

FOR PUBLIC COMMENT

Physician-Focused Payment Model Technical Advisory Committee

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 submitted by individuals and stakeholder entities for physician-focused payment models (PFPMs). MACRA requires the PTAC to make comments and recommendations to the U.S. Secretary of Health and Human Services regarding whether such proposals meet criteria for physician-focused payment models established by the Secretary.

This document describes the process that the PTAC will use for accepting and reviewing proposals and for making comments and recommendations regarding them. All timeframes stated in this process should be viewed as goals, not absolute deadlines, since the PTAC's ability to process applications within the stated deadlines will depend on the volume of proposals received. The PTAC reserves the right to make changes to the process at any time if it believes the changes will improve the efficiency and effectiveness of its work, and it welcomes comments and suggestions from stakeholders regarding ways to improve the processes it uses.

Phase I: Proposal Preparation and Submission

1. **Letter of Intent**: Stakeholders who are planning to submit a proposal to the PTAC must submit a brief letter describing the nature of the proposal and the expected date of submission at least 30 days in advance of submitting a proposal.
 - a. **Purpose and Non-Binding Nature of Letter**. The Letter of Intent is designed to assist the PTAC in planning for review of proposals. A stakeholder submitting a Letter of Intent is not required to submit a proposal, and a proposal may be submitted later than the expected date of submission indicated in the Letter of Intent. In addition, the details of the proposed payment model may differ from what was described in the Letter of Intent if the stakeholder believes the changes result in a model that better meets the criteria established by the Secretary of Health and Human Services or the stakeholder's goals. A stakeholder planning to submit multiple proposals should submit a separate Letter of Intent for each.
 - b. **Content of Letter**. The Letter of Intent should be no longer than two pages. It should briefly describe:
 - i. **Expected Participants**: (a) the types of patients expected to participate in the proposed payment model; and (b) the estimated number and types of physicians and other providers expected to participate in the proposed payment model
 - ii. **Goals of the Payment Model**: The improvements in clinical quality, patient outcomes, and/or healthcare spending that would result from the proposed payment model compared to the current payment system;

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- iii. **Model Overview:** (a) a description of the basic structure of the payment model (e.g., creating payments for currently unpaid services, bundling of current payments for specific patients in a defined episode, risk adjusted global capitation for specific patients, etc.), and (b) an indication as to whether the submitting organization believes the proposed payment model would be likely to meet MACRA requirements for an alternative payment model (i.e., an “advanced alternative payment model” as defined in currently proposed regulations);
 - v. **Implementation Strategy:** a brief description of the organization submitting the proposal, and if the submitting organization is not a provider organization, the names of any provider organizations that are committed to implementing the proposed payment model; and
 - vi. **Timeline:** (a) the date that the organization expects to submit the proposal, and (b) the earliest date the provider organizations involved believe they could be ready to implement the payment model if it is approved.
- 2. Request for Proposals: Once criteria for physician-focused payment models (PFPM) are established by the Secretary of Health and Human Services (HHS), the PTAC will issue a Request for Proposals (RFP).**
- a. **Content of Proposals.** The RFP will define the information stakeholders will need to submit in order for the PTAC to review a proposal and the format in which it should be submitted. The PTAC will seek to (a) avoid requesting information that is not essential to the review process and (b) permit submission of information in the most convenient way possible for stakeholders.
 - b. **Additional Information Regarding Proposals.** PTAC will provide public education sessions and informational materials, such as webinars, Frequently Asked Questions, etc., regarding the requirements of the RFP and the proposal review process. PTAC will not be able to provide help to individual stakeholders in preparing their proposals.
 - c. **Confidential Information.** All information included in a proposal submitted to the PTAC will be available for public review. Confidential or proprietary information should not be included in proposals.
- 3. Proposal Submission: Stakeholders may submit proposals following issuance of the RFP.**
- a. **Letter of Intent.** A proposal will only be accepted if a letter of intent has been submitted at least 30 days in advance.
 - b. **Deadlines for Submission.** There will be no deadlines for submission of proposals. Stakeholders may submit proposals at any time and submissions will be accepted on an ongoing basis after the RFP is issued.
 - c. **Acknowledgement of Receipt.** PTAC staff will acknowledge receipt of a proposal within 2 business days.

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- d. Approximate Timetable for Submission and Review. In general, proposals will need to be submitted at least 14 weeks in advance of a PTAC public meeting in order for the Committee to complete all of the steps necessary to formally consider the proposal at that meeting. The PTAC will seek to review and act on all proposals as quickly as possible, but the time for processing will be affected by the volume of proposals received. The PTAC intends to hold public meetings no less frequently than quarterly. The frequency of meetings may be modified to ensure proposals can be considered in an efficient and timely manner.
- 4. Review of Proposals for Completeness and Adherence to RFP Requirements: Upon receipt of a proposal, PTAC will determine whether the proposal contains the information required by the RFP.**
- a. Review for Completeness. PTAC staff will conduct an initial review to determine if a proposal contains all of the information required in the RFP. If staff determine that the proposal is incomplete and that the missing information could impair the PTAC's ability to fairly review the proposal, a member of the PTAC will review the proposal to determine whether: (1) the proposal will be returned for revision, or (2) the proposal will be forwarded to a Preliminary Review Team, with the missing information to be addressed through a request for supplemental information. This process will be completed within two weeks.
- b. Return of Incomplete Proposals. Proposals that require revisions to address missing information will be returned to the submitter with an explanation of what is missing or non-adherent and notifying them of the opportunity to revise and resubmit. Proposals that are revised and resubmitted after being returned in this manner will be reviewed within two weeks. If the problems have been addressed, the revised proposal will be forwarded to a Preliminary Review Team.
- 5. Identification of and Remedies for Conflicts of Interest and Lack of Impartiality: PTAC members with conflicts of interest or lack of impartiality related to a proposal will be identified and remedies determined.**
- a. Identification of Potential Conflicts and Lack of Impartiality. During the time in which a proposal is being assessed for adherence to RFP requirements, PTAC staff will send each PTAC member the name of the entity or entities submitting the proposal and a copy of the brief summary submitted as part of the proposal. Each PTAC member will be asked to identify any potential conflicts of interest and any reasons why they might be perceived as unable to make an impartial decision regarding a proposal.
- b. Remedies for Conflicts of Interest and Lack of Impartiality. In cases where a Committee member identifies that potential conflicts of interest or perceived lack of impartiality exist, the Committee will make a decision as to the appropriate remedy. Potential remedies will include decisions that the Committee member:
- i. will not participate on the Preliminary Review Team for the proposal;
 - ii. will not participate in Committee discussions regarding the proposal;

- iii. will not vote on the Committee recommendations regarding the proposal; and/or
- iv. will not be present for Committee discussions or votes regarding the proposal.

Phase II: Preliminary Review

6. **Formation of Preliminary Review Team: A proposal that contains the information required by the RFP will be assigned to a Preliminary Review Team consisting of a subgroup of PTAC members.**
 - a. Appointment of Preliminary Review Team. Within one week after a proposal has been determined to contain the information required by the RFP, the Chair of the PTAC will assign a subgroup of the members of the Committee to serve as a Preliminary Review Team.
 - b. Composition of Preliminary Review Team. No member of a Preliminary Review Team will have a conflict of interest with respect to a proposal. Each Preliminary Review Team will include at least one of the PTAC members who is a physician.
 - c. Assignment of Lead Reviewer. The Chair of the PTAC will designate one member of each Proposal Review Team as the lead reviewer. The lead reviewer will be responsible for working with the rest of the Team and PTAC staff to develop a draft recommendation regarding the proposal for consideration by the full PTAC.
7. **Preliminary Review of Proposal: A report containing findings regarding the proposal and a draft recommendation for discussion by the PTAC will be developed by the Preliminary Review Team.**
 - a. Identifying Questions and Concerns Regarding Proposals. If the Preliminary Review Team has questions about a proposal, the individual or entity that submitted the proposal will be invited to respond to those questions. If the Team feels that a proposal does not adequately address one or more of the criteria for physician-focused payment models, the submitter will be invited to provide additional information related to those criteria. The Preliminary Review Team will identify all of its questions and any additional information needed within 3 weeks.
 - b. Obtaining Responses to Questions and Concerns. The Team will decide on a case-by-case basis whether the most efficient and effective way of obtaining additional information and responses to questions would be through (1) a written response by the submitter, (2) a telephone discussion with the submitter, (3) an in-person discussion with the submitter, and/or (4) a request for a revised proposal. The Team will attempt to resolve questions without requiring resubmission, but if there are a large number of questions or concerns, the Team may decide to return the proposal to the individual or entity that submitted it and invite them to make revisions and resubmit the proposal.

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- c. Obtaining Additional Expertise in Reviewing Proposals. If the Preliminary Review Team determines that it needs additional expertise to assist in reviewing a proposal, it may invite one or more outside experts to provide comments on relevant aspects of the proposal. No individual with a conflict of interest or a relationship that could result in a lack of impartiality will be used as an outside expert. If any outside experts provide assistance, they will be publicly acknowledged when the proposal is presented to the PTAC for action. The Team may also identify specific issues regarding a proposal and request written input on those issues during the public comment period.
 - d. Analysis of Impacts on Spending. It will be essential for the PTAC to understand the impact of a PFPM on Medicare and other healthcare spending, but the PTAC recognizes that many individuals and entities who wish to submit proposals may face difficulties in obtaining the data needed to analyze spending impacts, and that in some cases, the data that would be desirable for analysis do not exist or cannot be obtained at a feasible cost. If a submitter is unable to include all of the analyses needed to show the impacts of their proposal, the proposal should describe the types of analyses that would be desirable and the efforts the submitter made to obtain the necessary data to complete those analyses. If the Preliminary Review Team is able to assist the submitter in obtaining the data needed to complete the analyses, it may request that the submitter complete and submit analyses using those data before further action is taken on the proposal.
 - e. Soliciting Public Comment. If the Preliminary Review Team feels that its questions and concerns about a proposal can be addressed without requiring submission of a new application, PTAC staff will post the proposal on the PTAC website and request public comment. In general, 3 weeks will be allowed for submission of public comments on a proposal. The PTAC will not formally respond to individual public comments, but it will consider the comments in making its decisions.
 - f. Report of the Preliminary Review Team. Based on its own review and the comments submitted by the public, the Preliminary Review Team will submit a written report to the full PTAC containing (a) its findings as to whether and how the proposal meets each of the criteria the PTAC is using to evaluate proposals and (b) a draft of what the PTAC should recommend to the Secretary of HHS regarding the proposal. This report will be completed within 2 weeks after the later of:
 - i. The close of the public comment period, and
 - ii. The date on which a response is received from the submitter with answers to the questions and additional information requested by the Preliminary Review Team.

Phase III: Full Committee Review

- 8. Public Meeting Deliberation and Recommendation: The PTAC will decide on its recommendation regarding a proposal during a public meeting.**
- a. Scheduling of Proposal Consideration. A proposal will be scheduled for consideration at a public meeting of the PTAC within 30 days after completion of the Preliminary Review Team's review or as soon thereafter as possible. The individual or entity that submitted a proposal will be notified of the date of the meeting and invited to attend. If requested by the submitter, the PTAC will defer consideration of the proposal to a future meeting so that the submitter can attend the scheduled meeting.
 - b. Order of Consideration. In general, proposals will be considered in the order in which the Preliminary Review Teams complete their work, but if the volume of proposals is high, priority will be given to proposals that address types of patients, types of physicians, and aspects of healthcare delivery, spending, and quality that are not adequately addressed by existing payment models and to proposals that would meet MACRA requirements for alternative payment models. If multiple proposals are submitted that have similar goals or approaches, they may be reviewed as a group. Proposals that have been resubmitted and that adequately address comments made by the Preliminary Review Team will also be given priority consideration.
 - c. Review and Preparation for Discussion by PTAC Members. Each PTAC member will receive a copy of the full proposal, any public comments submitted on the proposal, and the report of the Preliminary Review Team at least two weeks in advance of the PTAC meeting when the proposal will be discussed. If any member requests it, a preparatory phone call or meeting will be scheduled with the Preliminary Review Team to enable PTAC members to ask questions about the findings of fact in the Preliminary Review Team's report. If such a call or meeting is scheduled, the members of the PTAC will not discuss the Preliminary Review Team's proposed recommendations during the call or meeting. Discussions and decisions by the full PTAC about the merits of a proposal will only take place during a public meeting.
 - d. Remedies for Conflict of Interest and Lack of Impartiality. Before discussion of a proposal, the Committee will identify any conflicts of interest or concerns about lack of impartiality regarding any of the members and decide on an appropriate remedy.
 - e. Report of the Preliminary Review Team. The lead reviewer from the Preliminary Review Team will make a brief presentation to the PTAC that (i) summarizes the proposal, (ii) describes the Team's assessment as to whether the proposal meets each of the criteria being used by the PTAC, and (iii) proposes what the PTAC should recommend regarding the proposal.

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- f. Discussion by the Committee. Those members of the Committee who are not recused from participation will have the opportunity to (i) ask questions of the Preliminary Review Team, (ii) ask questions of the individual or entity that submitted the proposal, if they are in attendance, and (iii) propose an alternative recommendation for the Committee to make.
 - g. Decision by the Committee. At the conclusion of the deliberation period, the members of the Committee who are in attendance and who are not recused from voting will make a decision as to whether the proposal under consideration meets the criteria established by the Secretary of Health and Human Services and whether to recommend that the proposal be implemented. The PTAC may also decide that additional information or analyses are needed before a recommendation can be made, in which case the proposal will be tabled. A proposal will only be recommended to the Secretary of HHS if the decision is supported by a two-thirds or greater majority of the PTAC members who are in attendance and eligible to vote.
- 9. Follow-Up on PTAC Decisions: The PTAC will submit its comments and recommendations to the Secretary of Health and Human Services and make them available to the public.**
- a. Reports on Proposals. Following a decision by the PTAC, the lead reviewer from the Preliminary Review Team and PTAC staff will prepare a report summarizing the proposal, the Committee's evaluation of how the proposal meets the criteria for PFPMs, and its recommendation to the Secretary. This report will be reviewed and approved by the members of the Committee prior to being finalized. The report will be submitted to the Secretary of HHS and it will also be posted on the PTAC website. Reports on proposals receiving a favorable recommendation by the PTAC will be submitted and posted within 2 weeks after the PTAC decision is made; other reports will be submitted and posted within 30 days.
 - b. Requests for Reconsideration of PTAC Decisions. If a proposal is not recommended by the PTAC, the submitter can revise and resubmit the proposal, and it will be reviewed through the same process used for the original submission. Priority will be given to processing those resubmitted proposals that provide a clear indication that they have been revised to explicitly address the reasons that the PTAC indicated the proposal did not meet a particular criterion.