

Physician-Focused Payment Model Technical Advisory Committee

Response to Public Comments on PTAC Processes and Requirements

November 2, 2018

The Medicare and CHIP Reauthorization Act of 2015 (codified at 42 USC §1395(ee)) established the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to review physician-focused payment model (PFPM) proposals submitted by individuals and stakeholder entities and to make comments and recommendations to the Secretary of Health and Human Services (HHS). PTAC began designing processes and procedures for carrying out its charge shortly after it was chartered in early 2016, and began accepting proposals later that year. Since October 20, 2018, PTAC has delivered comments and recommendations to the Secretary on 19 PFPM proposals.

PTAC provides an important opportunity for practitioners and other stakeholders to have a role in the development of alternative payment models (APMs). Therefore, PTAC wants to ensure that its processes and procedures facilitate proposal submission and enable the Committee to conduct an efficient and meaningful review. To ensure PTAC is accomplishing these goals, the Committee sought public comment on various aspects of how it has conducted its work to date. PTAC received verbal and written comments during a public comment period that ended on September 7, 2018.

PTAC thanks the following organizations for providing feedback on the Committee's activities and identifying opportunities for improvement: the American Academy of Family Physicians, the American Academy of Physical Medicine and Rehabilitation, the American College of Physicians, the American Medical Association, the American Occupational Therapy Association, Inc., the American Physical Therapy Association, the American Society for Radiation Oncology, Call9 Inc., Hart Health Strategies, Inc., the Health Care Transformation Task Force, the National Committee for Quality Assurance, the National Kidney Foundation, and SimplyVital Health.

A summary of the comments that PTAC received and the actions the Committee is taking as a result are presented below. This includes changes that will be incorporated into forthcoming revisions to instructions and other materials. Also presented below are clarifications on or explanations for maintaining certain processes or requirements. The summary of comments and responses are organized under the following headings:

- PTAC requirements for submission of a letter of intent;
- PTAC requirements for submitted proposals;

- PTAC provision of initial feedback on submitted proposals;
- PTAC's proposal review and deliberation processes;
- Criteria used by PTAC to evaluate submitted proposals;
- Resources for submitters;
- PTAC's scope;
- Comments and recommendations for parties other than PTAC; and
- Errata

PTAC Requirements for Submission of a Letter of Intent

Summary of Comments Received: One commenter expressed appreciation for the public posting of letters of intent (LOIs) to the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) PTAC website, and another commenter acknowledged that LOIs are helpful for applicants. In response to PTAC's observation that many LOIs are submitted without being followed by a proposal, one commenter proposed letting LOIs expire after six months, so that potential submitters would need to resubmit an LOI before submitting a proposal. Another commenter suggested requiring a proposal to be submitted within a three to four month range of an LOI. Another commenter suggested no longer requiring LOIs or replacing them with a short online application to give PTAC notice of forthcoming proposals. Two commenters recommended changing the LOI to facilitate offering submitters initial feedback before a proposal has been submitted, such as by increasing the two-page limit so stakeholders can provide more details.

PTAC Response: PTAC has found the submission of LOIs to be a helpful planning tool, but agrees that there are opportunities for improvement. While PTAC will continue to require an LOI, the Committee will consider changes to the form of this advance notice of a proposal and the information requested.

Because the LOI is intended to aid with planning, PTAC also agrees with the suggestion that LOIs should expire after a period of time if no proposal is received; in the future, the Committee will no longer consider LOIs to be valid if six months have passed without a proposal submission. The Committee will incorporate this policy into forthcoming revisions to instructions.

However, the Committee is unable to adopt the suggestion of providing initial feedback based on the LOI. According to statute, on an ongoing basis, individuals and stakeholder entities may submit PFPM proposals that they believe meet the Secretary's criteria. The Bipartisan Budget

Act of 2018 gave PTAC the authority to provide initial feedback to individuals and stakeholder entities who submitted such models. In addition to the statutory requirement that feedback be given on proposals, the LOI does not provide enough information about a model to enable feedback. Furthermore, proposals frequently look significantly different from the initial description in the LOI.

PTAC Requirements for Submitted Proposals

Summary of Comments Received: Some commenters recommended lengthening PTAC's 25-page limit on proposals. One commenter suggested allowing more flexibility in formatting for proposals, based on the stakeholder's discretion. One commenter suggested that PTAC clarify which aspects of its suggested information for inclusion in the proposal are critical for inclusion in the proposal and which are simply beneficial to have. Another commenter mentioned that when writing a proposal based on a currently operating business model, it is difficult to determine how much information to include in the Model Overview without appearing to propose a proprietary model.

PTAC Response: PTAC agrees that the proposal submission requirements should be more flexible. The Committee wants to ensure that submitters can describe their proposed model in a way that is clear and effective and does not want the submission instructions to impose unnecessary burden. Therefore, PTAC will revise its proposal submission instructions to allow submitters more freedom in how they format and organize their proposal as long as the proposal clearly addresses the criteria which the PTAC is required to use in evaluating a proposal. The revised instructions will also more clearly convey which pieces of information are most critical for submitters to include in their proposal.

However, PTAC plans to maintain the 25-page limit (exclusive of appendices) at this time. Particularly in light of the other changes PTAC is making to the submission requirements, the Committee believes that submitters should be able to adequately describe how their proposed models meet the Secretary's criteria within the allotted pages. In addition, the PTAC preliminary review teams (PRTs) will still be able to seek additional, more targeted information through questions to the submitter. Moreover, submitters may continue to include appendices outside of the page limit.

In terms of seemingly proprietary models, the Committee expects that many submitters may propose models based on approaches that they have used or plan to use in their organization. While it can be helpful to understand how the proposed approach would work in a particular organization, PTAC will not recommend models that are only designed to be used in a single organization or that are only likely to be successful in specific organizations, so applicants should focus on explaining why and how the model would work more broadly. The Committee

will elaborate on this issue in its revised proposal submission instructions, FAQs, and/or webinar(s).

PTAC Provision of Initial Feedback on Submitted Proposals

Summary of Comments Received: Commenters suggested many changes to how PTAC implements its new authority to offer initial feedback. For example, multiple commenters urged offering initial feedback before a proposal is submitted. Many commenters expressed support of a more iterative initial feedback process that goes beyond addressing how well the proposal meets criteria established by the Secretary, suggesting that PTAC members offer technical assistance to submitters. One commenter suggested that the Committee offer preliminary technical support prior to PTAC posting a submitted proposal online.

Another commenter suggested that PTAC's initial feedback process of identifying issues without offering solutions is inconsistent with congressional intent. The commenter suggested that PTAC suggest potential alternatives for addressing issues it had identified, while clarifying that PTAC would not be obligated to recommend a proposal if the submitter did use one of the suggested alternatives. One commenter asked why the process is called "initial feedback" and whether that implies that there are future opportunities to receive feedback.

PTAC Response: As noted above, the Bipartisan Budget Act of 2018 gave PTAC the authority to provide initial feedback to individuals and stakeholder entities who submitted models. More specifically, statute specifies that PTAC may give initial feedback regarding the extent to which submitted models meet the Secretary's criteria and an explanation of the basis for the feedback. Therefore, the Committee cannot offer feedback before a proposal is submitted. The Committee has also been advised that the statute does not give PTAC the ability to offer technical assistance or feedback beyond the extent to which models meet the Secretary's criteria and an explanation of the basis for that feedback.

In terms of proposal postings, PTAC will continue to post submitted proposals to the ASPE PTAC website once they are verified as complete. PTAC is subject to the Federal Advisory Committee Act (FACA), which requires the Committee to conduct its business in a manner that is transparent and fosters public access to materials PTAC receives, reviews, develops, or uses in its deliberations.

PTAC's Proposal Review and Deliberation Processes

Summary of Comments Received: One commenter indicated that conversations between the PTAC Preliminary Review Team (PRT) and submitter seem helpful. Another commenter said

that posting materials online and offering opportunities for public feedback was desirable. One commenter suggested that PTAC consult with outside professionals with expertise related to a specific model as part of the deliberation process, including with non-physician providers as needed. The commenter recommended that this consultation occur before the conversation with the submitter. One commenter suggested that conference calls with submitters could be helpful, acknowledging that such calls would be helpful even with the constraints precluding technical assistance during these calls.

One commenter suggested creating a system by which an applicant could update versions of a submitted proposal based on feedback during the PRT process and beyond, to keep the public and HHS informed of the latest versions of all proposals. One commenter asked PTAC to provide a brief summary of their key conclusions from each public evaluation session. One commenter suggested allowing submitters to opt out of receiving any feedback, if a submitter wants to shorten the time to obtaining a recommendation from PTAC on the submitted proposal. A commenter proposed that PTAC provide written questions in advance of a public meeting so that the submitter can better prepare for public meetings, which the commenter felt are not conducive to extensive explanations from the submitter. A commenter suggested that written questions from the PRT to the submitter include a checklist of what the PRT believes is missing from each criteria.

One commenter suggested that the PRT provide the full Committee a summary of the PRT's findings for the Committee to review before the public meeting. Two commenters suggested that the Committee send the submitter written questions before the public meeting. One commenter stated that the reports to the Secretary are helpful to potential submitters. One commenter asked PTAC to try to review more alternative payment models each quarter.

A commenter recommended that PTAC be allowed to conduct preliminary reviews and convene as a group to discuss proposals outside of public meetings, so that submitters can modify or withdraw proposals before they are available for public consumption.

One commenter expressed support for the "limited-scale testing" recommendation category to help evaluate models. One commenter expressed appreciation that PTAC is recommending models and liked the "deserves priority consideration" recommendation category used during evaluation.

PTAC Response: PTAC agrees that dialogue with submitters has been very valuable. Under current processes, the PRT may engage the submitter in writing or through conference calls; written questions and answers and transcripts of phone calls are posted to the ASPE PTAC website. Additionally, PRTs are able to and frequently do consult with outside professionals as part of their review process; transcripts of these conversations are also posted to the ASPE PTAC

website. In terms of the ordering of the PRT's review, PRTs attempt to engage submitters and outside professionals, as needed, in an ideal manner for a given proposal, while balancing scheduling and providing a timely review. The input commenters provided on this process and the order of activities is appreciated and will be kept in mind.

PTAC understands very well the challenge of reviewing multiple and sometimes voluminous sources of information – the proposal, the submitter's written responses to the PRT's questions, transcripts from calls with the PRT, and other information from the submitter – to fully understand a proposed model. The PRT writes up a summary of the proposed model, taking into account all of these pieces, in a report that it provides to the full Committee before the public meeting. However, PTAC is concerned that creating a mechanism by which submitters can update their proposal multiple times throughout the PRT review may be burdensome to the submitter and potentially delay action by the PRT and the full Committee. PTAC notes that submitters who believe that it will be difficult for the PTAC or the public to accurately understand their proposed model using the materials that have been submitted have the option of withdrawing their proposal at any time prior to the full Committee's voting, revising the proposal and resubmitting it. Proposal revision and resubmission is allowed, for example, following receipt of initial feedback or the PRT report. PTAC wishes to underscore that the PRT's report represents a *preliminary* report from two to three PTAC members to the full PTAC and does not reflect the views of the full PTAC.

PTAC will explicitly inform submitters that they may opt out of receiving initial feedback. However, the Committee notes that submitters who choose to receive initial feedback are not required to respond or modify their proposal based on that feedback.

In terms of a checklist that conveys what the proposal is lacking in terms of each criterion, the PRT's initial feedback typically highlights major areas where the PRT believes the proposal does or does not meet the Secretary's criteria. The PRT report to the full Committee describes what the PRT believes are the strengths and/or weaknesses of the proposal relative to each criterion. The submitter receives a copy of this PRT report in advance of the public meeting at which the full PTAC discusses and reviews the submitted proposal, and the submitter has an opportunity to reply to the PRT's preliminary report in writing, verbally at the public meeting, or both prior to the full PTAC's deliberation on the proposal.

With respect to the recommendation that PTAC conduct preliminary reviews and convene as a group to discuss proposals outside of public meetings, FACA requires the Committee to conduct its work in a manner that is transparent and fosters public access to materials PTAC receives, reviews, develops, or uses in its deliberations. FACA also requires that all PTAC deliberations occur in public.

PTAC appreciates the positive feedback on some of its voting categories. The Committee is working on refining these categories and will keep this feedback in mind.

Criteria Used by PTAC to Evaluate Submitted Proposals

Summary of Comments Received: Many submitters suggested changes related to the criteria that PTAC applies to proposed models. Two commenters suggested revising criteria to promote patient-centered payment models. One commenter suggested prioritizing models that include non-physician providers such as physical therapists, in order to support those professionals' participation in Medicare APMs. One commenter supported the designation of three criteria as high priority. Another commenter recommended that PTAC continue to emphasize the evidence for the validity of the payment methodology.

One commenter proposed changing criteria to reflect the [Secretary's June 2018 response to PTAC's recommendations](#) so that proposals are assessed on some of the additional considerations that the Secretary mentioned, such as the use of proprietary tools and the relationship to current standards of care. The commenter also suggested counting up-front investments that practices make when starting an advanced payment model toward the financial risk associated with a model. One commenter suggested that PTAC assess how a proposed model would interact with existing models or with previously recommended models, perhaps as part of the existing integration and care coordination criterion. Another commenter appreciated that deliberations at the March 2018 public meeting included discussion of broader market dynamics.

PTAC Response: PTAC is required by statute to evaluate PFPMs based on the criteria established by the Secretary. PTAC cannot change the criteria, and recommendations for changes should be submitted to the Secretary. The Committee believes that the criteria are fairly flexible and can be interpreted broadly. How to apply the criteria appropriately has been and will continue to be a significant area of discussion for Committee members.

Resources for Submitters

Summary of Comments Received: Commenters suggested that PTAC offer public workshops, greater access to data, technical assistance on data-sharing, a Best Practices document, and FAQs to offer more clarity and support to submitters. One commenter offered suggestions for the "Characteristics of Models Likely to Be Recommended by PTAC" document. Although the appendix is helpful, the commenter wrote, PTAC should amend it to emphasize multidisciplinary models that include non-physicians. The commenter also suggested adding examples of favorably recommended models and the Committee's rationale for these recommendations.

PTAC Response: PTAC agrees that it is desirable to provide as much information to help submitters as possible. PTAC plans to develop revised proposal submission instructions, FAQs, webinars, and other resources. Although PTAC is not permitted to offer technical assistance to model submitters in the development of their specific models, PTAC hopes that providing information to submitters on the information needed to describe a proposal, sources of other data and information that might be useful to model developers, and the detailed reviews on the many proposals that have been submitted to date, will help address the need submitters have expressed for more support.

PTAC's Scope

Summary of Comments Received: One commenter expressed support for expanding PTAC's portfolio to include PFPMs with payers beyond solely Medicare, including Medicaid and CHIP and combinations of public and private payers. Another commenter asked, in relation to the September 2018 public meeting, why the Committee was reviewing a proposal that is potentially not an APM.

PTAC Response: PTAC is charged with the review of PFPM proposals. Part of the definition of a PFPM is that Medicare is a payer. However, PFPMs can include other payers, as long as Medicare is included as a payer.

With respect to the comment on PTAC reviewing proposals that are potentially not APMs, PTAC notes that, as stated above, all PTAC deliberations must occur in public. PTAC can only make a determination that a submitted proposal is not an APM during a public meeting. PTAC does not encourage the submission of non-PFPM proposals.

Comments and Recommendations for Parties Other than PTAC

Summary of Comments Received: Many commenters made suggestions that are outside of PTAC's purview. One commenter suggested that because the new authority to offer initial feedback does not include Centers for Medicare & Medicaid Services (CMS) offering technical assistance to submitters, CMS should make data available to PTAC to support the Committee's analysis. Another commenter wrote that CMS should change requirements around methodology development for untested models and allow qualitative description of reimbursement, with less of an emphasis on quantitative data on cost savings. A commenter suggested that if HHS is interested in a model, submitters could work with the Center for Medicare and Medicaid Innovation (CMMI) on further development of the reimbursement methodology. The commenter also suggested that CMMI consider establishing cooperative agreements or grants to stakeholders in the process of developing new PFPMs.

One commenter suggested that HHS be transparent in how it addresses PTAC recommendations. Another commenter stated that HHS needs to support model developers with data, technical assistance, and specific, tangible feedback, including alternative solutions. Another commenter suggested greater clarity from HHS on acceptable payment models, performance measures, and evaluations for model developers.

A commenter wrote that PFPs should consider and compensate multidisciplinary health care professionals. Another commenter stated that it is crucial for APMs to include quality measures that demonstrate the impact of non-physician providers on patient outcomes to incentivize cross-collaboration. The commenter recommended that quality measures include both quantitative and qualitative metrics, as well as both performance-based and patient-reported outcomes, to encourage interdisciplinary care without being burdensome.

PTAC Response: ASPE is charged in statute with providing technical and operational support to PTAC. ASPE staff will share these comments within HHS.

PTAC also clarifies that CMS does make data available in support of the Committee. PRT reviews are often supported by data analyses. These data tables are posted on the ASPE PTAC website.

ERRATA

Summary of Comment Received: One commenter informed PTAC that the Implementing New Authority Provided by the Bipartisan Budget Act of 2018 document uses some incorrect page numbers when it references the Proposal Submission Instructions.

PTAC Response: The comment is appreciated and these corrections will be included in future updates to the documents.