability.	Moreover, allowing the amount of payments to be changed from month to month ensures that a small practice will not be harmed if it enrolls patients with higher needs or if the needs of its patients increase. This is preferable to current Medicare APMs which only adjust annually for changes in patient health problems.
32	Key aspects of the payment methodology, including a process for determination of the payment amount, are not specified by the submitter.	It is not clear what aspects of the payment methodology have not been specified that are relevant to PTAC deciding whether the proposed APM meets the Secretary's criteria and whether to recommend that it be tested. Any payment methodology will require development of additional details, and it is unreasonable to expect that any applicant to PTAC will have completely specified all details before knowing if the APM is likely to be tested. In fact, CMS has failed to specify many of the key details in its APMs before soliciting applications.
<b>Value Over Volume</b>		
33	Provisions to ensure value over volume are not identified. For example, for the well-controlled group, the proposed payment model has the potential to pay providers generously for patients who would have done well anyway.	The proposed APM replaces fees for individual services with bundled monthly payments tied to outcomes, which clearly moves from a volume-based payment to a value-based payment system. Any payment system, not matter how it is designed, has "the potential to pay providers generously for patients who would have done well anyway," because there is no way to know in advance which patients would have "done well anyway." PCACP does a better job of targeting payments on patients who are unlikely to do well than any current CMS APM.
34	The monthly framework of the PCACP proposal and the ability to enroll patients who will be financially beneficial for the provider reduces accountability for providers.	The monthly bundled payments in PCACP create accountability for delivering services within a predetermined amount, and the adjustments in the payments create accountability for outcomes.
35	The framework of the proposal emphasizes value over volume, but the mechanics of the proposal seem insufficient to drive more value than what is currently available. The proposed model does not clearly address major drivers of ED visits among patients with asthma, such as social determinants of health, in the approach to improving outcomes for patients.	PCACP is specifically designed to ensure that patients with asthma receive the medications, education, and support that evidence has shown reduce exacerbations, ED visits, and hospital admissions.
36	The complex mechanics of the proposal may	As noted earlier, the proposed payment model is

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	reduce its ability to generate more value than is possible under current payments.	actually simpler in structure than either current fee for service payments or other APMs, and unlike other APMs, it does not impose unnecessary or burdensome administrative requirements on participants that distract them from delivering high-value care.
<b>Flexibility</b>		
37	It is unclear how the patient’s primary care provider and asthma care specialists would work together flexibly for the benefit of the patient.	PCACP is designed to provide flexibility for primary care providers and asthma care specialists to design the most effective way of delivering care to patients. The approach used would differ in different communities.
38	It is not clear which member of the Asthma Care Team receives the monthly payment, and the process for distributing the payment is not specified.	The Team would determine who receives the payment and how it would be distributed. The decisions would differ for different providers in different communities.
<b>Ability to Be Evaluated</b>		
39	The complexity of the proposed model could make it difficult to evaluate.	All APMs are difficult to evaluate, and the PRT report does not explain what aspects of the model it believes would be unusually difficult to evaluate.
40	It will be hard to determine whether the proposed model saved money or not. Data for a set of comparison patients are not identified.	It is hard to determine whether any APM saves money, as the evaluators of current CMS APMs can attest. PTAC has not required that applicants specify how comparison patients would be identified nor should it require that.
<b>Integration and Care Coordination</b>		
41	The proposed model does not specify how care would be coordinated between primary care physicians and specialists managing the patient’s asthma, such as when and whether handoffs would occur between providers.	The proposal clearly explains that patients with well-controlled asthma would be managed by primary care providers with support from asthma specialists, and that patients with difficult-to-control asthma would be managed by Asthma Care Teams consisting of either specialists or primary care providers with specialist support. It is impossible and inappropriate to be more specific than this, since the exact process for coordination will differ in different communities and for different patients.
42	The proposed model focuses on physician co-management and does not elaborate true care management outside of the office, other than occasional contact by a respiratory therapist. Some of these practices, such as phone calls to coordinate with other providers, are expected to occur under current standards of	The PRT report does not define what it means by “true care management” or what aspects of care management need to be defined or required. PCACP is intended to tie payments to evidence-based standard and outcomes, not to micromanage the way care is delivered. Moreover, PCACP is not merely designed to provide care management

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	care.	services to patients, but to ensure accurate diagnosis, select the most effective medications, and rapidly adjust treatment when patients experience problems.
43	The proposal does not address how care coordination might evolve over the course of the model, such as when a patient moves from a “difficult to control” to a “well-controlled” asthma patient.	The proposal clearly states that patients who have well-controlled asthma should be managed by a primary care practice with support from an asthma specialist and that a patient with difficult-to-control asthma should be managed by an Asthma Care Team that is either led by an asthma specialist or a primary care provider with support from an asthma care specialist. Most patients who have difficult-to-control asthma would not be moving back and forth between the categories; their asthma would only be classified as “difficult to control” if an effort to use standard asthma medications failed and they needed to use special medications or receive other types of support on an ongoing basis.
44	The submitter states that the distribution of payments between specialists and primary care providers would vary based on the division of time and work between the two providers in each circumstance. This negotiation between providers in each circumstance would be burdensome for providers in practice and may hinder coordination.	“Each circumstance” refers to the specific community and providers, not to each individual patient. In most cases, each type of PCACP payment would go to one physician practice with no need to divide or distribute the monies. If multiple practices are participating as a Team and sharing payments, then the division of payments would presumably be worked out initially and continue until there is a reason to change it.
<b>Patient Choice</b>		
45	The patients would be required to commit to receiving all asthma services from the participating provider, at least within the month within the program, which could limit patient choice.	Since the patient would have the choice of whether to seek care from the provider in the first place, and the patient could change their provider at the end of any month, this is not a problematic limit on patient choice, but it assures the Asthma Care Team that they have full accountability for the patient’s care during each month the patient continues to receive care from the Team.
<b>Health Information Technology</b>		
46	The proposed model does not fully address how health information technology could be shared and used to inform care delivery. The only technology specifically mentioned in the proposed model was certified electronic medical records.	The serious challenges with information sharing in current HIT systems are well known, and it is not clear how they could be solved by the participants in this APM. HHS has made it clear that it will reject any proposals that utilize “proprietary technologies” so PTAC cannot expect applicants to propose use of technologies other than CEHRT.

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47	The proposed model lacks sufficient scope for implementation as a stand-alone APM.	PCACP could improve care for as many as a million Medicare beneficiaries every year, which clearly surpasses any reasonable minimum threshold for the scope of an APM.
48	The proposed model excludes a significant share of potential enrollees because of common comorbid conditions such as COPD.	The patients excluded are designed to enable asthma specialists to focus on patients whose needs are primarily driven by their asthma, not by other problems, and to enable the physicians to be held accountable for how effectively they manage asthma care. Approximately half of Medicare beneficiaries with asthma would still be eligible even with an exclusion for COPD.
49	The Medicare FFS beneficiaries who meet eligibility criteria are likely to be dispersed across physician practices, potentially making it difficult for providers to achieve sufficient volume and financial incentives to achieve practice transformation.	Medicare beneficiaries are “dispersed across provider practices” in every APM. However, unlike most Medicare APMs which further reduce the number of eligible patients through complex attribution rules and only provide small supplemental payments, practices in PCACP will receive significantly different payments for each patient who is eligible, making it much easier for the practice to change the way it delivers care
50	The quality and outcome measures exclude patients with certain behaviors such as failure to stop smoking, which are behaviors that physicians should be working with their patients to address.	Including patients who fail to stop smoking or obtain prescribed medications in the quality and outcome measures is more likely to force physician practices to avoid treating the patients altogether than to improve the care for the patients. PCACP gives physician practices additional resources and flexibility so that they have greater ability to encourage patient adherence to treatment goals, but there are some barriers that are impossible for a physician practice to address (e.g., if the patient cannot afford the necessary medications, or if the patient simply refuses to take actions that are feasible for them to take). It is likely that these patients will have better outcomes than they would otherwise if they receive the improved care supported by PCACP, but it is inappropriate to expect that a practice will be able to achieve the same outcomes for these patients as those who are able and willing to adhere to their treatment plans. PCACP strikes an appropriate balance between access for patients and accountability for physicians.
51	With its three separate phases and multiple payment levels within each phase, the	The proposed model is simpler than the current fee-for-service system because it replaces 10 current

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	proposed model is overly complex. The PRT believes this complexity could make this model difficult for providers to implement and manage.	Evaluation & Management (E/M) payment codes (five of which could potentially be billed multiple times each month) as well as separate codes for spirometry and other tests. It is also simpler than the CMS Comprehensive Primary Care Plus (CPC+) APM, which includes a five-level Care Management Fee, a two-part Performance-Based Incentive Payment, and a Comprehensive Primary Care Payment <i>in addition</i> to the 10 current E/M payments and separate fees for testing. The criteria used to assign patients to different payment levels are based on the clinical information that the providers would already be collecting in order to manage patients' care effectively, so there would be less coding burden under PCACP than in the current fee-for-service payment system and other APMs.
52	It would be difficult to assess whether the proposed model achieved desired cost and quality outcomes.	It would be no more difficult to assess the impacts of this model on cost and quality outcomes than in any other APM.
53	The PCACP proposes a complicated approach when it is not clear how the current Medicare fee schedule falls short in supporting the types of care-related activities described in the proposal.	There is widespread agreement that the current Medicare fee schedule fails to adequately support high-quality ambulatory care for patients with chronic disease. Payments are still primarily tied to face-to-face visits with physicians, so they do not provide the flexibility for physician practices to deliver care in evidence-based ways, and Medicare payments support short visits that are not adequate to allow accurate diagnosis or allow development of a customized plan that could successfully address multiple causes of a patient's problem.
54	The proposed model includes the potential for gaming by providers to maximize bundled payments rather than facing a simpler prospective payment. Participating providers have discretion over which beneficiaries are enrolled and which PCACP category and associated monthly payment amount is most appropriate in a given month. The complexity of the model would make it particularly difficult to monitor implementation as a check on these incentives for gaming.	The PRT report does not define what it means by a "simpler prospective payment" or how such a payment would be less subject to some form of gaming. The "simple" payments in other Medicare APMs can force providers to avoid treating high-need patients or to focus on coding additional diagnoses in order to maximize payments. PCACP is designed to support the kind of care that physicians want to deliver to patients and to stratify payments based on the patient characteristics that require different amounts of time, so there will be less likelihood of "gaming" than in APMs that focus primarily on shifting financial risk to physician practices.
55	In practice, both primary care physicians and asthma specialists manage patients with	PCACP is the first APM that specifically defines separate roles for primary care physicians and

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	asthma. The proposed model does not describe how these providers would work together or share in PCACP payments, nor how these relationships might change over the course of a patient's disease.	specialists as well as supporting the creation of Asthma Care Teams that would include both PCPs and specialists.
56	The proposed model does not address coordination with other providers who may be involved in treating asthma exacerbations, such as ED physicians or hospital-based providers.	A primary goal of PCACP is to avoid ED visits and hospitalizations for patients.
57	The expectation that specialists and primary care providers would negotiate the distribution of PCACP payments in each circumstance is unrealistic, and the time involved could hinder true coordination of care.	In most cases, each type of PCACP payment would go to one physician practice with no need to divide or distribute the monies. If multiple practices are participating as a Team and sharing payments, then the division of payments would be worked out initially and continue until there is a reason to change it, so there would be no ongoing commitment of time nor any barrier to care coordination.
58	The proposed model does not address the core factors that are most likely to reduce excess utilization among Medicare beneficiaries with asthma, such as reducing environmental exposures to asthma triggers, smoking cessation, evaluation of the need for social supports, and ongoing patient education to improve health literacy. As a result, the proposed model is unlikely to affect spending and may not truly improve care and outcomes for Medicare beneficiaries with asthma.	The Environmental Scan prepared by PTAC's staff states that "self-management of asthma through education and treatment compliance are key to controlling severe asthma" and that "well-controlled asthma is associated with reduced use of health care resources and impairment." The PCACP model explicitly requires participating physicians to develop an Asthma Action Plan for each patient that follows evidence-based guidelines and that is explicitly designed to both prevent asthma exacerbations and quickly intervene when they occur, and the sample Asthma Action Plan included in the proposal explicitly discusses ways patients can control environmental factors and stop smoking. The PRT does not explain why it believes this type of evidence-based care would be ineffective or what it believes physicians should do differently.
59	There may be alternative opportunities to modify existing APMs to incorporate relevant asthma-specific measures to focus more on the needs of this subpopulation. For example, in a well-functioning ACO, asthma specialists could be held accountable for the cost and quality of the care they deliver.	Adding asthma measures to other APMs is unlikely to achieve the same improvements in quality or reductions in costs as an APM like PCACP that is specifically designed to support evidence-based care for patients with asthma. Patients will not receive better care simply because an ACO tries to hold asthma specialists accountable for cost and quality if the ACO does not provide the payments the asthma specialist needs to deliver care in better ways. Moreover, only 30% of Medicare

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		beneficiaries are enrolled in ACOs and the majority of counties in the country do not have enough Medicare beneficiaries to form an ACO, so failure to create a model like PCACP and merely adding more process measures to ACOs will prevent asthma patients living in rural and small communities from receiving better care.