American College of Allergy, Asthma, and Immunology (ACAAI)
PTAC PROPOSAL: Patient-Centered Asthma Care Payment (PCACP) Model

ACAAI Responses to PTAC Preliminary Review Team (PRT) Questions for Submitters dated 8/9/2019

1. The PRT would appreciate a clearer understanding of the size of the proposed model's target population within fee for service Medicare beneficiaries.

    a) Page 6 indicates that 3.5 million individuals age 65 and older have asthma and that 7.4 percent of adults ages 65 and older have asthma. On page 7, you note that there were approximately 238,920 Medicare patients newly diagnosed with asthma who did not have COPD as a comorbidity. What is the percent or number of Medicare FFS beneficiaries that you expect would qualify for your proposed payment model in each of the three categories? Please do not include Medicare Advantage enrollees; if possible, please also exclude Medicare beneficiaries enrolled in the Medicare Shared Savings Program (MSSP) or other risk sharing arrangements (though we realize such an exclusion may not be possible for many data sources).

    We don't have the data required to estimate the percent or number of Medicare beneficiaries expected to qualify for PCACP in each of the three categories.

    b) Please describe how any exclusions due to eligibility criteria (e.g., COPD as a co-morbidity) or likely diagnostic assessment (e.g., new onset cases of wheezing in the elderly might initially be identified as asthma but ultimately are other diseases such as emphysema) might affect the potential scope of the model.

    The two principal co-morbidities that would exclude patients from participating in the model are COPD and lung cancer. According to the CCW VRDC 100% Chronic Conditions File[1], approximately 61.2% of Medicare fee-for-service beneficiaries with asthma also have COPD as a chronic condition. The same source indicates 3.5% of Medicare fee-for-service beneficiaries with asthma also have lung cancer as a chronic condition. The other exclusions (allergic bronchopulmonary aspergillosis, other restrictive lung diseases, structural lung diseases and severe personality disorders) are minor and we do not expect them to materially impact participation in the model.

    In answer to the second part of your question, patients who are initially diagnosed with asthma or who present with asthma-like symptoms, but are ultimately identified to have other diseases, such as emphysema, would be initially eligible to participate in category 1 of the model. Category 1 is intended to include all patients experiencing asthma-like symptoms who have not received effective treatment for those symptoms. Once the patient is determined not to

[1] https://aspe.hhs.gov/system/files/pdf/255906/PMAAdditionalInfor.pdf; Table 1B: Presence of Chronic Conditions, Medicare Fee-for-Service Beneficiaries with COPD, Asthma and COPD-Asthma, 2015

have asthma, he or she would no longer be a part of PCACP. The patient may continue under the care of the same physician or be referred to a different physician for treatment, but either way, payments for future services would not be part of PCACP.

2. Much of the proposal bases the estimates of effectiveness and cost reductions on evidence pertaining to interventions in younger populations. For example, the studies mentioned on page 8 referenced from "Asthma Management and the Allergist: Better Outcomes at Lower Cost" are not specific to Medicare beneficiaries. Is there evidence pertaining to the Medicare population (e.g., primarily age 65 or older) behind the estimates of program effectiveness and cost reductions?

   It is our professional judgement that the outcomes and improvements referenced in the "Asthma Management and the Allergist: Better Outcomes at Lower Cost" are replicable in the Medicare population. The techniques and care management principles are applicable to all patient populations regardless of age. The problem has been that under traditional fee-for-service, allergists could not get paid for the extra work necessary to properly manage a Medicare patient's asthma. If you pay someone to do A but not B, they will do A and not B. We think that rather than paying for ER visits and hospitalizations due to poorly managed asthma patients, Medicare can pay smarter for Asthma care and ultimately, save money.

3. The PRT is interested in better understanding details of the payment model (e.g., specific payments amounts, payments between primary care physicians and specialists). Can you provide more details about the payment model, such as how bundled payments would be determined?

   ACAAI members developed the following payment estimates for categories 1, 2 and 3 of the model. These estimates are based on the professional judgment of ACAAI members as to the amount of time, services and resources that will be needed to manage the patient's care properly, and they will need to be revised once there is more direct experience in delivering the new and different services that will be supported by the APM. See Appendix 1 for category payment details.

	$PBPM
Category 1: Diagnosis and initial treatment for patients with poorly controlled asthma	$ 299
Bundled payment for allergy testing in category 1	553
Category 2: Continued care for patients with difficult-to-control asthma	247
Category 3: Continued care for patients with well-controlled asthma	37

   We've analyzed reimbursement figures for asthma-related emergency department (ED) visits and hospital admissions (IP) for Medicare FFS Beneficiaries Newly Diagnosed with Asthma who do not have a co-morbidity of COPD. In 2014 on average, PBPM spending on asthma-related ED visits and hospitalizations was $415 in the first year

after diagnosis. This equates to annual asthma-related ED and hospitalization costs of $4,980 per new asthma beneficiary.

We conservatively estimate the average new asthma patient will be in category 1 (diagnosis and initial treatment) of the model for 2.5 months ($299 PBPM x 2.5 months) and then in category 3 (continued care of patients with well-controlled asthma) for the remaining 9.5 months of the year ($37 PBPM x 9.5), and 50% of these patients will require skin testing ($553*.5). This adds up to a total average first year model cost of $1,371 per patient.

We would only have to reduce ED/IP spending by 27.5% to pay for the total year 1 payments under the model. And that is very conservatively estimating all these category 1 patients would be new, incremental asthma patients that would not otherwise incur any costs at all.

Since the ED and hospitalization cost data we used for this analysis was from 2014, and the APM payment amounts use 2019 data, we also did this calculation after adjusting ED/IP spending to reflect 2019 dollars. We adjusted the ED/IP cost data using two separate methods: 1) using the annual CPI all-items indices and 2) using the annual CPI indices for hospital services. After these adjustments, we found that the % savings in ED and hospitalization costs required to cover model costs dropped to 25.3% and 22.8%, respectively.

In terms of the distribution of the payments between the Allergist and the PCP, we don't believe it would be appropriate to determine a fixed payment split. The division of payments would vary based on the division of time and work between the two providers in each circumstance. In some care team arrangements, the PCP may take on a larger role and should be compensated accordingly, and vice versa.

4. The model includes three broad categories of asthma patients for payment purposes, plus additional subcategory levels within those broader categories (as described on page 29 in Appendix D). How would providers, particularly those in smaller practices, manage the complexity associated with these various payment levels and how they track and monitor patients whose condition improves/worsens that may require adjusting categorization and or payments?

   Many providers and practices already record this data about patient diagnosis/condition through ICD-10 codes (J45.2X, J45.3X, J45.4X and J45.5X to indicate mild, moderate and severe asthma). EHRs help practices of all sizes track and monitor patients and adjust treatment schedules as appropriate. We do not believe small practices will be at a disadvantage in this regard.

5. In the proposed model, the payment bundles for patients in Categories 1 and 2 are delivered monthly (page 11 and page 17). Why is a monthly payment that can change each month preferred for this model, as opposed to committing to a longer period?

   The model is designed to make sure payments match the actual services and costs incurred for different patients. In addition, a monthly payment saves Medicare money, as a 3-month period for category 1 will not be required for all patients. For example, a patient who is determined not to have asthma after one month would only get charged for one month under the model, rather than for 3 months. Additionally, the level of symptoms might change over the three months (a patient with moderate to severe symptoms in month 1 (level 4) might be determined not to have asthma in month 3 (level 2). That is also a cost-saving measure of the model. Finally, a reminder that CMS pays on a monthly basis in the Comprehensive Primary Care Plus program.

6. In category 1, providers have discretion to enroll patients with asthma symptoms and receive the Diagnosis and Initial Treatment Payment to support asthma-related clinical services for up to three months during the initial diagnosis phase (page 11). How would the model counteract potential incentives for providers to selectively enroll patients in the model who are likely to be financially beneficial?

   Payment for category 1 is stratified into five subcategories to reflect differences in the time and resources needed by physicians to determine a diagnosis and manage initial treatment plus the differences in risk of complications for each patient. If payments are set correctly for each subcategory, and properly reflect the level of care and services required for patients in that category, physicians will be incentivized to enroll all eligible patients in the model.

   The Asthma Care Team would be required to meet minimum quality standards for all patients in category 1. In addition, the Asthma Care Team's performance would be assessed on two measures of utilization/spending and four quality and outcome measures for all patients in category 1. Payments would be adjusted based on these assessments, so poor performing physicians would be penalized, and high performing physicians would be rewarded.

   One of the utilization/spending measures is the average number of months during which the Diagnosis and Initial Treatment Payments were billed before a diagnosis was assigned. Use of this measure would avoid any concerns that the Asthma Care Team was delaying determining that the patient did not have asthma in order to increase the number of months in which the practice could bill for the Diagnosis and Initial Treatment payment.

   Finally, CMS can use post payment review to determine whether the patient's medical record justifies the classification assigned to the patient by the physician.

7. Some aspects of care and care coordination seem consistent with the type of care incentivized by other ongoing CMMI models (e.g., CPC+, MSSP, etc.). Why do you believe that a separate APM is needed for Medicare FFS asthma patients rather than achieving better care for them through existing CMMI models (e.g., CPC+, MSSP, etc.)?

   The Asthma APM model is unique in that it addresses a specific chronic condition and provides for shared patient care and risk between PCPs and allergists. It is the only APM we are aware of that that focuses on care integration provided by allergists and pulmonologists and supporting full co-management of patients by PCPs. Other CMMI models aren't applicable to many allergists in small practices.

   In PCACP the payment amounts would be specifically designed to meet the needs of asthma patients and the performance measures would be focused specifically on the types of services and outcomes relevant to asthma patients. In contrast to "shared savings" payment models, PCACP would not tie the physician's payment to how much money they can save, but rather, PCACP is designed to provide adequate flexible resources to the physician in order to enable them to deliver care in the most efficient and effective way possible to patients with asthma.

   Finally, there is no change in payment for specialists under CPC+, even if they are managing most of the patient's care. Similarly, there is no change in payment for anybody under MSSP.

Appendix 1: ACAAI PCACP APM Payment Amount Estimates

Estimates based on the professional judgement of ACAAI members as to the time and resources needed to manage patients care properly

Category 1: Diagnosis and initial treatment for patients with poorly controlled asthma

Description	CPT	Physician Time*	2019 National Medicare reimbursement
Initial NP OV	99204	50-55 minutes	$ 167
FeNO	95012		$ 21
Pre/post bronchodilator PFTs	94060		$ 60
Inhaler education	94664		$ 17
Second OV	99214	35 minutes	$ 110
PFT	94010		$ 36
Third OV	99214	35 minutes	$ 110
PFT	94010		$ 36
Total cost before care manager			$ 557
% increase for Medicare underpayment **			30%
Total cost after increase for Medicare underpayment			$ 723
Care manager PBPM x 3 months [1]			$ 173
Total cost over 3 months w/ care manager			$ 896
Total category 1 cost PBPM			**$ 299**
Note: there is a separate bundled payment for allergy testing.			
Skin Testing x 60 tests	95004		$ 259
ID Tests x 20 tests	95024		$ 166
% increase for Medicare underpayment			30%
Total skin testing cost after increase for Medicare underpayment			**$ 553**
Category 1 cost assuming average of 2.5 monthly payments and 50% require skin testing			**$ 1,023**

* This is our best estimate of the time required to properly deliver this service.

** Assumes $260/hour for practice cost of delivering this care

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Category 2: Continued care for patients with difficult-to-control asthma

Description	CPT	Physician Time*	National Medicare reimbursement
Office Visit	99214	35 minutes	$ 110
PFT	94010		$ 36
Total cost before care manager			$ 146
% increase for Medicare underpayment **			30%
Total cost after increase for Medicare underpayment			$ 190
Care manager PPPM [1]			$ 58
Total category 2 cost PBPM			**$ 247**

* This is our best estimate of the time required to properly deliver this service.

** Assumes $260/hour for practice cost of delivering this care

Category 3: continued care for patients with well-controlled asthma

Description	National Medicare reimbursement
Care manager PPPM - assume MA [1]	$ 37
Total cost Category 3 PBPM	**$ 37**

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Asthma-related ED visits and hospitalizations

The Medicare 5% limited data set shows PBPM spending on asthma-related ED visits and hospitalizations of $415 in the first year after diagnosis. This amounts to annual asthma-related ED and hospitalization costs of $4,980 per new asthma beneficiary and excludes patients with a co-morbidity of COPD.

Source: Medicare 5% Limited Data Set
https://aspe.hhs.gov/system/files/pdf/255906/PMAAdditionalInfor.pdf
Table 3A: Medicare Reimbursement for FFS Beneficiaries Newly Diagnosed with Asthma; 2014; page 29; Beneficiaries without COPD as a comorbidity

	$ PBPM 2014 dollars	$ Annual PB 2014 dollars
Outpatient Emergency Department related to Asthma	9.83	118
Inpatient hospitalizations related to Asthma	405.18	4,862
Total ED and hospitalization costs	$ 415.01	$ 4,980

If the average new asthma patient is in category 1 of the model for 2.5 months ($299 PBPM x 2.5 months) and then in category 3 for the remaining 9.5 months ($37 PBPM x 9.5), and 50% of these patients require skin testing ($553*.5), the total first year model cost would be $1,371.

We would only have to reduce ED/IP spending by 27.5% to pay for that. And that is conservatively estimating all of these category 1 patients would be new, incremental asthma patients that would not otherwise incur any costs at all.

Cost of asthma-related ED and hospitalization costs in first year after diagnosis (2014 dollars)	$ 4,980
Model cost for first year asthma patients (2019 dollars)	$ 1,371
% savings in ED and hospitalization costs required to cover model costs (assuming 2014 ED/hospital costs)	27.5%

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Asthma-related ED visits and hospitalizations - adjusted to 2019 dollars

We want to point out that while the model APM payment estimates are in 2019 dollars, the ED and hospitalization costs are in 2014 dollars. We therefore want to adjust the ED and hospitalization costs by CPI amounts to reflect 2019 dollars.

	Consumer Price Index by Year		
	Overall CPI	Hospital Services CPI	
2015	0.7%	4.2%	
2016	2.1%	4.4%	
2017	2.1%	5.1%	
2018	1.9%	3.7%	
2019 (thru Sept)	1.7%	1.7%	* assumes hospital services CPI for 2019 = overall CPI

source: https://www.bls.gov/cpi/

Cost of asthma-related ED and hospitalization costs in first year after diagnosis Adjusted to 2019 dollars using overall CPI index	$ 5,418
% savings in ED and hospitalization costs required to cover model costs (assuming 2019 ED/hospital costs adjusted using overall CPI index)	25.3%
Cost of asthma-related ED and hospitalization costs in first year after diagnosis Adjusted to 2019 dollars using hospital services CPI index	$ 6,005
% savings in ED and hospitalization costs required to cover model costs (assuming 2019 ED/hospital costs adjusted using hospital services CPI index)	22.8%

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[1] Care manager cost

Average monthly cost of an RN including benefits	$	7,866
https://nightingale.edu/blog/nurse-salary-by-state/		
patient caseload for additional staff		100
Cost of nurse per patient per month	$	79
Average monthly cost of a Medical Assistant including benefits	$	3,664
https://www.salary.com/research/salary/benchmark/medical-assistant-salary		
patient caseload for additional staff		100
Cost of MA per patient per month	$	37
Assume 50% RN time and 50% MA time		
Average cost per patient per month	$	58

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:

We appreciate your thorough review of our Patient-Centered Asthma Care Payment (PCACP) Proposal. This model is designed to ensure the local delivery of healthcare; improve the diagnosis of asthma in the Medicare population; and provide a mechanism by which specialists most able to care for difficult- to-control asthma patients are involved in their care. It envisions collaboration with the patient's primary care physician using a payment model that is transparent, simple and holds the asthma specialist and the primary care team accountable for patient outcomes for asthma care.

It is important to emphasize that asthma cannot be cured, but it can be managed and controlled. The PCACP proposal provided a link to the *Asthma Management and the Allergist: Better Outcomes at Lower Cost*[1] (also known as the Blue Book).

The PCACP is based on the findings and studies set forth in the Blue Book and seeks to link the payment methodology to the recommendations outlined in this document. When evidence-based clinical guidelines are followed, people, of all ages, with asthma should expect:

- Fewer or no emergency care visits.
- Fewer or no hospitalizations.
- Fewer or no days in the hospital.
- Fewer or no sick care office visits.
- Fewer or no days missed from work or school.
- Increased productivity in their work and personal lives.
- Greater satisfaction with their care.
- Improved quality of life.

There is ample evidence, however, that many patients are not meeting these goals of asthma control. Much of the expense of asthma is attributable to costs that can be avoided or reduced when the disease is controlled. An estimated 80% are the result of asthma that is poorly controlled. This is true whether the patient is 7 or 70. While it is preferable to begin treating and managing asthma patients as early as possible, there is nothing unique about managing the condition in elderly patients compared to a younger population.

[1] Asthma Management and the Allergist: Better Outcomes at Lower Cost, ACAAI 2020

We know that improperly managed asthma patients are far more likely to be hospitalized or visit the emergency room. This is not only supported by the data; it is common sense. Sadly, the current fee-for-service payment system does NOT pay physicians to manage the care of patients with a chronic disease such as asthma. Fee-for-service will pay to diagnose a disease and it will pay physicians and hospitals for care resulting from improperly managed patients, but it does adequately pay for care management, especially when asthma has not been controlled.

The PCACP model is based upon a bundled payment approach and is designed to truly pay physicians – specialists and primary care providers working together – to manage a patient's care. That simple proposition will lead to improved quality of life for patients and save money to the system due to reduced hospitalizations, reduced ER visits and lower prescription drug spending.

We believe this model is the embodiment of what Congress intended when it authorized the Physician Focused Payment Model initiative: stimulate innovative and creative ways to redesign how Medicare (and ultimately other payers) pay for care that not only improves patient care but saves money to the system.

The PCACP is a unique model that, to the best of our knowledge, is unlike anything that CMS has yet put into operation. Existing innovation models such as ACOs are geared toward large integrated practices or health systems and have a primary care focus. However, in enacting MACRA, which established MIPS and APMs, Congress specifically instructed CMS' Center for Medicare and Medicaid Innovation to test innovation models that are "focusing primarily on physicians' services . . .furnished by physicians who are not primary care practitioners" and to focus on "practices of 15 or fewer professionals." 42 U.S.C. 1315a(b)(2). Another factor Congress considered important was "whether the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers . . ." We believe the PCACP is the type of model Congress specifically wanted to see implemented when it enacted MACRA.

For that reason, we were surprised that, when critiquing our model, the reviewers suggest on more than one occasion that a properly managed ACO could perhaps achieve what we are proposing through this model. Aside from the fact that recent data shows little or no cost savings from ACOs, we do not believe that this should be the benchmark against which the physician- focused models are to be judged. In fact, if that is the case it is unlikely that any physician- focused proposal could ever be accepted.

We contend that many of the so-called deficiencies identified in the Preliminary Review Team Report (PRT) are actually strengths of this model. Are there things that can be improved that would increase the likelihood that our proposal can add to the quality of life for asthma patients and save even more money to the system? Yes. But those improvements will, we believe, evolve organically as we learn the lessons of this model and make adjustments and refinements. But we cannot achieve those improvements until we put this model into the field, test it, and make adjustments as appropriate.

Our responses to your specific concerns are addressed below.

Criterion 1. Scope (High Priority)

- **Lack of Studies in Older Populations.** There are no studies specific to the Medicare population.

Nevertheless, we believe it is reasonable and appropriate to extrapolate studies done in younger populations. There is no reason to believe that the interventions effective in improving care and reducing ED visits in the younger population would not apply to the Medicare population. In fact, we believe this model can work with all age groups and, if Medicare were to engage in a pilot program, we believe this would incentivize use of the model among commercial payers and state Medicaid programs.

- **Exclusion Criteria.** Regarding exclusion criteria and patients with COPD, the decision to separate asthma from COPD was a deliberate one. The two diseases vary substantially although there is some overlap. Asthma, or the component of asthma in the mixed disorder is, by its very definition, "reversible." COPD, on the other hand, is in large part either irreversible or far less reversible. Clearly adding COPD to the mix would increase the numbers but would make treatment and categorization much more difficult.

  We also point out that that, while many elderly patients have both asthma and COPD, it is also true that many are misdiagnosed with COPD when they actually have asthma. The model does not exclude patients believed to have COPD or believed to have asthma, until a definitive diagnosis has been made. These patients would be initially eligible to participate in Category 1 of the model. If the patient is determined not to have asthma, they would no longer be part of the PCACP.

  Therefore, of the 61% of Medicare asthma patients believed to have both conditions, we believe there is a sizeable number that do not have COPD and would therefore be eligible for PCACP.

- **Inadequacy of the Medicare FFS Payment System.** Regarding a description of how the Medicare FFS payment system is causing failures in diagnosis and management, we believe our proposal describes this. However, we are happy to provide more detail. First, we note that many PCPs do not have special training in asthma which can result in less than optimal management as well as inconclusive diagnoses. The PCACP would provide a pathway for PCPs to continue to care for their patients in a unique co-management arrangement without a total transfer of care to the specialist. We believe this would result in more PCPs seeing the value of specialty care for their patients than under the current FFS system.

  Further, as set forth on page 9 of the PCACP proposal, asthma specialists and PCPs are not being adequately compensated for the full range of services the patient needs such as extra time spent on patient education with an asthma educator, addressing barriers to medication adherence, evaluation and modification of the patients' environment to reduce exposure to asthma triggers (such as removal of carpets, use of air conditioners), and tobacco use as well as frequent outreach and monitoring necessary to ensure the asthma care plan is working. Nor does it adequately cover ongoing communications between asthma specialists and PCPs.

  Although Medicare has recently expanded coverage of non-face-to-face services including interprofessional consultations, these codes are not designed for situations in which providers are co-managing a patient's care. For example, the specialist cannot bill the service if they have seen the patient within the previous 14 days or plan to see the patient in the next 14 days. In addition, the newly covered virtual check-in and online digital E/M services require that the patient initiate the contact and thus would not compensate providers for the type of proactive outreach to patients by the asthma care team. The principal care management and chronic care management codes, while a step in the rig ht direction, have reimbursement that is far too low to cover the costs of the resource intensive interventions that meet the needs of individuals with uncontrolled asthma. For example, the principal care management

code pays $22 per month – not enough to support the services of RNs, social workers, and asthma educators or to address environmental and social determinants of health.

We do not dispute that the fee for service system may work for certain patients. However, the PCACP offers a more comprehensive approach that we believe will be more effective and will reduce costs to the Medicare program.

- **Availability of Existing APMs.** Regarding availability of other APMs such as ACOs, many asthma specialists work in solo or small practices and do not have access to ACOs and, in fact, are often excluded from these models which are targeted toward large integrated health care organizations.

  We disagree that the model includes innovations in care delivery already available in Medicare. Our proposal, as noted above, described several innovations that are not available or covered by Medicare. Allergists/immunologists, as part of their training, are experts in identifying environmental triggers and implementing avoidance measures to triggers. These are routinely incorporated by allergists/immunologists in the treatment plans for patients with asthma. Incorporation of telemedicine, remote monitoring of both indoor and outdoor triggers using validated home assessment tools can also be incorporated into the model.[2]

  Further, the expected collaborative relationship between the PCP and the specialist is innovative and is not something that typically exists. We anticipate increased, regular phone/email communications between asthma specialists and PCPs to facilitate effective handoffs and to accurately diagnosis and treat asthma.

Criterion 2. Quality and Cost (High Priority)

- **Utilization.** Regarding the value over volume proposition, it is impossible to know, with certainty, the percentage reduction in utilization that could be achieved. We concede that our estimate may not be accurate. However, even if it is not 50%, even a lesser percentage such as 25% would still be significant and could save the program millions of dollars.

- **Role of Social Determinants of Health.** Social determinants of health play an important role in asthma management and are usually included as part of a standard allergy evaluation. Smoking evaluation and cessation efforts are part of a standard allergy evaluation which we may have not thought necessary to explicitly mention. It is certainly the intent of the model to encourage individuals to stop smoking through every means available. If, after a reasonable period of time, smoking cessation is not achieved, then we believe the intensive resources available to patients through the PCACP are unlikely to be successful and they would be disenrolled. The PCACP would also focus on environmental triggers of asthma and would include, for example, home assessments, removal of carpeting or other triggers, use

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Kader R, Kennedy K, Portnoy JM. Curr Allergy Asthma Rep. 2018 Feb 22;18(3):17.
Indoor Environmental Interventions and their Effect on Asthma Outcomes.
Barnes CS, Horner WE, Kennedy K, Grimes C, Miller JD; Environmental Allergens Workgroup. Home Assessment and Remediation.J Allergy Clin Immunol Pract. 2016 May-Jun;4(3):423-431.

of air conditioning, air filters, and the like. Including social workers and asthma educators in the asthma care team is intended to promote patient access to other services in the community.

- **Studies Do Not Have Adequate Controls.** Regarding the fact that studies we cited do not control for the fact that expenditures might decline after enrollment in an asthma management program regardless of whether the program is effective, this may be true in the short run, but if an asthma management program is not effective, there will be other exacerbations, additional ER visits, and hospitalizations. Therefore, we disagree with this observation.

- **Volume of Patients.** Regarding concerns about insufficient volume to allow for practice transformation, the PCACP was intended to work not only for Medicare but for all other payers. If CMS were to implement a pilot project, we believe other payers would be encouraged to participate thus increasing the volume of participating participants.

- **Objective Measures.** Regarding the use of objective measures to complement subjective measures, we agree that objective measures are appropriate. We note that the proposal includes in its quality measures spirometry results and ER visits and hospitalizations. (See p. 14). We also note that subjective measures such as patient satisfaction and perception of improvement are approved outcomes measures in the MIPS program. For example, the outcomes measure, *Optimal Asthma Control* (No. 398) relies on patient reported outcome tools. We believe our model includes a reasonable mix of both objective and subjective measurements.

- **Performance Measures.** We agree that detail as to the performance measures for defining poorly controlled asthma compared to well-controlled is needed. Asthma patients are often well controlled for long periods of time but, for reasons such as seasonal allergies or other comorbid conditions such as sinusitis, have exacerbations. This does not automatically move them from well controlled to difficult to control. However, there are several objective criteria that could be used in differentiating the two such as the number of exacerbations per unit of time defined by a hospitalization or emergency room visit, or, for example, two bursts of steroids within a 6 month period. These definitions could be easily established once a pilot project is approved. We share the concern that there be objective ways of differentiating asthma control given its link to payment.

- **Coordination of Payment with PCPs**. Regarding how payment would be coordinated between PCPs and specialists, this type of contractual detail would need to be established when the patient is enrolled. We would expect that as more care is moved from the specialist to the PCP, the PCP would receive a larger share of the bundled payment. However, we do not believe it is appropriate, in the proposal, to establish limits or rules for sharing in the bundled payment. A pilot trial would be the best way to address these issues.

Criterion 3. Payment Methodology (High Priority)

In assessing this Criterion, we believe it is helpful to go back to the PTAC's proposal guidelines.

Goal

Addresses how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

Response

We appreciate the reviewer's acknowledgment that the PCACP model recognizes that patient service needs and costs may vary at different stages of disease diagnosis and treatment. We also appreciate the acknowledgment that physicians who are not already participating in an environment or practice in a managed care environment may find the proposed PCACP payment approach beneficial.

- **How does this payment methodology differ from current payment methodologies?**
  First and foremost, this methodology is based on the fact that neither the existing fee-for-service payment system nor the various models being evaluated by CMMI nor Medicare Advantage plans establish an incentive to properly diagnose patients with asthma.

  Critics of a fee-for-service (FFS) payment system argue that the principal deficiency of a FFS model is that it pays physicians to do more, regardless of whether the "more" is clinically efficacious. This is often characterized as "paying for volume, not value."

  Under fee-for-service, the physician gets paid whether he or she properly diagnoses the patient with asthma or not. The physician gets paid for additional visits associated with the treatment of the patient's asthma and because there is no cure for asthma, the on-going palliative treatment is deemed medically necessary due to the underlying diagnosis of asthma, whether correct or not.

  The PCACP model is a vast improvement over either the FFS model or the managed care model because it relies on accurately diagnosing the patient with asthma. Misdiagnosis of Asthma is a significant problem that results in higher spending by Medicare and reduced quality of life for Medicare beneficiaries.

- **Improper Diagnosis of Asthma**
  In a 2017 study published in the Journal of the American Medical Association, roughly 1/3 of study participants were found to have been improperly diagnosed with Asthma by their primary care physician.[3] Importantly, upon further evaluation, the patients who were improperly diagnosed with asthma were found to have "relatively benign conditions".

  So first and foremost, the PCACP payment methodology is designed to ensure that patients diagnosed with asthma truly have that condition.

- **Medicare Savings**
  Properly diagnosing Asthma patients has the potential to improve the quality of life for millions of Medicare patients who have been misdiagnosed with asthma while at the same time, saving the Medicare program tens of millions of dollars each year in unnecessary prescription drug costs relieving the symptoms of a condition the patient does not have.

[3] JAMA. 2017;317(3):269-279. doi:10.1001/jama.2016.19627

Neither the current fee-for-service system nor Medicare Advantage nor existing APMs (including MIPS) have any incentive to properly diagnose patients with asthma.
As part of their critique of the PCACP model, the reviewers posited that the model is

> "overly complex, with multiple tracks assigned by provider assessment within the three main categories."

While there are multiple layers to this model, we think it is far less complex than the MIPs program.

Asthma specialists understand that each patient with asthma is unique and requires a treatment plan tailored to individual needs. Asthma specialists work with the patient to develop self-help plans that include at-home instructions for assessing asthma control, how to deal with asthma symptoms and when to seek help for an asthma exacerbation.

The PCACP model is designed to have payments mirror the complexity of the patients for whom we care and follow the treatment guidance and standards of care for Asthma patients.

If patients were less complex medically and socially and it might be possible to have a less complex model. Unfortunately, the complexity of patients is only increasing and as a consequence, we believe the payment models must be designed to reflect that reality.

We believe physicians can relate to – and will embrace - linking payment to complexity on a case by case basis. We also believe physicians will accept an evaluation system that measures improvement on a patient-by-patient basis rather than using aggregated MIPs scores that are based on a statistical norm that may or may not be applicable to the specific patient population under the care of a specific physician.

Dr. Karen Joynt Maddox at the University of St. Louis has written eloquently on the shortcomings associated with measuring providers against a benchmark statistical mean rather than on improvement of an individual patient based on their individual benchmark.[4] Measuring individual levels of patient improvement is more meaningful than measuring against a normalized benchmark for all, and PCACP supports this.

The PCACP model attempts to more properly categorize patients by level of acuity and then link payments to the acuity level of the patient. The model is designed to make sure payments adequately match services and costs incurred for different patients. In addition, a monthly payment saves Medicare money, as a 3-month period for category 1 will not be required for all patients.

For example, a patient who is determined not to have asthma after one month would only get charged for one month under the model, rather than for 3 months. Additionally, the level of symptoms might change over the three months (a patient with moderate to severe symptoms in month 1 (level 4) might be determined not to have asthma in month 3 (level 2). That is also a cost-saving measure of the model.

Finally, a reminder that CMS pays on a monthly basis in the Comprehensive Primary Care Plus program.

[4] Financial Incentives and Vulnerable Populations — Will Alternative Payment Models Help or Hurt? 3/15/2018

- **How would PCACP reduce hospitalizations and ER utilization?**
  Once a patient has been accurately diagnosed as having Asthma, the payment model is designed to facilitate appropriate management of that patient. Through appropriate patient management – based upon the unique medical, social, environmental circumstances of that patient – developed by the asthma specialist/primary care physician team, we are confident that the effect will be reduced hospitalizations and reduced ER visits by these patients.

  Patient management would follow the guidance outlined in Asthma Management and the Allergist - Better Outcomes at Lower Cost which has documented the potential savings.

  We believe that in most instances, hospitalization of an asthma patient for an asthma-related reason or a visit to the ER for an Asthma related reason, represents a failure on the part of the clinicians to properly manage that patient's asthma. While environmental factors can impact the exacerbation of asthma, the key to improving the patient's quality of life and eliminating unnecessary costs is proper management of the patient.

  Too often, the delivery system relies predominantly on primary care providers to manage asthma care to the exclusion of allergist/immunologists or pulmonologists who understand the complexity of this disease and are better positioned to assist the primary care provider in the management of that patient's asthma.

  As reported in *Asthma Management and the Allergist: Better Outcomes at Lower Cost*

  > "A substantial and growing body of published clinical data and economic research shows significant differences in treatment outcomes and costs between asthma care that is managed by generalists, who have no specialty training in the complexities of asthma, and disease management that is under the direction of an allergist. An evidence-based review of the literature indicates that aggressive management of asthma by a specialist improves outcomes for patients, lowers overall treatment costs for payers and reduces the indirect costs to society."

- **Can the Specialist/Primary care team "game" the system?**
  The reviewers speculate that it would be possible for participating physicians to "pre" diagnose patients for entry into the PCACP model and effectively "cherry pick" patients so that only the easiest to manage patients would be enrolled.

  We would be naïve to suggest that there might not be a specialist/primary care team that would or could try to game the system to "cherry pick" enrollees. We believe the model is designed to minimize the extent to which this might occur.

  We would note that this same criticism applies to both the current fee-for-service model as well as the managed care models and for conditions other than asthma. No model that relies upon fallible human beings to manage the program would be completely insulated from abuse. We believe however, that the way the payment model is designed, the vast majority of physicians would consider the payment fair relative to the patient's acuity and not attempt to game the system. Post-payment audits could (and should) be in place to allow for chart reviews to ensure that such gaming does not occur.

- **Exclusion of certain patients with similar but different (COPD) diseases from this model.**

First, although many believe that COPD and asthma are similar diseases because they compromise the respiratory system, they are markedly different both in terms of the cause of the respective medical conditions as well as their treatment. We don't have a clear understanding of the root cause of asthma, but we do know that COPD, in the United States, is largely related to smoking.

Establishing an Alternative Payment Model for COPD patients is something the provider community should consider but because it is a different disease requiring different treatment options, we have excluded COPD patients from this model.

- **Performance metrics and shared (downside) risk**
  We disagree with the characterization by the reviewers that the model does not describe the downside risk, particularly as it relates to ED visits.

  This is a disease specific bundled payment model. In our submission, we outlined four bundled options for the Specialist/Primary Care team. Under each option, the Specialist/Primary Care team accepts risk for costs above the bundled payment.

  The amount of the bundled payment is reflective of the expected costs for a properly managed asthma patient. Claims would be submitted and if total claims for services provided during the bundled payment period were LESS than the pre-determined bundled amount, Medicare would pay the difference to the Specialist/Primary Care physician team in the form of a bonus.

  Once claims payments for asthma related care exceeded the bundled payment amount, Medicare would withhold any payments above the bundled amount thus putting the Specialist/Primary Care Physician team at risk for any costs above the bundled amount.

  Here are the various options we propose:

  Option A: Inclusion of Medication Costs in the Bundled Payments

  Under Option A, the bundled payment would be designed to cover the cost of medications used to treat asthma in addition to physician services. Outlier payments or adjustments to the payment amounts would be made when new drug options become available that have significantly higher efficacy but also significantly higher cost, or when drug manufacturers increase prices of drugs.

  Option B: Inclusion of Emergency Department Visit Costs in the Bundled Payment

  Under Option B, the bundled payment would be designed to cover the cost of urgent care and Emergency Department visits related to asthma. Outlier payments and risk corridors would be established to protect physician practices from financial risk associated with price increases on hospital services or resulting from patients needing unusually expensive care.

  Option C: Inclusion of All Asthma-Related Services in the Bundled Payment

  Physician practices with the size and capabilities to do so could accept a bundled payment that would be designed to cover the average costs of all asthma-related services needed by patients during a month of care. Outlier payments and risk corridors would be established to protect physician practices from

financial risk associated with price increases on drugs or hospital services or resulting from patients needing unusually expensive care.

Option D: Population-Based Payment for Asthma Care

A fourth option would be for a physician practice or group of physician practices to accept a condition-based payment to manage the asthma-related care of all individuals with diagnosed asthma in a broader pre-defined population, such as all the patients in an accountable care organization or a Medicare Advantage plan's membership. The physician practice(s) would receive one monthly payment for all of the individuals with asthma in that population, regardless of which category/phase of care they were in, but the amount of the payment would be adjusted based on the proportion of patients in different phases of care (i.e., the relative costs of different phases of care would be used to risk-adjust the overall payment amount) and the characteristics of the patients. This monthly payment could be designed to cover all costs of asthma-related care for the patients (as Option C would do for a particular phase of care) or for a portion of those costs (as the basic payment model and Options A and B would do for each phase of care).

Reviewers noted that there have been some recent changes in Medicare payment policy, particularly as it relates to management of patients with multiple chronic conditions and, more recently, single chronic conditions.

While the new CCM and PCM initiatives are intriguing, they are not comprehensive and are too new to know whether they will work. Furthermore, neither of these initiatives involves risk on the part of the physician designated as the principle provider. As for the interprofessional consultation codes, as discussed in Criterion 1, above, these codes have requirements that limit their usefulness in this context.

We have noticed, throughout the PRT, that there appears to be a bias in favor of large integrated delivery systems versus independent physicians collaborating to improve patient care. We respectfully suggest that integrated delivery systems such as HMOs and ACOs are not the only way to achieve integration and when Congress enacted MACRA it specifically wanted to promote physician-based models of care.

- **Distribution of Payment**
  Our economy is replete with examples of individual, independent entities working in collaboration with one another to achieve an overall goal. Visit any construction site, for example and there are an abundance of independent "sub-contractors" operating under the oversight of a general contractor who assures appropriate integration of each of the independent parts to achieve the final goal.

  In this metaphor, the general contractor receives the payment from the customer and divides that amongst the various subcontractors for their respective roles in the project. This same economic model of independent entities working collaboratively to achieve the desire outcome can be just as successful in healthcare as it is in other sectors of our economy.

  We intentionally left the distribution of funds up to the Specialist/Primary Care physician team. We note that Medicare pays a predetermined amount of money to a Medicare Advantage plan without knowing the distribution of those monies to the in-network providers with whom the plan has contracted. We see no reason that the distribution/allocation of funds needs to be specified at this stage of the proposal.

The payer – in this case Medicare – need only evaluate the total outlay for the particular bundle and leave it up to the asthma management team to work out the distribution of payments amongst the participants.

Criterion 4. Value over Volume

The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

We appreciate that the reviewers recognize that the model is designed to tailor services to patient needs and links payment to the service/need paradigm.

The reviewers suggest that for patients with "well-controlled" asthma, the model has the potential to pay providers generously for patients who "would have done well anyway."

There is no question that for a variety of reasons, some patients are better managed than others. But we would also point out there are a variety of factors outside the control of a physician that can turn a "well managed" asthma patient into a hospitalized asthma patient.

The overall PCACP model is designed to have a bundled payment option for the well-managed patient that is intended to keep the patient in that "well-managed" category.

- **Value over Volume**
  We found the criticism that the model does not demonstrate a value over volume approach surprising. A bundled payment, almost by definition, is not a volume-based payment and the entire design of the model is to improve patient value by better managing the asthma patient.

  We also believe that physicians are fundamentally interested in delivering "value-based" care and it is the fee-for-service payment model (and the low per-service payments) that create perverse incentives to focus more on volume than value. Running a medical practice is – like it or not – a business. And as with most businesses, if you are feeling downward pressure on price, you try to become more efficient which means you make up in volume what you are losing in price. If you fairly compensate the provider for the services they deliver, you reverse that negative pressure and the physician is better able to provide the services at a price they consider fair. By properly aligning payment with costs (as we do with this model), you remove those perverse incentive to replace lower prices per service with greater volume.

- **Accountability**
  We take issue with the criticism that the monthly framework will promote cherry-picking. As addressed above, the monthly payment system is, in our view, one of the strengths since it does not lock a patient into a higher paying category for long periods of time.

- **Social Determinants of Health**
  We disagree with the statement that social determinants of health are one of the major drivers of ED visits among patients with asthma. The biggest driver of ED visits are asthma exacerbations is failure to adhere to medication schedules. To the extent that social determinants influence this, the intensive management of the patient envisioned by the PCACP is intended to address this.

Criterion 6. Ability to Be Evaluated

- **Complexity.** We have addressed complexity above. We believe a certain level of complexity is inevitable given the PTAC Criteria. We purposely included several levels of payment based on patient severity and co-morbidities to avoid overpaying physicians for unneeded services. Implementing the model on a pilot basis would provide an opportunity to identify realistic ways to simplify, and therefore better evaluate, the model.

- **Savings.** Regarding how to determine if the model saves money, it should be possible, using existing Medicare data, to compare the total spending per beneficiary related to asthma (ED visits, hospitalizations, medications, physician costs, related tests, etc.) for patients in the model to a similar cohort of patients under the Medicare Fee-for-service model. With statistically significant sample sizes for patients in PCACP and the Medicare fee -for-service model over comparable time-periods, a comparison should be relatively straightforward.

Criterion 7. Integration and Care Coordination

- **Care Coordination between Asthma Specialist and PCP.** We are happy to elaborate on how care would be coordinated between PCPs and specialists, as coordination of care between primary care physicians and specialists is essential to this model's success. PCP and specialist physicians and caregivers would communicate regularly, sharing clinical notes and communicating care plans and handoffs electronically and via phone. Specialists would typically take responsibility for the initial diagnosis, as well as for asthma patients who are difficult-to-control. After patients move to well-controlled status, PCPs would typically take primary responsibility. The division of care could vary, however, for each individual asthma care team, and it's important to give individual asthma care teams flexibility to design the optimal division of care for their team. Factors involved in the division of care include the level of available resources, asthma specialty training, on-call availability and more of both PCPs and specialists. We therefore believe it is important to leave the distribution of care up to each asthma care team to determine. Once defined, the asthma care team would work together to keep patients and their families informed of providers' respective roles and to ensure that effective referrals and transitions take place.

- **Patient Handoffs**. Regarding how handoffs would occur between providers, before implementing PCACP and creating an asthma care team, a specialist practice and PCP practice would work together to determine when handoffs would take place. To facilitate successful patient handoffs between providers, each provider's office would work with patients to schedule appointments with the other provider. We believe this is the type of detail that could be worked out in a pilot program.

- **Care Management Outside the Office.** Regarding concerns that the model does not elaborate on care management outside of the office, we respectfully disagree. As stated in the original model proposal, care management would include the following services:

    - Increased, regular phone/email communications between asthma specialists and PCPs to facilitate accurate diagnosis and effective treatment of asthma.

- Increased patient education (including the use of certified asthma educators) related to medication, including the use of shared decision-making to reviewing medication side effects and identify and address barriers to medication adherence.
- Regular staff and provider telephone or telemedicine contacts with patients to encourage and assist with medication adherence, respond to patient problems, etc.
- Current trends in our specialty include remote monitoring of indoor environments, routine use of outdoor pollen, mold spore, particulate levels to help patient reduce exposures to triggers.[5]
- Smoking cessation counseling for patients and family members who smoke – as pointed out earlier, as part of their specialty training asthma specialists are experts on avoidance of environmental triggers and routinely include smoking cessation and elimination of passive smoke exposure in their treatment plans for asthmatic patients.

- **Distribution of Payments.** Regarding how payment would be coordinated between PCPs and specialists, we would expect that as more care is moved from the specialist to the PCP, the PCP would receive a larger share of the bundled payment. However, we do not believe it is appropriate, in the proposal, to establish limits or rules for sharing in the bundled payment.

  We would encourage primary care and specialty providers to develop an initial payment structure prior to implementing PCACP and enrolling patients in the program so that negotiations don't hinder care coordination. Payment distributions should vary for each stage of the model based on the agreed-upon distribution of work between the two providers in each phase.

Sincerely,

James Tracy, DO, FACAAI
Advocacy Council Chair
The American College of Allergy, Asthma & Immunology

[5] Barrett MA, Humblet O. Marcus JE, Henderson K, Smith T4 Eid N, Sublett JW, Renda A, Nesbitt L, Van Sickle D, Stempel D, Sublett JL. *Effect of a mobile health, sensor-driven asthma management platform on asthma control.* Ann Allergy Asthma Immunol. 2017 Nov;119(5):415-421.