Physician-Focused Payment Model Technical Advisory Committee RESPONSE TO PUBLIC COMMENTS ON PROPOSAL REVIEW PROCESS

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to review proposals for physician-focused payment models (PFPMs) and to make comments and recommendations to the Secretary of Health and Human Services regarding whether such proposals meet criteria for PFPMs established by the Secretary. On April 20, 2016, the PTAC issued an initial draft of the process it was considering using to solicit and review proposals for PFPMs, and it requested public comment on this draft document by May 13, 2016. Input was specifically requested regarding the content of proposals, provision of technical assistance, and the timeline for review. Oral comments were solicited at the May 4 PTAC meeting in Washington, DC.

The members of the PTAC appreciate the many thoughtful comments and suggestions it received in response to this request. Based on this input, PTAC has made a number of modifications to the draft process and a description of the revised process is attached. The Committee's responses to the comments it received are summarized below.

The revised process is still a draft and further revisions and refinements are likely in response to (1) the final criteria for physician-focused payment models that are established by the Secretary of HHS in rulemaking, (2) the PTAC's experience in reviewing and making recommendations regarding proposed payment models after proposals begin to be submitted, and (3) additional feedback PTAC receives from the public. The PTAC welcomes comments and suggestions at any time; comments may be submitted by email to <u>PTAC@hhs.gov</u> or by mail to PTAC c/o Scott R. Smith, ASPE, 200 Independence Ave. SW, Washington DC 20201.

Types of Payment Models to Be Considered

Summary of Comments Received: Many commenters urged that PTAC consider and recommend a broad range of physician-focused payment models, including models focused on particular types of health problems and procedures as well as models designed to support comprehensive care for all of a patient's healthcare needs; models focused on short episodes of care as well as models designed to support care over an extended period of time; models focused on particular types of individuals, such as frail and disabled elderly; and models focused on the care delivered by physicians in an individual specialty as well as models that support primary care. Several commenters urged that PTAC give priority to proposals that address types of physicians, types of patients, and types of services that are not currently addressed by current alternative payment models in Medicare. Some commenters recommended that PTAC consider models that would improve the quality of patient care and outcomes of care, not just models that would reduce spending. Some commenters urged that PTAC not limit its recommendations to proposals that would meet the standard for "Advanced APMs" in the Notice of Proposed Rulemaking issued by HHS. Some commenters urged that PTAC encourage or require proposals

to support specific approaches to care delivery using healthcare professionals other than physicians, such as nurses, nurse midwives, and nurse practitioners.

PTAC Response: We want to encourage development of innovative proposals that would either (1) improve quality of care without increasing spending, (2) reduce healthcare spending while maintaining quality of care, or (3) both reduce healthcare spending and improve the quality of care. In the future, we may provide more detailed guidance regarding the types of payment models likely to meet the criteria for approval and to receive priority consideration by the PTAC.

Letters of Intent

Summary of Comments Received: In our draft process, we indicated that no Letter of Intent would be required, and several commenters endorsed that approach.

PTAC Response: Upon further discussion, we have concluded that we will be better able to plan for timely processing of proposals if we have some advance indication of the number and types of proposals we are likely to receive. Consequently, we have decided to require that a brief Letter of Intent be submitted at least 30 days prior to the submission of a formal proposal. This Letter of Intent will be at most two pages and will include very basic, summary information about the type of payment model that will be submitted and the goals it is expected to achieve.

Format and Content of Proposals

Summary of Comments Received: Several commenters recommended that a standardized form be created for electronic submission of proposals to PTAC. Some commenters made recommendations regarding the types of information that PTAC should request as part of proposals. Several commenters asked that application forms be made as simple as possible and that proposals not be rejected for technicalities related to the completion of application forms.

PTAC Response: We plan to request that individuals and entities submitting proposals provide the specific types of information that we feel we will need in order to determine whether a proposal meets each of the criteria we will be using to evaluate proposals. The information that PTAC requests be included in proposals depends on the criteria PTAC will be using to evaluate proposals. Under MACRA, the PTAC is charged with evaluating whether PFPMs meet criteria established by the Secretary of Health and Human Services. Although final criteria have not yet been established, proposed criteria included in the Notice of Proposed Rulemaking for implementation of MACRA provide an indication of what the final criteria are likely to include, so the PTAC plans to issue a draft list of the information to be requested in applications for public comment in the near future.

We also plan to develop a standard application form that applicants can use to submit the information on their proposals.

Access to Data

Summary of Comments Received: Many commenters expressed concern about the amount and type of data and analysis the PTAC might require be included in proposals showing the impact of a proposed PFPM because of the difficulties of obtaining data. Some commenters urged that we

not require submission of data regarding the impacts of a proposal but merely evaluate the soundness of the conceptual model.

PTAC Response: We believe it will be essential for the PTAC to make a quantitative assessment of the potential impact of a proposed PFPM on spending, but we recognize the difficulty that physicians and other organizations have in obtaining the types of data needed to analyze spending and project the impacts of PFPMs. Consequently, we will encourage submitters to provide as much data and analysis as they can, and to describe specifically what additional data and analysis they would like to provide and the reasons they cannot do so. We will then determine on a case-by-case basis whether additional analyses are needed before we can take action on a proposal, whether it is feasible to complete those analyses with available data, and whether there are ways that we can help submitters obtain these data.

We also recognize that in some cases, it may be impossible to provide a quantitative analysis of the impacts of a particular model because the changes in care delivery that would be supported by the model have not previously been attempted or there is inadequate data on those attempts. In these cases, if the proposal meets all other criteria, we may decide to recommend that the proposed payment model be implemented on a small scale in order to obtain data needed to determine whether broader implementation is warranted.

Technical Assistance

Summary of Comments Received: Many commenters requested that the PTAC provide technical assistance to individuals and entities interested in developing or submitting proposals. Specific areas of assistance requested included obtaining access to data, estimating expected savings, and structuring financial accountability to manage risk. Commenters requested assistance in the form of videos, FAQs, and one-on-one support. Some commenters urged that we proactively work to develop proposals in specific areas where payment models are needed.

PTAC Response: We are actively exploring what kinds of technical assistance could be provided by PTAC, CMS, and other organizations and we will share more details on that in the future.

Addressing PTAC Questions and Concerns About Proposals

Summary of Comments Received: Several commenters urged that when the PTAC had questions or concerns about a proposal, it should engage in a discussion about those questions or concerns with the individual or entity that submitted the proposal, rather than simply requesting written responses to questions or returning the application for revision and resubmission.

PTAC Response: We agree that an interactive approach would be desirable whenever possible. We do not want to create unnecessary work for submitters or take actions that would unnecessarily delay review and recommendations on meritorious proposals. However, we are also concerned that the challenges associated with scheduling conference calls or in-person meetings could delay our ability to recommend implementation of desirable proposals that require only minor clarifications. Consequently, the revised process indicates that we will use different mechanisms for addressing questions or concerns – requesting a written response to a specific question, holding a telephone conversation, holding a face-to-face meeting, or requesting

a revised application – and that we will decide on the appropriate mechanism on a case-by-case basis based on the nature of the information we need and the preferences of the submitter.

Ensuring Appropriate Technical Expertise for Review of Models

Summary of Comments Received: A number of commenters endorsed requiring that every Preliminary Review Team include one of the physician members of PTAC, but they expressed concern that physicians from all specialties were not represented on the PTAC and they urged PTAC to include specialists on Preliminary Review Teams who have expertise in the types of care involved in a proposal. Some commenters recommended that PTAC consider the perspectives of the patients who would be affected by a proposal as well as physicians and other providers. Some commenters asked for more information about how outside experts would be chosen to assist in PTAC reviews, urged that experts who have conflicts of interest should not be utilized, and recommended that any involvement by outside experts be made public.

PTAC Response: We do not believe that is possible to ensure that Preliminary Review Teams include individuals with all of the types of expertise and experience that might be relevant to a particular proposal. We will look first to the proposal itself to tell us whether physicians from the relevant specialties and other individuals with appropriate expertise have been involved in the development of the proposal and have indicated their support for its implementation. We will also rely on the public comment period to determine whether there are different perspectives on a proposal from other individuals with relevant expertise.

If a Preliminary Review Team believes that it needs assistance from someone with specialized expertise to assist in the review of a proposal, we will try to identify someone with that expertise who has no conflicts of interest with respect to the submitter or the proposal, and we will publicly acknowledge which experts were involved when the proposal is presented to the PTAC for action.

Process for Public Comment

Summary of Comments Received: Commenters requested greater clarity about when the public comment process for proposals would occur and urged that comments be submitted and considered by the PTAC prior to the meeting at which a decision is made about a proposal.

PTAC Response: The revised process indicates that we will solicit public comment as part of the information-gathering process by the Preliminary Review Team so that the Preliminary Review Team's recommendations to the PTAC can be informed by the public comments. We plan to allow 3 weeks for public comment in order to provide sufficient time for interested parties to review a proposal and to comment on it without causing lengthy delays in the processing of a meritorious proposal.

Weighting and Scoring of Evaluation Criteria

Summary of Comments Received: Commenters asked that PTAC solicit public comments on the criteria weights and scoring system it would use to evaluate proposals.

PTAC Response: We are currently discussing how to evaluate proposals against individual criteria and how to use the criteria to make an overall recommendation on a proposal. We plan to solicit public comment on the method we develop before it is implemented.

Addressing Multiple Proposals on a Similar Topic

Summary of Comments Received: A few commenters recommended that if PTAC receives multiple proposals that address similar issues, development of a common approach should be encouraged, but PTAC should not try to force a one-size-fits-all model.

PTAC Response: If we receive multiple proposals that address similar issues, we will offer to facilitate collaboration among the submitters. If submitters do not wish to collaborate on a common approach, we will proceed with a review of their individual proposals, but we may attempt to schedule the discussion and decisions on all of the proposals at the same PTAC meeting so that we can better determine whether the proposals are sufficiently different that each should be pursued or if one is superior to the others.

Timeline for Review and Recommendation

Summary of Comments Received: Many commenters urged that the PTAC review proposals quickly, and several recommended that reviews be completed within 90 days.

PTAC Response: We are committed to review proposals as quickly as possible, but we also want to ensure that we review proposals adequately and fairly, and that we provide adequate time for submitters to respond to concerns and questions from the PTAC and for the public to comment on proposals. The revised review process is structured in a way that should result in the completion of review and recommendations for most proposals within 4 months. Proposals that provide complete information on all criteria may be able to complete the process within 90 days. However, at this point we do not know what volume of proposals we will receive, and if the volume of proposals is high, we may not be able to complete reviews of all proposals within the timeframes we have established.

We would welcome recommendations on ways to further streamline the process and we would also welcome any comments on aspects of the process that potential submitters believe will require more time.

Appeal Process

Summary of Comments Received: Several commenters recommended that PTAC establish a process for appealing a decision when the PTAC does not recommend a proposal or when the Secretary of HHS chooses not to implement a proposal recommended by the PTAC.

In situations in which the PTAC has not recommended a proposal, we believe the best approach is for the submitter to prepare a revised proposal that addresses the specific reasons the PTAC identified for not recommending the original proposal. We will follow the standard review process for these revised proposals, but we will give expedited consideration to them if they explicitly indicate how they have addressed the reasons we cited for non-recommendation.

PTAC Response: As for proposals that are recommended by the PTAC but are not implemented by the Secretary of HHS, the statutory role of PTAC is to make recommendations to the

Secretary; we do not have the authority to oversee an appeals process related to decisions by the Secretary.