Physician-Focused Payment Model Technical Advisory Committee

Physician-Focused Payment Models:

PTAC Proposal Submission Instructions

Revised November 16, 2018

TABLE OF CONTENTS

A. Introduction

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created new ways for the Medicare program to pay physicians for the care they provide to Medicare beneficiaries. MACRA also created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) as a means to: 1) solicit (and obtain expert review of) proposals from individuals and stakeholder entities for new Medicare physician-focused payment models (PFPMs); and 2) provide expert comments and recommendations on these proposals to the Secretary of Health and Human Services (HHS). This document describes how individuals and stakeholder entities may submit proposals for new PFPMs to PTAC, and how best to craft these proposals to assist PTAC in its timely and effective review of submitted proposals. It also provides an overview of the processes PTAC uses to review proposals.

B. How to Submit a Proposal

Who May Submit a Proposal. Any individual or organization may submit a proposal. There is no limit on the number of proposals that a stakeholder may submit.

When a Proposal May Be Submitted. Stakeholders who are planning to submit a proposal to PTAC first must submit a nonbinding letter of intent (LOI) at least 30 calendar days in advance of submitting a proposal. Instructions for submitting LOIs are found on the PTAC website. After this 30-day period, stakeholders may submit the corresponding proposal at any time; submissions will be accepted on an ongoing basis.

If no proposal is received within six months after submission of a LOI, the LOI will be considered to be "expired," and it will be necessary to submit a new LOI at least 30 calendar days in advance of submitting a corresponding proposal. The new LOI may have the same content as an expired LOI.

How to Send a Proposal to PTAC. Proposals must be submitted to PTAC electronically in either PDF or MS Word format. Additional information in MS Excel files may also accompany MS Word submissions. Proposals are submitted to PTAC by uploading them to the PTAC's submission system website. A guide on how to upload proposals to the submission system website is available on the PTAC website. Submitters may contact PTAC@hhs.gov with any questions about uploading their proposals. Staff who work at the Office of the Assistant Secretary for Planning and Evaluation (ASPE) support the PTAC and will respond to any questions.

C. How to Describe Your Proposal

Submitters may organize and present their proposal in the manner they believe is most clear, concise, and effective. However, based on the first two years of PTAC work, PTAC has found that the most effective proposals are those that clearly describe:

1. At the beginning of the proposal, the payment problem(s) that the proposal is aiming to address;

2. 2. Why the payment problem(s) cannot be fixed under existing Medicare payment rules and procedures or why it is undesirable to try and do so.

3. The proposed ***payment model*** in as much detail as possible. (This is different from the anticipated or proposed changes in the ***care model*** that are expected to result from or be implemented along with changes in payment.) Effective descriptions of payment models specify:

    a. The entity that will receive the Medicare payment from the Centers for Medicare & Medicaid Services (CMS), and how the funds from payment will be distributed to eligible professionals, the patient's primary care provider, and other providers (including hospitals, post-acute care providers, etc.) who would participate in or be affected by the model.

    b. The types of patients who would be eligible for the payment.

    c. How the payment model will resolve the payment problems.

    d. The financial incentives the payment model will create and any evidence of their effectiveness.

4. The anticipated effects of the payment model from the perspective of the beneficiary, including effects on patient choice, quality and safety of care, and care coordination.

5. Any changes in patient care that are required in order to receive the payment and the types of changes in care that are expected to result.

6. The savings for the Medicare program that are expected to result and how the effects of the proposed payment model on cost and quality can be evaluated.

7. How the proposal will satisfy each of the Secretary's ten criteria for PFPMs (see Section E, below).

PTAC suggests that the above seven items can be used by submitters as an outline for their submitted proposals, but underscores that PTAC wishes to give maximum flexibility to submitters to organize and present their proposals in the way in which each submitter believes it can most clearly, concisely, and effectively describe its proposed PFPM. PTAC is statutorily required to evaluate the proposal against the Secretary's ten criteria, so regardless of the way in which the proposal is structured, submitters should be sure to point out where information relevant to each of the ten criteria is located.

D. Administrative Requirements for Proposals

Regardless of the manner in which a submitter chooses to organize its proposal, all proposals must:

1. Include a One-page Transmittal Letter from the Submitter

   If the submitter is an organization, a letter of support from the governing board or responsible officer also is required, unless the individual submitting on behalf of the organization clearly serves in that capacity (e.g., CEO). This letter will not count against the page limit discussed below.

2. Include a Cover Page

   Proposals must include a cover page that provides: the title of the proposal; the name and address of the submitting individual or organization; and the name, mailing address, phone number, and e-mail address of the primary point of contact for the proposal. This information will not count against the page limit discussed below.

3. Include an Abstract and Table of Contents

   The proposal must include a one-page abstract and a table of contents. This information will not count against the page limit discussed below.

4. Adhere to Prescribed Formatting for the Main Body of the Proposal

   Submitters must use standard letter paper size (8.5" x 11"). All text should be no less than 12-point font, with one-inch margins and single-spaced lines. Pages should be numbered. Graphics and tables may be included. The main body of the proposal should not exceed 25 pages, excluding any citations and appendices. Citations may be included as endnotes; any style that enables clear identification of the source material is acceptable.

5. Use Appendices as Needed

Essential information must be covered in the main body of the proposal. Supplemental information and information that is useful in elaborating on the model's design (e.g., detailed specifications for quality measures to be used in the model) may be included in appendices. The appendices do not count toward the page limit, but submitters should understand that all PTAC members may not be able to review the material in the appendices. Letters of support (if included) should be placed in appendices.

E. How PTAC Evaluates Submitted Proposals

As directed by section 1868(c) of the Social Security Act, PTAC evaluates submitted proposals using criteria for PFPMs established by the Secretary of HHS. These criteria are specified in federal regulations at 42 CFR § 414.1465. PTAC conducts its evaluations by reviewing information submitted as part of each proposal.

To help all submitters put forth their best evidence about how their proposal will satisfy the Secretary's criteria, each of the 10 criteria and corresponding types of descriptive information that could be included in a description of a proposed model are listed below. PTAC does not expect each proposal to include all of the information listed under each criterion (as all of these items will not be relevant to every proposal), so as an aid to submitters, the information elements that PTAC believes are essential for all submitted proposals to address are distinguished from information elements that individual submitters, using their own judgment, might find relevant to their proposals and helpful to address. Proposals may also include other information not listed below that explains how the proposed model meets the Secretary's criteria. Finally, PTAC recognizes that some types of information may apply to more than one criterion, and if so, it is acceptable to cross-reference sections in order to avoid repetition.

Criterion 1 of 10. Scope (High-Priority Criterion[*]): Aim to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

The goal of this section is to provide PTAC with a sense of the overall potential impact of the proposed model on physicians or other eligible professionals and beneficiary participation.

Essential Descriptive Information:

- What payment problem is the proposal aiming to address?

[*]Criteria designated as "high priority" are those PTAC believes are of greatest importance in the overall review of the payment model proposal.

- Why can this payment problem not be fixed under existing Medicare payment rules and procedures, or why would that be undesirable?
- What types and numbers of physician or other eligible professionals' practices would be able to participate in this payment model?
- Are there any alternative payment models (APMs) already available for these practices to participate in, and why do those APMs not address the goals of this proposal?
- What are the size and characteristics of the beneficiary population anticipated to benefit from the model?

Optional Information Items if Relevant:

- Has the payment model been implemented by other payers, and if so, what was the experience?

NOTE: <u>PTAC is not likely to recommend to the Secretary payment models that:</u>

1. Are targeted to a single health care provider, facility, institution, or system. Parties submitting proposed PFPMs to PTAC should present information in their proposal explaining how the PFPM submitted to PTAC would be feasible for implementation by multiple health care providers, facilities, institutions, or systems, as appropriate.

2. Require use of proprietary tools or tools that are not already developed. In prior responses from the Secretary of HHS to PTAC reports on submitted models, HHS has communicated concerns about proposed models that require the use of specific proprietary products. Because HHS cannot endorse, promote, or rely on a unique product, submitters should be aware that to the extent that a proposed model requires such use of proprietary tools, this will significantly reduce the likelihood that PTAC will recommend implementation of the proposed model.

<u>Criterion 2 of 10. Quality and Cost (High-Priority Criterion)</u>: The proposal is anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.

The goal of this section is to better understand the "value proposition" that will be addressed by the proposed PFPM.

Essential Descriptive Information:

- How much savings is expected, and how will the savings be achieved?

- What aspects of the quality of care will be improved?
- If the goal is to achieve savings, what will be done to assure the quality of care does not decrease in areas where spending decreases?
- What measures of quality and spending will be used? How will these be collected, and how will changes be assessed?
- What current barriers exist to achieving the desired savings/quality goals, and how would these be overcome by the payment model?

Optional Information Items if Relevant:

- What approach will be used to develop any innovative metrics proposed for inclusion in the model, such as specialty-specific measures or patient-reported outcome measures? How will this approach leverage existing measures, standards, value sets, etc.?
- What data sources will be used to support total cost of care, resource utilization, or clinical quality metrics?
- How will participants receive timely feedback on performance measures?
- Have any analyses been performed to estimate the impact of the model on spending and quality of care?

<u>Criterion 3 of 10. Payment Methodology (High-Priority Criterion)</u>: Pay APM Entities with a payment methodology designed to achieve the goals of the PFPM criteria. Addresses in detail through this methodology how Medicare and other payers, if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the Physician-Focused Payment Model cannot be tested under current payment methodologies.

The goal of this section is to better understand the payment methodology for the proposed model, including how it differs from both existing payment methodologies and current alternative payment models.

Essential Descriptive Information:

- What types of entities would receive payment from Medicare under the APM?
- How would the amounts of payment be determined under the proposed model? How would performance on spending or quality measures affect the payment?
- How would the payments flow from the initial payment recipient to other individual physicians, eligible professionals, hospitals, or other providers or suppliers? (Diagrams accompanied by text are helpful.)
- How does the proposed payment methodology differ from current Medicare payment methodologies/Center for Medicare and Medicaid Innovation (CMMI)

models for physicians or other eligible professionals, and why can it not be tested under current payment methodologies/CMMI models?

- What degree of financial risk will the entity and physicians or other eligible professionals bear as a consequence of this proposed model (e.g., will physicians be at financial risk for their portion of care within the framework of the model, and how will this be determined)?
- Will payments be risk adjusted? If yes, what methodology will be used for risk adjustment? Will any other limits on financial risk be used?
- What is the role of physicians or other eligible professionals in setting and achieving the target levels of performance under the payment model?

Optional Information Items if Relevant:

- Will the proposed model include other payers in addition to Medicare, and if so, is a different payment methodology needed for those payers?
- Where relevant, how will the model ensure:
  - eligibility of patients is accurately determined, and patients are not excluded inappropriately?
  - the accuracy and consistency of identification/coding of diagnoses/conditions?
  - the appropriateness of any service or procedure for which payment would be made?
  - services are accurately assigned to the correct episodes of care?
- Are you aware of any barriers that exist in state or federal laws or regulations to implementing the payment model (such as current coverage limitations in Medicare or state-specific scope-of-practice limitations)?
- If the payment will be made to an entity other than a physician practice or entity that is owned by physicians or other eligible professionals:
  - What role will physicians or other eligible professionals play in implementing the PFPM payment methodology?
  - Would there be any requirements for how physicians and other eligible professionals who will be compensated through the PFPM would be involved in the governance of the organization or entity?
  - How would payments or incentives for the individual physicians and other eligible professionals who are part of the organization or entity change?
  - How would the payments or incentives for individual physicians and other eligible professionals encourage high performance on the accountability measures that are part of the PFPM?

NOTES:

1. In general, PTAC will only recommend PFPMs that directly affect the method and/or amount of payments for one or more services delivered, ordered, managed, or coordinated by one or more types of physicians or other eligible professionals. If a proposed payment model would change the method and/or amount of payments to both physicians/eligible professionals and other types of health care providers (e.g., hospitals, home health agencies, skilled nursing facilities), PTAC will be more likely to recommend the model as a PFPM if a substantial portion of the payment supports services that are delivered or ordered by physicians or other eligible professionals.

2. In general, PTAC will be unlikely to recommend a proposed PFPM if the only change it makes is to give a physician or other eligible professional the ability to bill for a single type of service that is not currently eligible for payment under the Medicare Physician Fee Schedule or to alter the fee level for a service that is currently billable, particularly if there is no change in the measures or methods of accountability that would otherwise apply under MIPS. There is already a process for proposing and making these types of changes through the regulations governing the Medicare Physician Fee Schedule.

<u>Criterion 4 of 10. Value over Volume</u>: Provide incentives to practitioners to deliver high-quality health care.

The goal of this section is to better understand how the model is intended to affect practitioners' behavior to achieve higher-value care through the use of payment and other incentives. PTAC acknowledges that a variety of incentives might be used to move care toward value, including financial and nonfinancial ones.

Essential Descriptive Information:

- Will incentives (financial or nonfinancial) be used to encourage physicians and other eligible professionals to deliver high-value health care? If yes:
  - What are these incentives? Be sure to indicate whether the incentives are financial or nonfinancial.
  - Why do you believe these incentives will influence physicians or other eligible professionals' behavior?
  - Has the submitter had prior experience with the use of these incentives? If yes, what have been the effects (both beneficial and adverse)? Were there any unintended consequences of the use of these incentives?

<u>Criterion 5 of 10. Flexibility</u>: Provide the flexibility needed for practitioners to deliver high-quality health care.

The goal of this section is to better understand the extent to which the model provides practitioners with flexibility to deliver high-quality health care.

Essential Descriptive Information:

- How would the model provide practitioners with flexibility to deliver high-quality health care?
- Would the model restrict or discourage the use of services that practitioners are currently able to use?

Optional Information Items if Relevant:

- To what extent will participation in the model impose new operational burdens and reporting requirements on practitioners?
- To what extent can the proposed model be successfully used in the full range of clinical settings where eligible patients receive care (e.g., rural physicians and/or patients, physicians in a tertiary/quaternary setting, specific subgroups of patients, etc.)?
- Are there methods for updating the proposed model to account for changing technology, including new drug therapies or devices?
- How will model participants prepare and build any new infrastructure needed to implement the proposed model?
- To what extent would the proposed model require changes in workforce compared to more traditional arrangements?

<u>Criterion 6 of 10. Ability to Be Evaluated</u>: Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

The goal of this section is to describe the extent to which the proposed model can be evaluated.

Essential Descriptive Information:

- What are the evaluable goals of the proposed PFPM for various types and levels of participants (e.g., Medicare program, APM entity, patient population, provider entity, individual physicians)?
- How can the impact of the PFPM on these goals be evaluated?
- What difficulties are anticipated in conducting such an evaluation, and how might these be overcome?

Optional Information Items if Relevant:

- Are there any evaluations of the proposed care model or payment model under development or underway or that have been conducted? If yes, identify these evaluations and how they may be accessed.

<u>Criterion 7 of 10. Integration and Care Coordination</u>: 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 goal of this section is to understand the extent to which integration and care coordination among practitioners and across settings would likely be achieved by the proposed model.

Essential Descriptive Information:

- What types of organizations and individual practitioners (physicians, non-physicians, and other eligible professionals) would need to be involved in the implementation of this model in order to achieve desired outcomes?
- How would the model support integration and care coordination of these organizations and practitioners?
- How will the model encourage and support coordination with organizations and practitioners that are not directly participating in the payment model?

<u>Criterion 8 of 10. Patient Choice</u>: Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

The goal of this section is to describe how patient choice and involvement will be integrated into the proposed PFPM, along with attention to population health.

Essential Descriptive Information:

- Who is the targeted patient population that this proposed payment model intends to serve, and what are their clinical and health needs?
- How does the design of this model reflect and address the clinical, social, and demographic characteristics of this target population?
- How is individual patient choice preserved under the model?
- How will the unique needs and preferences of individual patients be respected and addressed?

Optional Information Items if Relevant:

- Would the payment model reduce disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and/or geography?

- Would the payment model expand the number or types of patients who can receive services supported by APMs (e.g., would the proposed payment model address populations that are not currently addressed in current CMMI models)?

<u>Criterion 9 of 10. Patient Safety</u>: Aim to maintain or improve standards of patient safety.

The goal of this section is to describe how patients would be protected from any adverse unintended problems in health care delivery brought about by changes in payment methodology and provider incentives.

Essential Descriptive Information:

- Are there any risks of unintended consequences for beneficiaries? If so, how would beneficiaries be protected against these potential concerns (e.g., denial of needed care, overutilization, or less than optimal patient outcomes)?
- What measures would be used to ensure the provision of necessary and appropriate care and to monitor for any potential stinting of care?

Optional Information Items if Relevant:

- How will disruptions in care transitions and care continuity be addressed for patients participating in the model?

<u>Criterion 10 of 10. Health Information Technology</u>: Encourage use of health information technology to inform care.

The goal of this section is to understand the role of information technology in the proposed payment model and the extent to which the model encourages use of health information technology to inform care.

Essential Descriptive Information:

- Will the use of information technology be required as part of the payment model?
- Will use of information technology be necessary to succeed under the model?
- To what extent is the type of information technology that will be required or needed readily available to the providers who would be expected to participate?

Optional Information Items if Relevant:

- Will the measures of quality used in the model be derived from electronic health records (EHRs)?
- Describe any information technology innovations in the model that will improve outcomes, consumer experience, and/or the efficiency of care delivery.

- How would patients' privacy be protected if new providers or caregivers will have access to personal health information (PHI)?
- Will the proposed model require greater interoperability of EHRs than exists today? If so, how?
- How will any health IT requirements included in the model ensure that clinicians have the flexibility to choose from a variety of solutions to meet their needs and leverage existing technology assets where possible?

F. After a Proposal Is Submitted

1. Administrative Review

Once a proposal is submitted through PTAC's online submission system, the proposal is reviewed by ASPE PTAC staff to ensure that it meets all of the administrative requirements specified in Sections B and D above, as shown in the Submission Checklist below. If a proposal is incomplete or non-adherent to some requirements, ASPE PTAC staff will return the proposal to the submitter for revision. Submitters can resubmit the revised proposal at their convenience (as long as it is within six months of the LOI) and without penalty.

Proposal Submission Checklist

Requirement	Yes / No Comments if "No"
Letter of intent submitted ≥30 days before the proposal.	
Proposal includes a one-page transmittal letter from the submitter.	
If submitter is an organization, a letter of support from the governing board or responsible officer is included, unless the individual submitting on behalf of the organization clearly serves in that capacity (e.g., CEO).	
Proposal includes a cover page that includes the: • title of the proposal • name and address of the submitting individual or organization • name, mailing address, phone number, and e-mail address of the primary point of contact for the proposal	
Proposal includes a one-page abstract.	
Proposal includes a Table of Contents	
Proposal meets formatting requirements: • Proposal is submitted on standard letter paper size (8.5" x 11"). • All text is no less than 12-point font, with one-inch margins and single-spaced lines. • Pages are numbered.	

2. Communications with PTAC and ASPE PTAC Staff

Within one week of receiving a proposal, ASPE PTAC staff will email the submitter to either acknowledge receipt of a proposal that meets the administrative requirements or communicate

the extent to which a proposal did not meet the above administrative requirements. Subsequent to this initial email, all submitter communications with PTAC (with two exceptions) will be with ASPE PTAC staff as opposed to with PTAC members. The two exceptions are:

a. When a PTAC Preliminary Review Team (PRT) holds a conference call with a submitter to obtain clarification of certain aspects of a proposal in "real time"

b. When the full PTAC talks with a submitter at a public meeting at which the PTAC deliberates on a submitted proposal

Other than these two occasions, email is the primary form of communication between PTAC and a submitter. Submitters can communicate with ASPE PTAC staff about their proposal through the following email address: PTAC@hhs.gov and may also reach the ASPE PTAC staff by telephone at (202) 690-6870. Office hours are Monday through Friday, between 9:00 a.m. and 5:00 p.m. (EST).

3. Solicitation of Public Comments on Each Submitted Proposal

Once a submitted proposal is found to have met the administrative requirements, it is posted in its entirety on the ASPE PTAC website for a three-week public comment period. An announcement of the proposal submission, a website link to the proposal, and a deadline for public comments are distributed through the PTAC listserv.

After the public comment period closes, the submitted comments are compiled by ASPE PTAC staff and sent to the PTAC members for consideration during the evaluation of the proposal. Submissions received after the public comment period closes are accepted, although PTAC members are not required to read them prior to evaluating the proposal.

All public comments received are also posted on the ASPE PTAC website, in a section titled "Public Comments," under the proposal to which they relate.

4. Preliminary Review of the Proposed Model

Simultaneous to solicitation of public comments, a Preliminary Review Team (PRT) consisting of a subset of PTAC members is appointed by PTAC's Chair and Vice Chair. Each PRT typically consists of three PTAC members; at least one is a physician. A PRT Staff Lead also is assigned to work with the PRT. The role of the PRT is to conduct a preliminary evaluation of the proposal

and write a draft report to the full PTAC for use in the full PTAC's review and public deliberation on the submitted proposal.

As it conducts its work, a PRT may identify a need for additional information to better understand the proposed model:

- If additional information from the submitter is needed, a request will be sent to the submitter from the PRT Staff Lead via the following email address: PTAC@hhs.gov. The PRT will decide, on a case-by-case basis, the most efficient and effective way to obtain this information; e.g., a written response, telephone discussion, face-to-face meeting. While a specific deadline may not be given, the time the submitter takes to respond may delay the remainder of the review process and, therefore, extend the timeline in which deliberation and voting by the full PTAC can be completed.
- The PRT will also determine whether it needs additional information from parties other than the submitter, and if so, it may seek such additional information from clinical consultants, subject matter experts, and/or data analyses.

Any additional information obtained by the PRT will be posted to the ASPE PTAC website under the "Additional Information and Analyses" section for the specific proposal to which it relates. Such information is posted three weeks prior to the public meeting at which the full PTAC will deliberate and vote on the proposal.

Using the proposal, all additional information or analyses gathered, and any public comments received, PRT members will evaluate the proposal and determine the extent to which the criteria promulgated by the Secretary in regulations at 42 CFR § 414.1465 are applicable to the proposal. For those proposals to which the PRT determines the Secretary's criteria apply, the PRT will determine for each criterion whether it believes the proposal:

a. Does not meet the criterion
b. Meets the criterion
c. Meets the criterion and deserves priority consideration.

If all of the members of the PRT do not agree on how to evaluate the proposal on one of the criteria, the PRT report will describe the nature of the disagreement. The PRT may also provide initial feedback to the submitter on the proposal as described in section 5 below.

The time required for PRT review varies and is contingent upon several items. These items include, but are not limited to, the volume of proposals currently under review by PTAC, the submitter's availability to respond to requests for additional information, the availability of clinical and/or subject matter experts, and/or the time needed to analyze data or complete

other research.

After completing its review, the PRT summarizes its review and recommendations in a written report to the full PTAC, known as the PRT Report, which:

- Contains a qualitative rating for each of the Secretary's 10 criterion
- Provides a rationale for the PRT's qualitative rating for each criterion
- Highlights overall strengths and weaknesses of the proposal as determined by the PRT
- States the PRT's recommendations and explains the basis for the recommendations (which may include results of analyses conducted or information obtained from clinical or subject matter experts)

The PRT Report is posted to the ASPE PTAC website at least three weeks prior to the public meeting at which the full PTAC plans to deliberate and vote on the proposal.

5. Initial Feedback

Section 1868 (c)(2)(C) of the Social Security Act enables PTAC to provide initial feedback to submitters of proposed models regarding the extent to which such models meet the Secretary's criteria and an explanation of the basis for the feedback. PTAC has determined that the PRT that is reviewing a proposal will determine, at its discretion, whether to provide initial feedback on a proposal. No initial feedback will be provided by the PTAC other than through this PRT, and the PRT may choose not to provide initial feedback on a proposal. Also, a submitter may choose not to receive initial feedback.

Initial feedback, when given, will consist of: 1) an assessment of whether the proposed model meets the Secretary's criteria, and 2) "an explanation of the basis for the feedback." As such, 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.

As part of providing initial feedback, PTAC and PTAC PRT members will ***not*** provide:

- Instructions to the submitter on how to remedy or fix any identified shortcoming(s)
- Data or analyses whose only purpose is to aid further development of a proposal
- Individualized consultation by themselves or through a consultant
- Technical assistance in the development of the proposed model

Initial feedback always will be provided to the submitter in writing and will be posted to the PTAC section of the ASPE PTAC website as part of PTAC's public record of its review of the proposal, including any supporting data the PRT used to inform its feedback. If a PRT subsequently holds a conference call with the submitter, the initial feedback already given may be reviewed, and a transcript of that call will be made public.

It is important to note that:

- Initial feedback represents the opinions of the PRT only 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.
- 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 HHS.

Submitters who do not wish to receive initial feedback should notify the PTAC staff.

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

- Make no change to the submitted proposal and make no response to the PRT
- Make no change to the submitted proposal but respond to the PRT in writing
- Withdraw the submitted proposal
- Revise and resubmit the proposal to PTAC

Submitters who choose to respond to the initial feedback or formally revise and resubmit their proposal to PTAC should be aware that these actions may lengthen the amount of time it takes for PTAC to review, deliberate on, and vote on the submitted proposal. PTAC encourages submitters to withdraw, revise, and resubmit proposals when key elements of the proposal are changed following submission or when the proposal would benefit from significant clarification. Revising and resubmitting the proposal ensures that PRT and PTAC members act on a complete submission.

PTAC discourages submitters from proposing changes at the public meeting or immediately prior to the public meeting because PTAC members need sufficient time to review and reflect upon the final proposal prior to deliberation and voting, and because PTAC would be unable to obtain public comments on such changes prior to its vote. Without such opportunities to review

and reflect upon the final proposal prior to deliberation and voting and to obtain public comments on proposed changes to the model, PTAC may choose to base its vote on the proposal as it was originally submitted (i.e., without the proposed changes). As indicated below, responses to the PRT report should be submitted at least 5 business days prior to the PTAC meeting.

6. Submitter's Response to the PRT Report

Submitters will receive a copy of the PRT Report on their proposed model no later than 24 hours prior to its dissemination and posting to the ASPE PTAC website. This posting typically occurs three weeks prior to the PTAC meeting at which the PTAC will deliberate on the proposal. The PRT Report is not binding on the PTAC, and PTAC may reach different conclusions from those reached by the PRT members. Submitters may provide a written response to the PRT Report. This written response should be submitted by email to ASPE PTAC Staff at PTAC@hhs.gov no fewer than five business days prior to the public meeting at which the proposal is scheduled to be reviewed. Responses submitted subsequent to this deadline may be accepted; however, the PTAC members may not be able to review the information and incorporate it into their deliberations.

7. PTAC Deliberations on Proposals

In compliance with the Federal Advisory Committee Act (FACA), all PTAC deliberations on submitted proposals must take place at public meetings. PTAC holds these public meetings quarterly, typically in March, June, September, and December of each year.[†] Meetings are held in Washington, DC, typically at the following location:

U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Great Hall
200 Independence Avenue, SW
Washington, DC 20201

Submitters are advised in writing of the public meeting at which their proposal is expected to be deliberated and voted on. ASPE PTAC staff will work with the submitter to determine a mutually agreeable time frame within the meeting schedule for their proposal's review, although an exact start time for the review of each proposal cannot be guaranteed because the

[†] The dates of PTAC meetings, and related information, are posted on the ASPE PTAC website. In addition, advance notice of public meetings is published in the Federal Register, and meeting announcements are distributed through the PTAC listserv.

length of time that PTAC will need to deliberate on each proposal in the meeting's agenda cannot be known precisely.

Submitters have the option of attending the meeting in person or via teleconference. Representatives joining by teleconference will be given a dedicated conference line for speakers (separate from the general participation teleconference line). The dedicated conference line will be opened at the start of the segment for the submitter's statement and questions and answers. Submitter representatives will be able to participate freely during this period. Representatives joining by telephone are encouraged to monitor the status of the meeting through the live video stream or general participant's teleconference line so that they will know when their proposal review is beginning. It is also recommended that representatives joining by telephone remain in communication with representatives from their organization who are attending in person in order to coordinate participation.

On the scheduled day of proposal review, submitters have the option of making a public statement to PTAC for up to 10 minutes. Submitters' statements to PTAC are a verbal address only and do not allow for the use of PowerPoint slides or other media. In these statements, submitters are advised to focus their comments and discussion on the findings and conclusions of the PRT Report. In addition to the 10-minute statement to the PTAC, submitters are requested to be available to answer any questions posed by the PTAC members. Submitters are encouraged to limit the number of representatives addressing the PTAC during the 10-minute statement. A maximum of six representatives should be identified, including those who may answer the PTAC's questions. Additional representatives are welcome to attend the meeting in person, via teleconference, or to view the live video stream.

While the average time PTAC takes to deliberate and vote on each proposal is two to three hours, the length of time for completing the deliberation and voting process varies and submitters should expect to be available the entire day on which their proposal is being deliberated and voted on. Understanding that submitters may choose to travel to Washington, DC to attend the meeting in person, every effort will be made to complete deliberations and voting related to a given proposal within the scheduled day, although PTAC cannot guarantee this.

Prior to the public meeting, each PTAC member will have independently reviewed the submitted proposal, along with all supplemental information (including public comments, analyses, any initial feedback, the PRT Report, and the submitter's response to the PRT, if applicable). At the public meeting, the PRT will present its findings to the full Committee, the submitter will be provided the opportunity to make a public statement and respond to any questions from Committee members, and the Committee will hear comments from the public. After this process, PTAC members will deliberate and score the proposal on each criterion

established by the Secretary of HHS. Voting will occur with the use of electronic voting technology, which will compile and display results on the projection screen.

After rating each proposal on each individual criterion, each PTAC member will vote to place the proposal into one of the following recommendation categories:

PTAC RECOMMENDATION CATEGORIES

- **Not Recommended for Implementation as a PFPM.**
- **Recommended**
    a. Proposal substantially meets Secretary's criteria for PFPMs. PTAC recommends implementing the proposal as a payment model.
    b. PTAC recommends further developing and implementing the proposal as a payment model as specified in PTAC comments.
    c. PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.
    d. PTAC recommends implementing the proposal as part of an existing or planned CMMI model.
- **Referred for Other Attention by HHS**

A two-thirds majority of votes is required to determine the final recommendation to the Secretary of HHS.

Recordings of past PTAC meetings, including all voting and deliberation procedures are available on demand on the HHS YouTube channel. Video recordings are made available approximately one month after each public meeting.

8. Report to the Secretary of HHS

After the voting and deliberation portion of the meeting, PTAC will decide on topics to highlight in the Report to the Secretary of HHS. ASPE PTAC staff, in consultation with the full PTAC, will then draft the report, reflecting the voting results and the rationale for the recommendation. Reports to the Secretary of HHS are typically transmitted four to six weeks following a public meeting; however, there is no statutory timeline for this transmission. Once available, reports to the Secretary of HHS are posted on the ASPE PTAC website. Submitters are notified by email, typically 24 hours prior to the report's posting to the website.

MACRA requires the Secretary of HHS to review PTAC's comments on proposals and to post a detailed response to those comments and PTAC's recommendations. The Secretary's Response is posted on the CMS website. The timeline for posting the Secretary's Responses is not mandated in law.

The Secretary's Responses are also posted to the ASPE PTAC website. Examples of each of these documents can be found on the ASPE PTAC website, within the Proposal Submissions tab, under the header entitled Reports to the Secretary. In addition, Reports to the Secretary are posted under the proposal to which it relates, also under the Proposal Submissions tab.

9. Withdrawal and Potential Resubmission of a Submitted Payment Model

A submitter may withdraw a proposal for a PFPM submitted to PTAC at any time prior to the PTAC's vote on the proposal at the public meeting. The PTAC will not send any comments or a recommendation to the Secretary on any proposal that is withdrawn prior to PTAC's voting. Once PTAC begins voting on a proposal, PTAC will complete its voting and transmit its comments and recommendation to the Secretary in accordance with PTAC's mandate from MACRA.

After a proposal has been withdrawn, a party may resubmit the proposed PFPM to PTAC at any time. A new LOI is not required for the resubmission as long as the resubmission occurs within six months. To the extent that the schedules of PTAC members allow, a resubmitted proposal will be assigned to the same PRT members who evaluated the initial proposal submission.

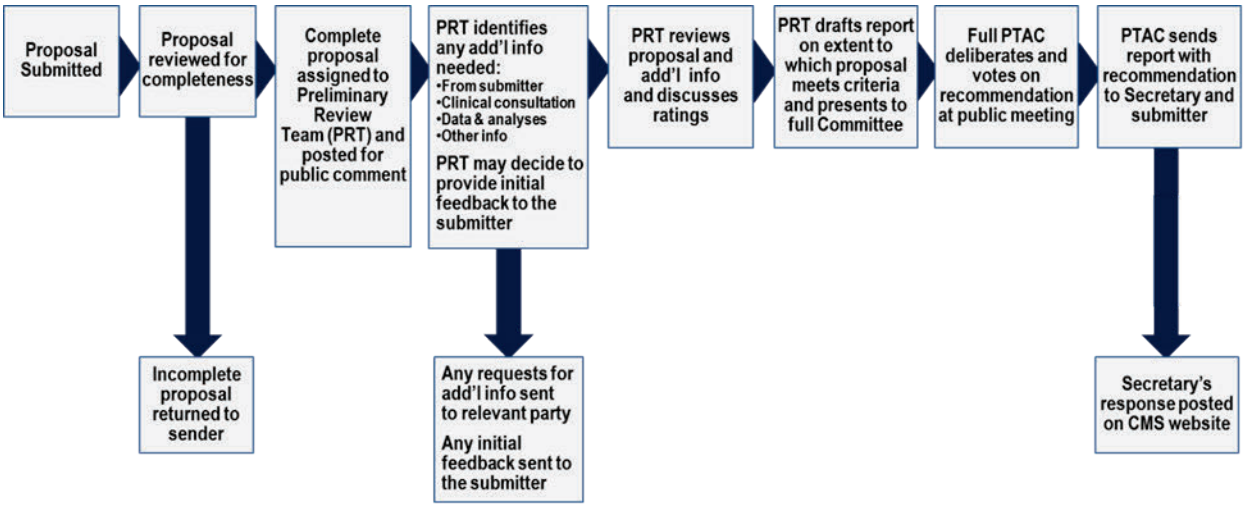
10. Appeals Process

There is no appeal of PTAC determinations and recommendations to the Secretary provided for in statute.

11. Summary

PTAC's proposal receipt, evaluation, and recommendation process is summarized in the graphic below.

PTAC PROPOSAL RECEIPT, EVALUATION AND RECOMMENDATION PROCESSES



G. Appendices

1. Physician-Focused Payment Models: Key Statutory and Regulatory Language

Physician-Focused Payment Model Technical Advisory Committee (PTAC) Duties Defined. Section1868(c)(2) of the Social Security Act defines PTAC duties as:

> "(B) Stakeholder submission of **physician-focused payment models**. — On an ongoing basis, individuals and stakeholder entities may submit to the Committee proposals for physician-focused payment models that such individuals and entities believe meet the criteria described in subparagraph (A)." [Subparagraph A refers to the Secretary's CRITERIA FOR ASSESSING PHYSICIAN-FOCUSED PAYMENT MODELS. EMPHASIS ADDED]
>
> (C) Committee review of models submitted. — The Committee shall, on a periodic basis, review models submitted under subparagraph (B), prepare comments and recommendations regarding whether such models meet the criteria described in subparagraph (A), and submit such comments and recommendations to the Secretary."

Physician-Focused Payment Model (PFPM) Defined. Federal regulations at 42 CFR § 414.1465 define PFPMs as:

> "(a) Definition. A physician-focused payment model (PFPM) **is an Alternative Payment Model** [*emphasis added]*:
>
> (1) In which Medicare is a payer;
>
> (2) In which eligible clinicians that are eligible professionals as defined in section 1848(k)(3)(B) of the Act are participants and play a core role in implementing the APM's payment methodology; and
>
> (3) Which targets the quality and costs of services that eligible professionals participating in the Alternative Payment Model provide, order, or can significantly influence."

Alternative Payment Models (APMs) Defined. Federal regulations at 42 CFR § 414.1305 define APMs as:

> *"Alternative Payment Model (APM)* means any of the following:
>
> (1) A model under section 1115A of the Act (other than a health care innovation award).
>
> (2) The shared savings program under section 1899 of the Act.

(3) A demonstration under section 1866C of the Act.

(4) A demonstration required by Federal law."

Eligible Professionals Defined. Federal regulations at 42 CFR § 414.1305 define "eligible clinicians" as:

"Eligible clinician means "eligible professional" as defined in section 1848(k)(3) of the Act, as identified by a unique TIN and NPI combination and, includes any of the following:

(1) A physician.

(2) A practitioner described in section 1842(b)(18)(C) of the Act.

(3) A physical or occupational therapist or a qualified speech-language pathologist.

(4) A qualified audiologist (as defined in section 1861(ll)(3)(B) of the Act)."

Section 1848(k)(3) of the Social Security Act defines "eligible professional" as any of the following:

(1) A physician.

(2) A practitioner described in section 1842(b)(18)(C). [(C) A practitioner described in this subparagraph is any of the following:

(i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5)).

(ii) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)).

(iii) A certified nurse-midwife (as defined in section 1861(gg)(2)).

(iv) A clinical social worker (as defined in section 1861(hh)(1)).

(v) A clinical psychologist (as defined by the Secretary for purposes of section 1861(ii)).

(vi) A registered dietitian or nutrition professional.]

(3) A physical or occupational therapist or a qualified speech-language pathologist.

(4) Beginning with 2009, a qualified audiologist (as defined in section 1861(ll)(3)(B)).

2. Resources for Submitters

From time to time, PTAC provides public education sessions and informational materials, such as webinars and FAQs, regarding the requirements of the Proposal Submission Instructions and the proposal review process. This information can be found on the PTAC website, which includes:

- Instructions for submitting a letter of intent and proposal to PTAC
- A description of the process PTAC uses to review proposals; all proposals received by PTAC, public comments on these proposals, and copies of the PTAC's reports to the Secretary on these proposals
- Responses to Frequently Asked Questions (FAQs)
- A list of *"Characteristics of PFPMs Likely to Be Recommended by PTAC"*
- The "*Guide for Navigating Publicly Available Files for Those Developing Physician-Focused Payment Models*"
- Numerous tables presenting data on Medicare beneficiaries, utilization of Medicare services, and Medicare payment
- Reports on issues related to PTAC work, such as, "*Examples of Health Care Payment Models Being Used in the Public and Private Sectors*."