Physician-Focused Payment Model Technical Advisory Committee

Physician-Focused Payment Models: PTAC Proposal Submission Instructions

Revised as of June 5, 2020

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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).
2. Provide expert comments and recommendations on these proposals to the Secretary of Health and Human Services (HHS; "the Secretary").

This document describes how individuals and stakeholder entities may submit proposals for new PFPMs to PTAC and how best to craft these proposals to help PTAC ensure a timely and effective review of submitted proposals. This includes recommended information for inclusion in proposed model submissions. It also provides an overview of the processes PTAC uses to review proposals, as well as information on how PTAC evaluates proposals and makes comments and recommendations to the Secretary.

PTAC seeks to inform the Secretary in a manner that raises awareness of important issues in health care delivery, costs and alternative payment models. This process involves evaluating stakeholder-submitted proposals based on the 10 criteria set forth by the Secretary, on which PTAC will base its recommendations. PTAC may also extend its expert opinion to further inform the Secretary about certain issues or factors that a given proposal raises and/or identify alternative approaches relating to the proposed payment model. PTAC will include its expert opinion on such details in its comments and recommendations to the Secretary as part of its evaluative process. PTAC may provide additional feedback to the Secretary based on its expert assessment of a proposal; however, the Secretary is not required to respond to any feedback that is provided outside of PTAC's comments and recommendations relating to the criteria established by the Secretary in regulation.

Additionally, PTAC seeks to ensure that stakeholders have a forum for conveying their ideas on how to deliver higher-value care; see PTAC's Vision Statement, found below and on the Assistant Secretary for Planning and Evaluation (ASPE) PTAC website. To that end, PTAC's Proposal Submission Instructions have been updated to facilitate more submissions from a wider range of stakeholders.

Finally, the Proposal Submission Instructions reflect the Committee's commitment to review stakeholder input on care delivery issues, alternatives to payment, and other factors that can inform transformative efforts to achieve value-based care. This commitment is reflected in the Committee's **Vision For the Future Statement**, as follows:

> PTAC was created to contribute to a national priority to improve the efficiency and effectiveness of the U.S. health care delivery system. We believe that proposed solutions

from frontline stakeholders in our delivery system can substantially enhance quality, improve affordability and influence policy development and system transformation.

PTAC provides a forum where those in the field may directly convey both their ideas and their concerns on how to deliver high value care for Medicare beneficiaries and others seeking health care services in our nation. PTAC is committed to ensuring our stakeholders have access to independent, expert input and that their perspectives and innovations reach the Secretary of Health and Human Services.

PTAC will continue to submit comments and recommendations regarding physician-focused payment models submitted by stakeholders to the Secretary, as required by statute. In addition, we will expand our communications with the Centers for Medicare & Medicaid Services (CMS) and stakeholders to identify opportunities to further inform and prioritize the work CMS, including the Center for Medicare & Medicaid Innovation (CMMI), and other policy makers are undertaking to modernize health care.

B. How to Submit a Proposal

PTAC welcomes submission of proposed models. PTAC gathers information delivered from the field, reviews stakeholder-submitted information, and provides comments and recommendations to the Secretary based on expert review and input. Therefore, PTAC encourages all stakeholders that may have information and/or possible innovative approaches and solutions related to care delivery, payment or other policy issues to submit PFPM proposals.

Who May Submit a Proposal

Any individual or organization may submit a proposal.

As provided in its Vision Statement, PTAC seeks to raise awareness about deficiencies in the health care delivery system impacting access, outcomes, and value that have been identified by frontline stakeholders in the field. PTAC believes that solutions proposed by the public can inform enhancements that drive high-quality care, improve affordability, influence policy development, and help transform health care delivery systems.

There is no limit on the number of proposals that a stakeholder may submit. Those interested in submitting a proposal may find it useful to review the resources available under the "Directions for Public Submissions" of the Proposal Submissions section of the ASPE PTAC website.

Note: While PTAC will use the Secretary's 10 criteria to review all proposals, it recognizes that stakeholders who develop and submit a PFPM proposal have varying degrees of resources available, which can influence their ability to address certain criteria in detail (most notably, payment methodology). Certain proposals may have strengths within some criteria and weaknesses in others; however, when evaluated as a whole, a given proposal may raise important care delivery, payment or policy issues. Therefore, PTAC encourages stakeholders to submit PFPM proposals that address innovative approaches in care delivery, regardless of the level of sophistication of their payment methodology; it is PTAC's intention to provide recommendations and comments on such issues in its report to the Secretary.

When a Proposal May Be Submitted

PTAC requests that stakeholders first submit a nonbinding letter of intent (LOI) at least 30 calendar days in advance of submitting a proposal. This LOI assists in identifying necessary resources to support proposal review.

Instructions for submitting LOIs are available on the ASPE PTAC website. After the 30-day period, stakeholders may submit the corresponding proposal at any time; submissions will be accepted on an ongoing basis.

If a proposal is not received within six months of the LOI, the LOI will be considered "expired." Submitters are asked 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 Microsoft (MS) Word format. Additional information in MS Excel files may also accompany submissions. Proposals should be uploaded to PTAC's submission system website. A guide on how to upload proposals is available under "Directions for Public Submissions" in the Proposal Submissions section of the ASPE PTAC website.

Submitters may contact PTAC@hhs.gov with any questions about uploading their proposals. Staff who work at ASPE in support of PTAC will respond to any questions.

C. How to Describe Your Proposal

Submitters may organize and present their proposals in any manner they believe is most clear, concise and effective. Based on several years of proposal review, PTAC is seeking to identify how a given proposal might help to raise awareness on important issues in payment and patient care that impact health care quality, access and value. A few examples include:

- Gaps in care or suboptimal care and their relationship to payment policy.
- The extent to which PTAC can directly and indirectly provide a substantial inventory of policy information on these issues to influence policy development, research, and stakeholder awareness.
- The extent to which PTAC can help activate the stakeholder community to recognize important care delivery and payment issues and respond by submitting models.

With that, PTAC believes that the most effective proposals describe:

1. The care delivery and/or payment problem(s) that the proposal aims to address, at the beginning.
2. The care delivery and/or payment problem(s) or challenges, and if applicable, why they cannot be fixed under existing Medicare policies and procedures or why it is undesirable to try and do so.

3. The proposed care delivery and payment model described in as much detail as possible, including descriptions that explain and specify how:
    a. Care delivery issues are being addressed (e.g., health care service challenges, population, access, costs, geographical considerations such as rural providers), and other challenges the model overcomes (e.g., small practices, engagement by providers in model testing, etc.).
    b. Types of patients who would be eligible for the payment.
    c. How the model will resolve the care delivery and cost/payment problems.
        i. Note: Depending on the level of sophistication of the model's payment methodology, this may include a high-level description of the appropriate type of payment methodology, and/or a detailed discussion of how the methodology would work.
    d. How certain existing alternative payment models, or other novel ones, would best address costs/payment issues associated with the care delivery problem.
    e. The entity that will receive the Medicare payment from CMS and how the funds will be distributed to eligible professionals, including primary care providers and other providers (including hospitals, post-acute care providers, etc.) participating in or affected by the model.
    f. Value-based outcomes and/or incentives the model creates and any evidence of their effectiveness.
4. Anticipated effects of the model from the perspective of the beneficiary, including effects on patient choice, access, quality and safety of care, and care coordination.
5. Any changes in patient care that are required in order to receive payment and expected changes in care.
6. Expected savings for the Medicare program 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 10 criteria for PFPMs (see Section E, below).

Submitters may use the above items as an outline, but PTAC would like to emphasize that submitters have maximum flexibility to organize and present their proposals in ways they believe will most clearly, concisely and effectively describe their proposed PFPMs. PTAC is statutorily required to evaluate each proposal against the Secretary's 10 criteria. Therefore, regardless of the proposal's structure, submitters should be sure to point out information that is relevant to each of the 10 criteria.

D. Administrative Requirements for Proposals

Regardless of how a submitter chooses to organize a 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 email 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 1-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 not all PTAC members may be able to review 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 10 criteria for PFPMs established by the Secretary. These criteria are specified in federal regulations at 42 CFR § 414.1465 (see below).

PTAC conducts its evaluations by reviewing information submitted with each proposal. PTAC also considers additional information from various sources, such as clinical consultants, subject matter experts, literature reviews, and/or data analyses.

To assist all submitters in putting forth their best evidence about how their proposal will satisfy the Secretary's criteria, each of the Secretary's 10 criteria and examples of corresponding types of 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). However, if all information relevant to one (or more) criteria is absent, PTAC's ability to fully and comprehensively deliberate on a proposal may be affected.

As an aid to submitters, the information elements that PTAC believes are essential for 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.

PTAC recognizes that there are varying degrees of resources available to stakeholders who seek to develop and submit a PFPM proposal. PTAC assesses proposals holistically and does not require proposals to be flawless in every respect to merit evaluation by PTAC.

Criterion 1 of 10. Scope (High Priority[1]): 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.

Suggested Descriptive Information:

- What care delivery and/or payment problem is the proposal aiming to address?
- How are the current care delivery and payment issues together affecting beneficiary health care, and how is the proposal addressing these issues?
- What are the size and characteristics of the beneficiary population(s) anticipated to benefit from the model?
- Why can this 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 the 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?

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

Optional Information Items if Relevant:

- Has the model been implemented by other payers, and if so, what was the experience?
- Parties submitting proposed PFPMs to PTAC should present information in their proposal explaining how the model would be feasible for implementation by multiple health care providers, facilities, institutions, or systems, as appropriate.

NOTE: PTAC is not likely to recommend to the Secretary payment models that:

1. Are targeted to a single health care provider, facility, institution, or system.
2. Require use of proprietary tools or tools that are not already developed. In prior responses from the Secretary to PTAC reports on submitted models, the Secretary has communicated concerns about proposed models requiring 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 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)</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.

Suggested Descriptive Information:

- What aspects of the quality of care will be improved? (What is the quality issue?)
- How much savings is expected, and how will the savings be achieved?
- 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?
- How will quality be evaluated?
- What approach will be used to develop innovative quality 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.?

Optional Information Items if Relevant:

- 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)</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 PFPM 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 APMs.

To facilitate PTAC's review of each proposed model, submitters are encouraged to provide as much detail as possible regarding their proposed payment methodologies. To assist potential submitters in determining which payment methodology may be most appropriate for their model, the Resources section of the ASPE PTAC website includes a document that summarizes some of the major types of payment methodologies that are typically used in Alternative Payment Models (APMs) (please see Appendix G.2 for additional information about how to access this information). However, notwithstanding this information, PTAC is also receptive to innovative payment methodologies that submitters may propose.

Suggested Descriptive Information:

- What types of entities would receive payment from Medicare under the APM?
- How might the proposed model align with or be integrated into an existing APM? If an existing payment model is identified, please provide a rationale for its selection.
- 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/CMMI models for physicians or other eligible professionals?
- Can the proposed model be tested under current CMMI models?
- What degree of financial risk will the entity and physicians or other eligible professionals bear through participating in 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 and/or 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?

<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 incentives.

Suggested Descriptive Information:

- What drivers are used to ensure physicians and other eligible professionals deliver high-value health care?
  - ➢ 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 related to 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.

Suggested 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?
- 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.)?

Optional Information Items if Relevant:

- To what extent will participation in the model impose new operational burdens and reporting requirements on practitioners?
- 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.

Suggested 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.

Suggested 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?
- How might the model move the burden of care coordination from the beneficiary and to the care delivery system?
- How might the model reduce disparities in care coordination services?

<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.

Suggested 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 served by 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.

Suggested 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, access issues, 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.

Suggested 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?
- Describe any information technology innovations in the model that will improve outcomes, consumer experience, and/or the efficiency of care delivery.

Optional Information Items if Relevant:

- Will the measures of quality used in the model be derived from electronic health records (EHRs)?
- How would patients' privacy be protected if new providers or caregivers will have access to personal health information (PHI)?
- Will the proposed model require use of electronic patient health information and greater interoperability of such patient data than exists today? If so, how?
- How will any health information technology 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

When a proposal is submitted, ASPE conducts an initial administrative review of the proposal. After a submitted proposal has been found to have met the administrative requirements, it is posted on the ASPE PTAC website for public comment and scheduled for substantive review by a preliminary review team. While most proposals are reviewed on a flow basis as they are received, PTAC may prioritize the review and subsequent public deliberation of proposals**,** based on the types of issues presented by stakeholders and in a manner that is most informative to both the public and the Secretary. For example, PTAC may decide to group its deliberations and recommendations associated with a particular disease.

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.

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 email 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. • The main body of the proposal does not exceed 25 pages, excluding any citations and appendices.	

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.

All submitter communications with PTAC (with two exceptions) will be via email 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 PTAC deliberates on a submitted proposal.

Other than these two occasions, email is the primary form of communication between PTAC and a submitter. Submitters may communicate with ASPE PTAC staff about their proposal via

email at PTAC@hhs.gov or may 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 and is open for public comment for three weeks. An announcement of the proposal submission, with a website link to the proposal and a deadline for public comments, is 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.

4. Preliminary Review of the Proposed Model

Simultaneous to the 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 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 the need to obtain additional information to better understand the proposed model:

- If additional clarifying 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 degree to which clarifying information is needed and 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, literature reviews, and/or data analyses. Next, the PRT will evaluate the proposal against the Secretary's 10 criteria, as described in more detail below.

Completion of the PRT's Review:

Additional information obtained by the PRT relating to the proposal that is presented to PTAC will be posted to the ASPE PTAC website under the link titled "Additional Information and

Analyses" for the specific proposal to which it relates. Such information is typically posted approximately four weeks prior to the public meeting at which the full PTAC will deliberate 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 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 will describe the nature of the disagreement in its report to the full PTAC. 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 and themes 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. This report, known as the PRT Report:

- 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 findings and explains the basis for the findings (which may include results of analyses conducted or information obtained from clinical or subject matter experts)
- Is not binding on PTAC, and the full Committee may reach different conclusions from those reached by the PRT members.

The PRT Report is typically posted to the ASPE PTAC website approximately four weeks prior to the public meeting at which the full PTAC will deliberate 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 reviewing a proposal will determine, at its discretion, whether to provide initial feedback on a

proposal. No initial feedback will be provided by PTAC other than through this PRT, and it is important to note that providing initial feedback is optional on the part of the PRT, and that the PRT may choose not to provide initial feedback on a proposal.

In the event that a determination is made by the PRT to provide initial feedback, when given, it will consist of:

- An assessment of whether the proposed model meets the Secretary's criteria.
- 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 proposed models relative to the Secretary's criteria.

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.

In cases when initial feedback is provided, it will always be provided to the submitter in writing and will be posted to 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 PTAC. The full Committee 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.

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.

6. Submitting Additional Material and Revising and Resubmitting Proposals

PTAC encourages submitters to develop and describe their payment models as fully as possible in their written proposals to PTAC and in any subsequent communication with the PRT during the PRT's preliminary review of the proposal. It is not uncommon for a submitter to clarify certain details of its proposal in response to questions from a PRT, and PRTs welcome these opportunities for clarification. However, it has been PTAC's experience that either in the course of a PRT's review of a proposal and communications with a submitter, or upon a submitter's receipt of the PRT's report to the full PTAC (see item 7, below), some submitters may: 1) propose significant changes to the payment model from what was described in the original proposal; 2) submit additional information that is inconsistent with the information that was included in the original proposal; and/or 3) submit substantial amounts of new information after the PRT report has been completed.

It is PTAC's policy that if a submitter wishes to change its proposed payment model, or if the submitter identifies a better way of showing how the proposed payment model meets the Secretary's criteria, the submitter may withdraw, revise, and resubmit its proposal at any time. PTAC views this as the best course of action when key elements of the proposed payment model are changed after submission or when a submitter wants PTAC to base its review on information that is substantially different than what was included in the initial proposal.

Revising and resubmitting the proposal ensures that the public, PRT, and PTAC members are basing their comments and decisions on the most accurate, complete, and understandable information about a proposed model. Even if the additional information that is being submitted is consistent with the original proposal, if a substantial amount of new information is being submitted, it will likely be easier for the public and PTAC to understand and accurately evaluate a revised proposal.

Once a PRT report has been completed, PTAC may take into consideration additional information and responses by the submitter. PTAC discourages submission of substantial amounts of new information after the PRT's report to PTAC has been completed, even if the information does not change the payment model and is consistent with information included in the original proposal. PTAC discourages this because it will be difficult for PTAC members—prior to making a decision—to review all of this new material and reconcile it with the report developed by the PRT and with the comments submitted by the public.

If PTAC receives additional information from a submitter after the PRT report is completed but at least 10 business days prior to the planned PTAC deliberation on a model, the PRT will review the new material and determine whether or not the new material represents either: 1) a substantial amount of new information on the proposed model; or 2) a significant change in one or more key elements of the proposal. If the PRT finds that the new material represents either of these two scenarios, the PRT may recommend to the submitter that it formally revise

and resubmit its proposal so that the PRT can prepare a new report to PTAC based on this information.

When a PRT recommends to a submitter that it formally revise and resubmit its proposal, a submitter may elect either to do so or to have its proposal (and the new material) deliberated and voted on by the full PTAC as originally scheduled. If a submitter chooses not to revise and resubmit its proposal as recommend by the PRT, a submitter needs to be aware that the full PTAC may not have the time needed to fully review the additional material. Further, the PRT may issue a disclaimer that the PRT's report to the full PTAC may not reflect the proposed model as represented by the new information and material.

In addition, PTAC strongly discourages submitters from proposing any significant changes to the proposed payment model or substantial amounts of new material at the public meeting or fewer than ten business days before the public meeting. Such changes or new material may not provide PTAC members with sufficient time to review and reflect upon this material alongside the proposal prior to deliberation and voting, and PTAC would be unable to obtain public comments on the material prior to its vote. Without the ability to do so, PTAC may choose to base its vote on the proposal as it was originally submitted (i.e., without the proposed changes), or it may decide to give the submitter the option to withdraw and formally revise and resubmit the proposal.

7. 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 will occur four weeks prior to the PTAC meeting at which PTAC will deliberate on the proposal. The PRT Report is not binding on PTAC, and the full Committee 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 ten business days prior to the public meeting at which the proposal is scheduled to be reviewed. Responses submitted subsequent to this deadline will be accepted; however, the PTAC members may not be able to review the information and incorporate it into their deliberations.

8. 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.[2] Meetings are held in Washington, DC, usually at the following location:

[2] 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.

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 to the extent possible. However, the exact start time for the review of each proposal cannot be guaranteed because the 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 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 to coordinate participation.

On the scheduled day of proposal review, submitters have the option of making a public statement to PTAC for up to ten 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 ten-minute statement to 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 PTAC during the 10-minute statement. A maximum of six representatives should be identified, including those who may answer the PTAC members' 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, D.C., 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, and the submitter will be provided the opportunity to make a public statement and respond to any questions from Committee members. The Committee will then hear comments from the public; this time may also include presentations from guest speakers or subject matter experts to provide input on the proposal topic. After this process, PTAC members will deliberate and score the proposal on each criterion established by the Secretary of HHS. Voting will occur with electronic voting technology, which will compile and display results on the projection screen.

After rating the proposal on each criterion, PTAC members 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.

9. 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. ASPE PTAC staff, in consultation with the full PTAC, will then draft the report, reflecting the voting results and the rationale for the recommendation.

Proposals that are submitted to PTAC are likely to bring awareness to policy, care delivery, and payment issues that may be more or less known, and such information may be expressed in each proposal in varying degrees of detail that can be useful in informing the Secretary about these issues. In addition to its comments and recommendations on a given proposal, PTAC may at times extend its expert opinion to further inform the Secretary about certain issues or factors that a given proposal raises, and/or PTAC may discuss alternative approaches relating to the

proposed payment model. Thus, PTAC may include, as part of its expert input, additional comments and recommendations to the Secretary. While PTAC may provide such additional feedback to the Secretary, the Secretary is not required to respond to any feedback outside of PTAC's comments and recommendations relating to the criteria established by the Secretary in regulation.

Reports to the Secretary of HHS are typically transmitted six to eight weeks following a public meeting; however, there is no statutory timeline for this transmission. Once available, reports to the Secretary 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 to review PTAC's comments and recommendations on proposals and to post a detailed response to those comments and PTAC's recommendations. The Secretary's responses are 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 as a link on 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 titled "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.

Additionally, in cases where PTAC decides to extend its expert opinion to further inform the Secretary about certain issues or factors that are raised by a given proposal or multiple proposals, and/or to discuss alternative payment approaches during a public meeting, PTAC may provide a supplemental report to the Secretary that includes comments and recommendations regarding these issues. However, the Secretary is not required to respond to any feedback outside of PTAC's comments and recommendations relating to the criteria established by the Secretary in regulation.

10. Withdrawing, Revising, and Resubmitting a Proposal

A submitter may withdraw a proposal for a PFPM submitted to PTAC at any time prior to PTAC's vote on the proposal at the public meeting. 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 later resubmit the proposed PFPM to PTAC at any time. If the resubmission occurs within six months of the withdrawal, a new LOI is not required for the resubmission. Six months after withdrawal, a submitter's LOI expires. If the submitter wants to then resubmit the proposed PFPM, a new, brief LOI will be required, although the submitter will not need to wait thirty days to submit their proposal. This new LOI can be very short, simply containing an estimated date of submission, with no additional information about the proposed model required.

To the extent practicable, a resubmitted proposal will be reviewed by the same PRT members who reviewed the initial proposal submission.

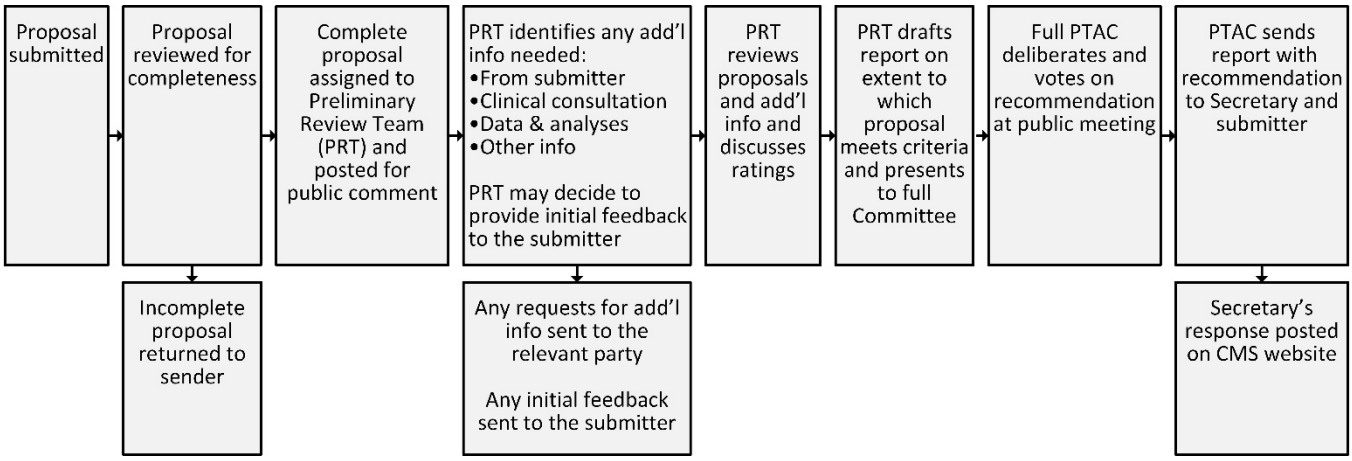
11. Appeals Process

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

12. Summary

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

PTAC PROPOSAL RECEIPT, EVALUATION, AND RECOMMENDATION PROCESSES*



* PTAC may also provide additional feedback to the Secretary based on its expert assessment of a proposal; however, the Secretary is not required to respond to any feedback that is provided outside of PTAC's comments and recommendations relating to the criteria established by the Secretary in regulation.

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 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 Model (APM) 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 Professional 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:

(i) A physician.
(ii) 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.]
(iii) A physical or occupational therapist or a qualified speech-language pathologist.
(iv) Beginning with 2009, a qualified audiologist (as defined in section 1861(ll)(3)(B)).

2. Resources for Submitters

PTAC provides a variety of informative materials to assist stakeholders in developing and submitting proposals for review. These resources include overviews of previous models proposed to PTAC, data requested by PRTs during previous PRT reviews, and webinars and frequently asked questions about the proposal submission process. These materials are updated on an as-needed basis and may be found on our website using the following links:

ASPE PTAC Website

- Frequently Asked Questions
- Resources for Submitters