American Academy of Neurology (AAN) Proposal – Initial Feedback on the Proposal for a Patient-Centered Headache Care Model by the Preliminary Review Team, Physician-Focused Payment Model Technical Advisory Committee (PTAC)

May 24, 2018

The members of the Preliminary Review Team (PRT) for the Physician-Focused Payment Model Technical Advisory Committee (PTAC) have reviewed the proposal submitted by the American Academy of Neurology for a patient-centered headache care model. Under the Bipartisan Budget Act of 2018 (P.L 115-123), Congress gave PTAC new authority to provide initial feedback to submitters of proposed models as part of the committee's review process. This new authority allows the PRT to provide initial feedback to the submitter only that consists of (i) *the extent to which a proposed model meets the Secretary's criteria* for physician-focused payment models (PFPMs), and (ii) *an explanation of the basis for the feedback*. The initial feedback may identify (at the discretion of each PRT) shortcomings, strengths, or both of submitted models relative to the Secretary's criteria for PFPMs.

<u>Disclaimer:</u>

Initial feedback is preliminary feedback from a Preliminary Review Team (PRT) subcommittee of the PTAC and does not represent the consensus or position of the full PTAC;

- *Initial feedback is not binding on the full Committee. PTAC may reach different conclusions from that communicated from the PRT as initial feedback; and*
- *Provision of initial feedback will not limit the PRT or PTAC from identifying additional weaknesses in a submitted proposal after the feedback is provided.*
- *Revising a proposal to respond to the initial feedback from a PRT does not guarantee a favorable recommendation from the full PTAC to the Secretary of Health and Human Services (HHS).*

Initial Feedback

The PRT reviewed the proposal, sent follow-up questions to AAN and talked with the submitter on a call to discuss their written responses. The PRT also consulted with a consultant neurologist at the University of Pennsylvania who reviewed the proposal, and also examined some Medicare data analyses to support their review of the proposal. Based on all this information, the PRT discussed its initial feedback on April 6, 2018.

Please find attached to this feedback, supporting information including the transcripts of the calls between AAN and the PRT, between the PRT and the consultant neurologist, and data analyses prepared by ASPE's contractor to support the PRT's evaluation of the proposal.

Overall, the PRT found the submitted model has significant limitations in terms of the criteria specified by the Secretary[1]. The first two of the ten criteria, (1) *Scope* and (2) *Quality & Cost* are fundamental to

[1] 42 CFR§414.1465

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.

the overall structure of the proposed model; therefore the PRT expects these will have downstream effects on elements that will impact other PFPM criteria as well. The PRT did not further evaluate the proposal in terms of the third criterion, *Payment Methodology*, given the PRT's fundamental concerns with the scope of the model as well as addressing quality and cost in Medicare. To illustrate how the proposed model falls short against other criteria, the PRT also provides some initial feedback based on the 7th criterion, *Integration and Care Coordination*.

The PRT thinks this proposal needs some fundamental restructuring to clarify the intent of the model prior to carrying out a complete review. The PRT felt there is a fundamental disconnect between the written proposal and the AAN's response to the PRT's questions. Whereas the actual proposal would set up a headache center model designed to manage patients with migraine and cluster headaches, the response to questions emphasized the desire to have a model focused more on diagnosing headaches, in many cases other than migraine and cluster. In the PRT's call with the AAN, it appeared the AAN committee felt that current payment under Medicare's Physician Fee Schedule for evaluation and management visits does not impede the ability for physicians to evaluate a patient to determine the correct headache-related diagnosis, even though the proposal discusses issues with difficult-to-diagnose patients (refer to transcript of call with AAN). The submitter could consider pursuing a focus that would have greater application for the Medicare population.

The PRT feels the submitter should reconsider what target patient population has a significant quality and cost problem for Medicare that needs to be addressed through the proposed model, and develop approaches throughout the model that are consistent with the target patient population. For example, if the main problem is missed or undiagnosed headache patients, then the model might target primary care or ER physicians who may have missed an opportunity for an appropriate diagnosis, and propose how specialists could be consulted, perhaps through specialized centers, to support the initial diagnosis and prevent delays in appropriate care. In terms of strengths of the proposal, the PRT feels that the intent to address diagnosis accuracy may be worthwhile, but would need more detail in a proposal on the extent of the problem for Medicare and how this could be addressed through a potential model with alternative care delivery and payment approaches.

The PRT would like to remind the submitter that under the Secretary's criteria[2] for PFPMs the focus of a proposed model should address a significant problem for the Medicare population to meet the criteria for *(1) scope*, as well as in terms of *(2) quality and cost*. The first two criteria are central to the successful definition of a proposed new model. While a proposed model may have broader application for Medicaid and commercial populations, i.e. patients less than 65 years, it will primarily be evaluated by the PTAC in terms of scope for Medicare, such as costs and potential savings to Medicare. *(See CY2017 Quality Payment Final Rule – the rule finalized that PFPMs be tested as APMs with Medicare as a payer, and that while PFPM could include other payers in addition to Medicare, other payer arrangements are not PFPMs.)*

[2] See CY2017 Quality Payment Program Final Rule, Federal Register, Vol 81, No 214, November 4, 2016, p77494

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.

The proposed model should also consider how to address the identified problem and enhance value to Medicare and patients, by improving *Integration and Care Coordination* – another criterion, as patients are often seen across settings by many different types of providers, both primary care clinicians and specialists.

The PRT feels the definition and goals of the model would be clearer if they were better clarified. As the submitter considers potential revisions to the proposal based on this initial feedback, the remaining criteria, including the third *Payment Methodology* criterion, would also need to be considered in accordance with the fundamental purpose of the model.

Specific feedback and explanation supporting the initial feedback follows for three of the ten criteria.

1. **Scope**

Scope is a high priority criterion for proposed models. Under this criterion, proposed models should *"aim to either directly address an issue in payment policy that broadens and expands CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited."* Proposals need to demonstrate a model seeks to address a problem for quality and cost in the Medicare population that cannot be resolved under the current Medicare Physician Fee Schedule. The intent of the model (as indicated in the proposal and AAN's response letter) emphasizes a focus on undiagnosed or difficult-to-manage headaches. However, the proposal itself seems to focus on managing well-defined migraines and cluster headaches, which are a relatively small problem in the Medicare population (see attached supporting data). This inconsistency is a major source of concern for the PRT, as the stated intent of the model and the actual proposed model appear to be very different.

Given the ambiguity in the target patient population for the proposed model, the PRT evaluated the *Scope* criteria against the two potential populations – (i) Medicare patients with migraines and cluster headaches, and (ii) undiagnosed or difficult-to-manage Medicare patients:

> *Scope – (i) Medicare patients with migraines and cluster headaches:* There does not appear to be a compelling problem for the management of Medicare beneficiaries with diagnosed migraines and cluster headaches, as confirmed by the PRT's discussion with a consultant neurologist and analysis of the prevalence of Medicare claims for patients with diagnosed migraines/cluster headaches and corresponding ER visits and hospitalizations. In short, the PRT is not convinced management of migraine and cluster headache syndromes is a significant problem in the Medicare elderly patient population. A migraine/cluster headache center model might be a relevant innovation for a younger patient population that includes commercially insured and Medicaid patients. It seems to the PRT that the submitter was attempting to make the case that for neurologists, a model with this type of headache-focused clinic that relies a lot on non-physician health professionals might serve the purpose of off-loading some of the management of easier-to-manage migraine patients. However, the submitter's proposal needs to be specifically targeted or relevant to the Medicare patient population.

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.

The PRT notes that the consultant neurologist confirms the PRT's understanding that migraine onset is typically in childhood to early adulthood, not in late life. Indeed, the neurologist suggested that a patient over 40 years presenting with migraine symptoms is considered to be a red flag requiring different diagnostic possibilities than classic migraine. An older patient with headache symptoms is more likely to have primary headache syndromes that are not migraine or cluster headaches, or may have secondary headaches, such as from mass lesions, temporal arteritis or headaches associated with other systemic diseases. The AAN's response letter to the PRT also confirmed this point. The neurologist also noted that in his experience treating both children and the geriatric population with headaches, elderly patients with migraines only tend to be easier to treat. (See full transcript with Dr. Rubenstein, consultant neurologist.)

The proposal submission referenced MEPS data in the proposal that appears to incorrectly overstate the prevalence and costs of headaches in the Medicare population. The PRT sought to verify the referenced figures by reviewing recent Medicare claims. (See analyses attached.) These showed migraines and cluster headaches affect less than 1 percent of all Medicare beneficiaries 65 years and older. Among those diagnosed with migraine or cluster headaches, less than 3 percent have migraine-related emergency room visits and only about 8 percent have related hospitalizations in a year. The PRT concluded any savings would likely be insufficient to cover the costs of a model, including the proposed 5 percent incentive payments for model participants.

Scope – (ii) Undiagnosed or difficult-to-manage Medicare patients: In the submitter's response to the PRT's questions there was indication of interest in addressing misdiagnosis or patients with difficult-to-manage headaches. The submitter also raised other conditions but did not specifically propose how diagnostic accuracy would be addressed in the model. Misdiagnosis may be a compelling problem, but it is not presented in significant detail for the PRT to evaluate. Specific diagnosis codes for difficult-to-manage or commonly misdiagnosed were not provided for inclusion in the model. The PRT would be interested in learning more about whether and how this proposed model would address headache diagnosis accuracy for the Medicare population and why the current Medicare fee schedule would be inadequate to support improved diagnostic accuracy. (See the PRT's discussion with Dr. Rubenstein, consultant neurologist in transcript.)

The PRT sought to clarify the intent of the model through written questions to the AAN and a subsequent follow-up call. From the call with the AAN, Dr. Kaufman indicated the AAN's committee was initially interested in complex or undiagnosed patients, but ultimately decided to focus the model on the management of patients with migraines. He indicated that making the correct diagnosis can be made mostly relying on the routine evaluation and management codes under Medicare's Physician Fee Schedule (PFS), albeit perhaps requiring a number of patient visits.

In summary, the proposed scope of this model to manage Medicare patients with diagnosed with migraine or cluster headaches is too small due to relatively low prevalence of this condition and low rates of associated ER visits and hospitalizations in the Medicare population. The model appears to be further narrowed by focusing on headache specialists as the primary health care provider for the management of headaches, supported by other clinicians and ancillary staff. A broader scope that

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.

includes undiagnosed, misdiagnoses or difficult-to-manage Medicare patients could be a more compelling problem for Medicare to address, if the AAN considers, on reflection, that the PFS is inadequate to support improved diagnoses. However, a revised proposal would require more supporting information such as prevalence, associated utilization, spending and health outcomes.

2. Quality and Cost

Overall, the PRT found the proposal to be weak in describing the quality and cost problem for Medicare patients with migraines or cluster headaches, and how the proposed model would specifically address any issues in this area. Under the *Quality and Cost* criterion, the proposed model should either "*(1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost."*

In terms of quality, the PRT does observe some strengths in the proposed model in improving the quality of care for headache patients by extending the potential for patients to receive supporting services from other types of clinicians and ancillary support staff. However it is not clear why those other types of clinicians are needed and how patients could benefit from their services. The consultant neurologist confirmed that a model that paid other types of professionals could help in the management of headache patients, such as physical therapists, and to a lesser extent, nutritionists. However the specific nature of the quality problem is not fully described in the model. Is there a quality issue for headache patients in receiving guideline-indicated care treatments and medications, inappropriate testing, or lack of patient education and support to understand and self-manage headache triggers? Does physical therapy or changes to a patient's diet prevent those headache triggers through better management of stress, exercise or other mechanisms? Without a full description of the quality problem, it is difficult to for the PRT to assess whether the proposed model adequately addresses and improves upon the current care delivery.

In terms of cost, given the limited scope of the issue of migraines in the Medicare population, it appears value would also not be enhanced be in a significant way through the proposed model approach since it focuses on well-controlled, easier-to-manage migraine and cluster headache patients, who do not have significant costs associated with their care.

The PRT would like more information on what are the potential drivers of the estimated $4000 in annual costs for a Medicare patient with headache. The PRT would like the proposal to better identify what are the opportunities for reducing that spending amount, whether this would be from reducing unnecessary imaging or preventing ER visits and hospitalizations. The consultant neurologist agreed that imaging costs can be curtailed by having headache specialists manage care who have expertise and experience in using physical examination results and health history to guide care, and use care protocols to prevent unnecessary imaging in patients. He also noted that ER visits and hospitalizations could be prevented through better follow-up care and patient contact to prevent intractable pain and vomiting associated with headaches. Detailing the specific drivers and expected pathway for reducing costs would better support how likely a model would save costs for Medicare and support the proposed payment model,

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.

care management fees and financial incentives. This would help the PRT evaluate the likelihood of the model's success.

In summary, there does not appear to be a significant quality or cost issue for Medicare patients with migraines. There is also insufficient detail about the quality or cost problems among undiagnosed, difficult-to-manage or complex patients for the PRT to assess if the model is adequately addressing a problem for this subset of patients, or if the model were to include complex patients in addition to patients with migraine or cluster headaches. It is possible that a case for improved quality and reduced cost can be made for headaches other than migraine and cluster headaches, as suggested in the AAN's response letter. That case would need to be made in a revised proposal.

3. Integration and Care coordination

Overall the proposal as written is weak on the Secretary's 7th criterion in terms of *Integration & Care Coordination* whether the model were to target either Medicare patients with migraines, or target undiagnosed, difficult-to-manage or complex patients. Under this criterion, the proposed model should *"encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM."* The model discusses different types of providers would be included in the model, primary care providers, physical therapists, nutritionists, in addition to the care coordinator and headache specialist but does not describe how they would coordinate, communicate and share information across settings about a patient participating in the model.

One of the weaknesses of the proposal is the lack of care coordination between the proposed headache care specialist and the patient's primary care provider. There is insufficient discussion about the interaction between the headache specialist and the primary care provider to manage diagnosed headache patients beyond the existing referral system. Overall, the PRT finds the current description and proposed coordination approach to be superficial, which included a too facile placement of the primary care physician on the headache team. How would it work? From the PRT's conversation with the clinical expert as well as PRT members' own clinical experiences, it was also clear that many of the potential neurologists are in varying practice settings, particularly outside of integrated clinical networks, which further emphasizes the need for clear metrics around coordination.

For example, the proposal also does not discuss potential opportunities to coordinate with hospitals and ER departments as well as patients with emergent situations, so that patients with worsening symptoms can receive preventive or emergent support. It is not clear from the model whether the model's care coordinator (the go-to person for the patient to contact) can provide timely medical advice to prevent an ER visit or hospital admission if the patient calls for advice, or if a patient visit or consultation is needed with the headache specialist.

In addition, the model does not discuss how high-risk, high-cost or high-utilizer patients might be pro-actively identified, stratified through retrospective data analysis or via real-time monitoring and targeted to prevent costly admissions. More detail in the proposed model would help to clarify how care

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.

coordination will be implemented and the mechanisms to improve quality and reduce costs, as well as patients' experiences.

If the submitter intends to focus on the issue of misdiagnosed patients, there may need to be stronger coordination between primary care physicians and specialists to address the lack of recognition of complex or secondary headaches among primary care providers that may contribute to under-diagnosis or misdiagnosis. The PRT would need to better understand exactly how a practicing neurologist would coordinate with a patient's primary care physician.

In summary for the *Integration & Care Coordination* criterion, the PRT feels the proposal could be improved by clearly stating how care can be better coordinated across settings, with different types of providers including primary care providers, and in emergent situations for the target patient population.

Summary: Initial Feedback

Based on the first two key criteria, the PRT finds the proposal as written has significant issues due to the limited scope and applicability for Medicare, and weak description of the quality and cost problem, as well as insufficient attention to care coordination and integration outside of the neurologist's practice. Without a clearly defined problem for Medicare, this limits the relevance of the proposed model for national implementation even though the model may be trying to improve care for all headache patients. The PRT suggests the proposal could also be improved for clarity, consistency and organization, with supporting rationale and relevant data. Most of the cited literature references do not distinguish between younger and elderly patients, and the reference to $4000 in Medicare spending for headache patients we believe should be annual costs, not per visit. This suggests the submitter may not be adequately explaining or understanding the underlying problems and drivers of spending in Medicare headache patients.

Overall, the PRT wonders why the AAN has chosen to focus on the care of headaches as a proposed model, given many other neurological conditions that have higher relevance for Medicare, with high costs and quality concerns among the Medicare patient population. A stronger rationale is needed to support a proposed model, whether the proposal is perhaps a broader headache care model for Medicare, or perhaps a model focused on new or newly diagnosed patients, or a model addressing other prevalent neurological conditions in Medicare. A strong proposal needs to clearly address a problem for Medicare.

The PRT looks forward to hearing from the submitter about their preferred next steps. See next section for potential options available to the submitter, after reviewing the initial feedback.

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.

Next Steps for Submitter

Upon receipt of initial feedback from the PRT, a submitter may choose to:

i) Make no change to the submitted proposal and make no response to the PRT;
ii) Make no change to the submitted proposal, respond to the PRT in writing
iii) Withdraw the submitted proposal; or
iv) Revise and resubmit the proposal to PTAC.

If the submitter chooses not to withdraw the submitted proposal, the PRT will then review and evaluate the current or resubmitted proposal against all of the Secretary's criteria for the PTAC's review.

The PTAC meets about four times a year to review proposals. The next meetings scheduled for this year (2018) are June 14-15, September 5-7 followed December 10-11. In general, submitters can expect the submitter's proposal, the PRT's report and supporting information to be finalized and posted on the PTAC's website one month prior to the public meetings. Please note the initial feedback on the proposal is shared with the submitter and will be posted.

For more information about the updated process, please review the attached document detailing the new policies and procedures for providing initial feedback, *"Implementing New Authority Provided by the Bipartisan Budget Act of 2018 (P.L. 115-123)".*

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.