Physician-Focused Payment Model
Technical Advisory Committee

# Physician-Focused Payment Models: PTAC Proposal Submission Instructions

**Revised as of June 30, 2022**

# Table of Contents

## Introduction

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) 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; "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.

## A. Overview of the PTAC Proposal Review Process

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 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 proposed 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 and Medicaid Innovation (CMMI), and other policy makers are undertaking to modernize health care.

Consistent with the Vision Statement's emphasis on increasing awareness about important payment and patient care issues that have been identified by frontline stakeholders and encouraging stakeholders to respond to these issues by developing proposed models, PTAC has updated the Committee's proposal submission process to further enhance stakeholders' ability to submit innovative PFPM proposals.

- PTAC has implemented an additional "track" for proposal review to provide additional flexibility for stakeholders whose proposals may raise important care delivery, payment, or policy issues but may have varying degrees of resources available, which can influence their ability to address certain criteria in detail (most notably, payment methodology). Additional details regarding these enhancements can be found in Section C, "How to Submit a Proposal", and Section G, "Two-Track Process for Proposal Review."

- PTAC has reduced the burden associated with submitting a proposal by providing additional flexibility in how submitters may describe their proposals. Additional information regarding this enhancement can be found in Section D, "How to Describe Your Proposal."

- PTAC has incorporated the Committee's insights about innovative care delivery, payment, and policy issues that may be particularly relevant for PFPM proposals.

- PTAC has published a *Common Alternative Payment Model (APM) Approaches: Reference Guide* that summarizes some of the major types of payment methodologies that are typically used in APMs as a resource to assist stakeholders when designing proposed payment models, available on the ASPE PTAC website.

Submitting a PFPM proposal to PTAC provides an opportunity for stakeholders to share their innovative ideas with the broader policy community and receive feedback during a public deliberation on their proposal by the Committee's members, who have national recognition for their expertise in PFPMs and related delivery of care under the Medicare program. During the deliberation, PTAC will vote on the extent to which the submitter's proposal meets each of the Secretary's 10 criteria for PFPMs. Additionally, for Track 1 proposals, the Committee will also vote to place the proposal into one of several recommendation categories (see Section H, "After a Proposal is Submitted," and Appendix 3, Section i, "PTAC Deliberation on Proposals").

After the Committee's deliberation, PTAC will submit a report to the Secretary reflecting the Committee's findings; the voting results regarding the extent to which the proposal meets the Secretary's criteria; and, for Track 1 proposals, the rationale for the vote on the overall recommendation. 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 Secretary's responses are also posted as a link on the ASPE PTAC website (see Appendix 3, Section j, "Report to the Secretary of HHS").

The report that PTAC submits to the Secretary summarizing the Committee's comments on each proposal that the Committee deliberates on provides an opportunity for increased visibility of the stakeholder's care delivery and payment model innovations to the broader healthcare policy community. While it is unlikely that a proposed model that is submitted to PTAC will be implemented exactly as it was submitted, there are opportunities for innovative approaches to be considered for inclusion in larger models that are being developed by CMMI. For example, the recommendations in several of PTAC's reports to the Secretary have contributed to the design of several CMMI models, including the Kidney Care Choices Model and Primary Care First. There are also opportunities for these innovative approaches to be considered by other payers.

Additionally, the submitter's proposal will be posted on the ASPE PTAC website, along with other materials related to the Committee's review of the proposal. The ASPE PTAC website provides an inventory of policy information on issues related to PFPMs and value-based care that can help to influence policy development, research, and stakeholder awareness.

## B. How to Submit a Proposal

PTAC welcomes submission of proposed models on a rolling basis. 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. Those interested in submitting a proposal may find it useful to review the resources that are available on the Submit a Proposal page and the Resources page of the ASPE PTAC website, including the Committee's *Common Alternative Payment Model (APM) Approaches: Reference Guide*.

There is no limit on the number of proposals that a stakeholder may submit. However, in the event that a stakeholder submits more than one proposal, the Committee assesses the extent to which each proposal is distinct from the stakeholder's previous proposal submissions. In the event that a stakeholder is resubmitting a proposal that was previously submitted to PTAC, the proposal should include a brief description of up to one page specifying the changes that have been made to the proposal. (For more information, see Section E, "Administrative Requirements for Proposals.")

PTAC encourages stakeholders to submit PFPM proposals that address innovative approaches in care delivery, regardless of the level of sophistication of their proposed payment methodology; it is PTAC's intention to provide recommendations and comments on such issues in its report to the Secretary. Additionally, the Committee has implemented an additional track for proposal review to provide greater flexibility for stakeholders who are submitting PFPM proposals. (For more information, see Section G, "Two-Track Process for Proposal Review.")

**When a Proposal May Be Submitted**

PTAC requests that stakeholders first submit a nonbinding letter of intent (LOI) at least 30 calendar days before 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 before 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 via email as indicated below, in either PDF or Microsoft (MS) Word format. Additional information may also accompany submissions, in PDF or MS Excel format.

When submitting a proposal to PTAC, submitters have the option of selecting a preferred track for the review of their proposal. (For additional details, see Section G, "Two-Track Process for Proposal Review.") Submitters may contact PTAC@hhs.gov with any questions about submitting their proposals to PTAC. Staff who work at ASPE in support of PTAC will respond to any questions.

The following information should be included in the email that is used to submit a given proposal to PTAC:

To: PTAC@hhs.gov

Subject: PTAC Proposal Submission

- Include proposal title.
- Include name of submitting individual or organization.
- Attach PDF or MS Word version of proposal.
- If applicable, attach any additional information in either PDF or MS Excel format.
- Optional: Indicate the preferred track for the review of this proposal. (For additional details, see Section G, "Two-Track Process for Proposal Review.")

## 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:

- Identifying gaps in care or suboptimal care and their relationship to payment policy.
- Developing approaches for improving patient-centered care delivery for patients by addressing their clinical, behavioral health, and social needs, and reducing disparities.
- Improving care coordination between primary care and specialty care providers, and transitions across settings.
- Developing innovative approaches for addressing care delivery and payment issues related to the development of population-based Alternative Payment Models, and enhancing physicians' readiness to participate in models that include two-sided risk.

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

1. The care delivery and/or payment problem(s) that the proposal aims to address, at the proposal's 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 model described in as much detail as possible, including descriptions that explain and specify:
    a. Care delivery issues that are being addressed (e.g., health care service challenges, population, access, costs, geographical considerations such as rural providers), and other challenges the proposed model overcomes (e.g., small practices, engagement by providers in proposed model testing).
    b. Types of patients who would be eligible for the proposed model.
    c. Types of providers who would be eligible to participate in the proposed model.
    d. How the proposed care delivery model will resolve the care delivery and cost/payment problems that the proposed model seeks to address.
        i. *Note: Depending on the level of sophistication of the proposed model's payment methodology, this may include a discussion of how the proposed care delivery model would work, and a high-level or detailed description of the proposed care delivery model's anticipated impact on any cost/payment problems.*
    e. Value-based outcomes and/or incentives the proposed model creates and any evidence of their effectiveness.
4. The proposed payment model described in as much detail as possible, including descriptions that explain and specify:
    b. How the proposed payment model will resolve the care delivery and cost/payment problems that the proposed model seeks to address.

i. *Note: Depending on the level of sophistication of the proposed model's payment methodology, this may include a high-level description of the appropriate type of proposed payment methodology and/or a detailed discussion of how the proposed methodology would work.*

c. How leveraging certain existing APMs, or developing other novel ones, would best address costs/payment issues associated with the care delivery problem, if relevant.

d. 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) participating in or affected by the proposed model.

5. Anticipated effects of the proposed model from the perspective of the beneficiary, including effects on patient choice, access, quality and safety of care, and care coordination.

6. Any changes in patient care that are required in order to receive payment and expected impacts on care delivery.

7. Expected savings for the Medicare program and how the effects of the proposed payment model on cost and quality can be evaluated.

   i. *Note: Depending on the level of sophistication of the proposed model's payment methodology and the availability of actuarial support, this may include a high-level description of the expected impact on costs and/or a more detailed estimate of savings.*

8. How the proposal will satisfy each of the Secretary's 10 criteria for PFPMs (see below and Section F, "How PTAC Evaluates Submitted Proposals, for additional information").

   i. *PTAC is statutorily required to evaluate each proposal against the Secretary's 10 regulatory criteria for PFPMs:*

      1. *Scope*
      2. *Quality and Cost*
      3. *Payment Methodology*
      4. *Value over Volume*
      5. *Flexibility*
      6. *Ability to Be Evaluated*
      7. *Integration and Care Coordination*
      8. *Patient Choice*
      9. *Patient Safety*
      10. *Health Information Technology*

ii. *Therefore, regardless of the proposal's structure, submitters should be sure to point out information that is relevant to each of the 10 criteria. This can be accomplished in several ways – for example, by including a list of each of the criteria and a reference to the relevant page(s) in the proposal, or by including a brief discussion of how the proposal relates to each of the criteria.*

iii. *PTAC has implemented an additional "track" for proposal review to provide additional flexibility for stakeholders whose proposals may raise important care delivery, payment, or policy issues but may have varying degrees of resources available, which can influence their ability to address certain criteria in detail (most notably, payment methodology). Therefore, it is possible that some proposals may include only limited information related to one or more of the criteria. This can be noted where appropriate.*

Submitters may use the above items as a potential outline for their proposals, 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.

## D. Administrative Requirements for Proposals

Regardless of how a submitter chooses to organize a proposal, all proposals must:[1]

### 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). The transmittal letter (and letter of support, if applicable) 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.

[1] This information is also referenced in the Proposal Submission Checklist on page 23.

### 4. Include a Summary of Key Elements

The proposal must include a summary of the following key elements of the proposal:

- Provider Eligibility;
- Patient Eligibility;
- Accountable Entity;
- Care Delivery Model; and
- Payment Model.

  *Note: Depending on the level of sophistication of the proposed model's payment methodology, this may include a brief discussion of how the proposed care delivery model would work.*

This brief summary will not be counted against the page limit discussed below.

### 5. 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 in no less than a 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.

### 6. 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 proposed model's design (e.g., detailed specifications for quality measures to be used in the proposed 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. Appendices may be in PDF or MS Excel format.

### 7. If Resubmitting a Proposal, Include a Brief Summary of Changes Made

If the submitter is resubmitting a proposal that was previously submitted to PTAC, the proposal should include a brief description of up to one page specifying the changes that have been made to the proposal. (For more information, see Section H, "After a Proposal Is Submitted.") This brief summary of changes that have been made will not count toward the page limit discussed above.

## 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.

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. Therefore, the Committee has implemented an additional track for proposal review to provide greater flexibility for stakeholders whose proposals may raise important care delivery, payment, or policy issues, but may not include all information relevant to one or more of the criteria (for more information, see Section G, "Two-Track Process for Proposal Review").

Appendix 2 includes a list of each criterion and a description of information elements that PTAC believes are essential relating to each criterion. 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.

## F. Two-Track Process for Proposal Review

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). PTAC does not expect each proposal to include all of the information listed under each criterion (as all of these items may 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. Therefore, the Committee has implemented an additional track for proposal review to provide greater flexibility for stakeholders whose proposals may raise important care delivery, payment, or policy issues but may not include all information relevant to one or more criteria.

Consistent with the Vision Statement's emphasis on increasing awareness about important payment and patient care issues identified by frontline stakeholders and encouraging stakeholders to respond to these issues by developing proposed models, PTAC has updated the Committee's proposal submission process to further enhance stakeholders' ability to submit innovative PFPM proposals. As noted above, the Committee has published a *Common Alternative Payment Model (APM) Approaches: Reference Guide* as a resource to assist stakeholders when designing proposed payment models. The Committee has also implemented an additional “track” for proposal review to provide greater flexibility for stakeholders whose proposals may raise important care delivery, payment, or policy issues but may have varying degrees of resources available, which can influence their ability to address certain criteria in detail (most notably, payment methodology).

The PTAC proposal review process begins with a solicitation of public comments on the proposal and a preliminary review of the proposal (including additional information that is needed to better understand the proposed model). The preliminary review of the proposal is followed by deliberation and voting during a public meeting on the extent to which the proposal meets each of the Secretary’s 10 criteria.

When a proposal is reviewed at a public meeting, submitters whose proposals are in both tracks have the option of attending the meeting in person or remotely; making a public statement to PTAC for up to 10 minutes; and answering the PTAC members’ questions. Additionally, the Committee members will deliberate and score proposals in both tracks on each criterion established by the Secretary of HHS.

- During the standard PTAC proposal review process (referred to as “Track 1”), the full Committee also votes on an overall recommendation to the Secretary regarding the proposal. Track 1 is most appropriate for proposals that include most of the information elements that PTAC believes are essential for submitted proposals to address, particularly relating to the proposed payment methodology. (See Section F, “How PTAC Evaluates Submitted Proposals,” for additional details regarding these information elements.) The full Committee’s findings will then be summarized in a report to the Secretary, as described on page 32.
- During the additional track for proposal review (referred to as “Track 2”), the full Committee will not vote on an overall recommendation regarding the proposal because there is insufficient information for PTAC to be able to fully and comprehensively deliberate on the proposal. Track 2 is most appropriate for proposals submitted by stakeholders whose proposals may raise important care delivery, payment, or policy issues but may have varying degrees of resources available, which can influence their ability to address certain criteria in detail (such as payment methodology). The full Committee’s findings will then be summarized in a report to the Secretary, as described on page 32.

Stakeholders will have the option of indicating the preferred track for the review of their proposal at the time that the proposal is submitted. (For additional details, see Section C, “How to Submit a Proposal.”) Stakeholders will also have an opportunity to indicate if they agree with the proposed track for the review of the proposal that has been identified during the preliminary review process.

See Section H, “After a Proposal Is Submitted,” for additional details about the Committee’s proposal review process.

## G. After a Proposal Is Submitted

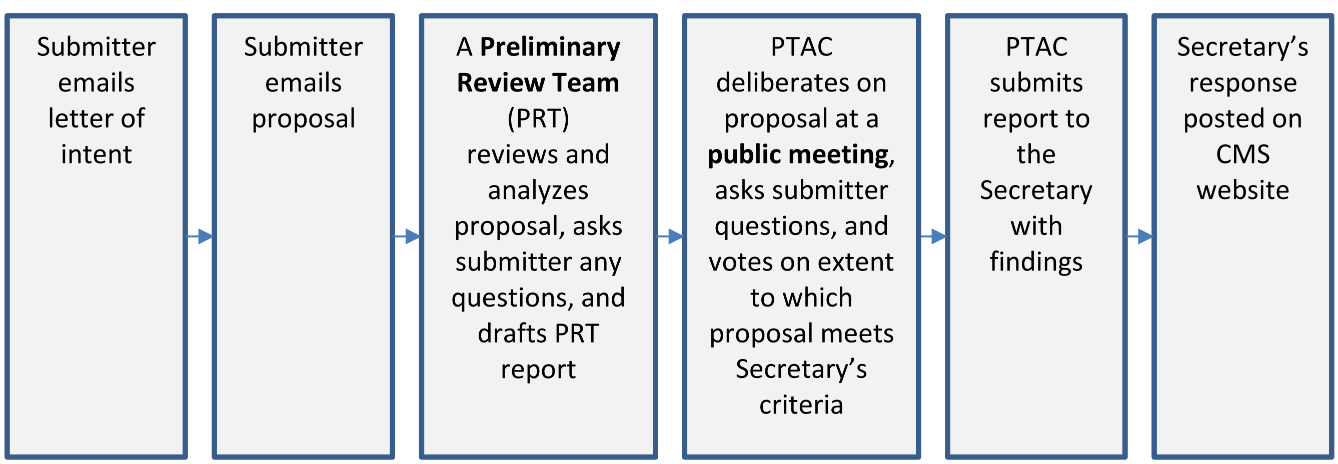
When a proposal is submitted, a Preliminary Review Team (PRT) consisting of a subset of PTAC members is appointed by PTAC's Chair and Vice Chair. The role of the PRT is to conduct a preliminary evaluation of the proposal and write a report to the full PTAC for use in the full PTAC's review and deliberation on the submitted proposal.

The Committee's deliberation on the proposal will take place during a public meeting. At the public meeting, the PRT will present its findings to the full Committee on the extent to which the proposal meets the Secretary's criteria, and the submitter will have an opportunity to make a public statement and respond to any questions from Committee members. After the Committee hears comments from the public, PTAC members will deliberate and score the proposal on each criterion established by the Secretary of HHS.

Subsequently, ASPE PTAC staff, in consultation with the full Committee, will draft a report to the Secretary reflecting the Committee's findings, which will be transmitted to the Secretary of HHS and posted on the ASPE PTAC 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 following diagram provides a high-level overview of the Committee's proposal review process. Appendix 3 includes additional details about PTAC's proposal review process.

**OVERVIEW OF PTAC PROPOSAL REVIEW PROCESS**



# H. 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 <u>physician-focused payment models</u>. — 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 <u>Alternative Payment Model</u> [*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:**

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.

  vii. A physical or occupational therapist or a qualified speech-language pathologist.

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

## 2. List of the Secretary's 10 Regulatory Criteria

This section provides a description of each of the Secretary's 10 regulatory criteria for PFPMs and examples of corresponding types of information that could be included in a description of a proposed model. The information may help submitters present their best evidence about how their proposal will satisfy the Secretary's criteria.

The descriptions under each criterion distinguish between information elements that PTAC believes are essential for a proposal and information elements that individual submitters might find relevant to their proposals. 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 a proposal in order to avoid repetition.

**Criterion 1 of 10. Scope: 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.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- 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 proposed model?
- Why can this problem not be fixed under existing Medicare payment rules and procedures, or why would that problem be undesirable?
- What types and numbers of physicians' or other eligible professionals' practices would be able to participate in the proposed model?
- Are there any APMs already available for these practices to participate in, and why do those APMs not address the goals of this proposal?

***Examples of Additional Information Items Used in PTAC's Review if Relevant:***

- Has the proposed 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 proposed 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 proposed 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 proposed 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.

**Criterion 2 of 10. Quality and Cost: 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.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- What aspects of the quality of care will be improved? (What is the quality issue?)
- How much in 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 proposed payment model?
- How will quality be evaluated?
- What approach will be used to develop innovative quality metrics proposed for inclusion in the proposed model, such as specialty-specific measures or patient-reported outcome measures? How will this approach leverage existing measures, standards, value sets, and other factors?

***Examples of Additional Information Items Used in PTAC's Review 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 proposed model on spending and quality of care?

**<u>Criterion 3 of 10. Payment Methodology:</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 proposed model, the Resources page of the ASPE PTAC website includes a *Common Alternative Payment Model (APM) Approaches: Reference Guide*, which summarizes some of the major types of payment methodologies that are typically used in APMs. PTAC is also receptive to innovative payment methodologies that submitters may propose.

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- 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 regarding the selection of this payment model that is linked to one or more of the Secretary's 10 criteria.
- 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 proposed 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 proposed payment model?

***Examples of Additional Information Items Used in PTAC's Review if Relevant:***

- Will the proposed model include other payers in addition to Medicare, and if so, please explain any differences in appropriate payment approaches between Medicare and other payers?
- Where relevant, how will the proposed model ensure:
  - That the 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?
  - That 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 proposed 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 proposed PFPM payment methodology?
  - Would there be any requirements for how physicians and other eligible professionals who will be compensated through the proposed 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 proposed 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 proposed 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.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- What incentives 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?

**Criterion 5 of 10. Flexibility: 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 proposed model provides practitioners with flexibility to deliver high-quality health care.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- How would the proposed model provide practitioners with flexibility to deliver high-quality health care?
- Would the proposed 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)?

***Examples of Additional Information Items Used in PTAC's Review if Relevant:***

- To what extent will participation in the proposed 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 proposed 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.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- 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 proposed PFPM on these goals be evaluated?
- What difficulties are anticipated in conducting such an evaluation, and how might these be overcome?

***Examples of Additional Information Items Used in PTAC's Review 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.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- What types of organizations and individual practitioners (physicians, non-physicians, and other eligible professionals) would need to be involved in the implementation of this proposed model in order to achieve desired outcomes?
- How would the proposed model support integration and care coordination of these organizations and practitioners (including integration between primary care and specialty care providers, where applicable)?
- How will the proposed model encourage and support coordination with organizations and practitioners that are not directly participating in the proposed payment model? How will the proposed model incentivize coordination with non-medical providers and resources?
- How might the proposed model move the burden of care coordination from the beneficiary to the care delivery system?
- How is information shared across the care delivery team to support integration and care coordination?

- How might the proposed model reduce disparities in care coordination services?

***Examples of Additional Information Items Used in PTAC's Review if Relevant:***

- How would the proposed model incentivize patient-centered care delivery?
- How would the proposed model address patients' behavioral health and social needs?
- Would the proposed model provide any resources, supports, or infrastructure to participating providers to facilitate care coordination? If so, how?

**Criterion 8 of 10. Patient Choice: 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.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- 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 proposed model reflect and address the clinical, social, and demographic characteristics of this target population?
- How is individual patient choice preserved under the proposed model?
- How will the unique needs and preferences of individual patients be respected and addressed?

***Examples of Additional Information Items Used in PTAC's Review if Relevant:***

- Would the proposed payment model reduce disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and/or geography?
- Would the proposed 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)?
- How would the proposed model incorporate shared decision-making?

**Criterion 9 of 10. Patient Safety: 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 proposed payment methodology and provider incentives.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- 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?

***Examples of Additional Information Items Used in PTAC's Review if Relevant:***

- How will disruptions in care transitions and care continuity be addressed for patients participating in the proposed 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 proposed model encourages use of health information technology to inform care.*

***Examples of Primary Descriptive Information Used in PTAC's Review:***

- Will the use of information technology be required as part of the proposed payment model?
- Will the use of information technology be necessary to succeed under the proposed 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 proposed model that will improve outcomes, consumer experience, and/or the efficiency of care delivery.

***Examples of Additional Information Items Used in PTAC's Review if Relevant:***

- Will the measures of quality used in the proposed 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 proposed 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?

### 3. Additional Details About PTAC's Proposal Review Process

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 (PRT). 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.

#### *a. 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 Section C, "How to Submit a Proposal," and Section E, "Administrative Requirements for Proposals," as shown in the Proposal 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<br>Comments if "No" |
|---|---|
| Letter of intent submitted ≥30 days before the proposal. | |
| Proposal includes 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 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:<br>● Title of the proposal.<br>● Name and address of the submitting individual or organization.<br>● 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 includes a summary of key elements. | |

| Requirement | Yes / No<br>Comments if "No" |
|---|---|
| Proposal meets formatting requirements:<br>● Proposal is submitted on standard letter paper size (8.5" x 11").<br>● All text is in no less than a 12-point font, with one-inch margins and single-spaced lines.<br>● Pages are numbered.<br>● The main body of the proposal does not exceed 25 pages, excluding any citations and appendices. | |
| Proposal identifies how the proposed model addresses the Secretary's 10 regulatory criteria. | |
| If the submitter is resubmitting a proposal that was previously submitted to PTAC, the proposal should include a brief description (up to one page) specifying the changes that have been made to the proposal. This description will not count toward the 25-page limit. | |

### *b. 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, rather than with PTAC members. The two exceptions are:

a. When a PTAC 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 a 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. (ET).

### *c. 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.

***d. Preliminary Review of the Proposed Model***

During the same time that public comments are being solicited, a 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 discussed in Section C, "How to Submit a Proposal," and Section G, "Two-Track Process for Proposal Review," stakeholders will have the option of indicating the preferred track for the review of their proposal at the time that the proposal is submitted. The PRT will propose a track for the review of the proposal (Track 1 or Track 2) based on its initial assessment of the proposal. ASPE PTAC staff will notify the submitter about the proposed track for the review of the proposal that has been identified during the preliminary review process, and the submitter will have an opportunity to indicate if they agree with the proposed track for the proposal's review. In the event that the submitter disagrees with the proposed track that has been identified based on the initial assessment of the proposal, the proposal will be reviewed based on the submitter's preferred track for proposal review.

Additionally, in the event that a stakeholder has submitted more than one proposal to PTAC, the PRT's initial assessment will also include an assessment of the extent to which the proposal is distinct from the stakeholder's previous proposal submissions. For resubmitted proposals, this will include a review of the submitter's brief description specifying the changes that have been made to the proposal, as described in Section E, "Administrative Requirements for Proposals." If the PRT determines that the proposal is not sufficiently distinct from a previous proposal that has already been deliberated and voted on by the full Committee, the PRT will propose that the current proposal not proceed to a full Track 1 or Track 2 review. Where applicable, ASPE PTAC staff will notify the submitter about the PRT's findings regarding the proposal's distinctness from a previously submitted proposal that has already been deliberated and voted on by the full Committee, and the submitter will have an opportunity to respond. If the submitter disagrees with the PRT's findings, the PRT's findings will be shared with the full Committee during the next public meeting, and the full Committee will determine if the proposal is sufficiently distinct to proceed to a full Track 1 or Track 2 review.

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 is needed from the submitter, 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, or a 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. The PRT will next evaluate the proposal against the Secretary's 10 criteria, as described 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 on 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 Appendix 3, Section e, "Initial Feedback").

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 criteria.
- 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 by 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 on the ASPE PTAC website approximately four weeks prior to the public meeting at which the full PTAC will deliberate on the proposal.

#### *e. 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 on 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 only the PRT 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 those 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.

### *f. Submitting Additional Material and Revising and Resubmitting Proposals*

PTAC encourages submitters to develop and describe their proposed 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 about their 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 Appendix 3, Section g, "Submitter's Response to the PRT Report"), some submitters may: 1) propose significant changes to the proposed 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 their 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, or 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. When resubmitting a proposal, the proposal should include a brief description (up to one page) specifying the changes that have been made to the proposal, as described in Section E, "Administrative Requirements for Proposals."

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 proposed 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 proposed 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 they formally revise and resubmit their proposal so that the PRT can prepare a new report to PTAC based on this information.

When a PRT recommends to a submitter that they formally revise and resubmit their proposal, a submitter may elect either to do so or to have their 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 their 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 10 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.

### *g. 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 on 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 10 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.

### *h. Supplemental Analyses (Optional)*

In addition to evaluating stakeholder-submitted proposals based on the 10 criteria set forth by the Secretary, 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. As part of its evaluative process, the PRT may determine that additional information is needed to facilitate the Committee's ability to provide additional feedback on such topics. The PRT will separately summarize the findings from any supplemental analyses that are conducted related to a given proposal, and present this information to the full Committee. The information from any supplemental analyses will typically be posted on the ASPE PTAC website on the day of the public meeting at which the full PTAC will deliberate on the proposal.

### *i. 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, D.C., but they can be held virtually. Meetings held in Washington, D.C., are usually held 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

[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.

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 remotely. Representatives will be given detailed logistical information in advance of the public meeting. As described in the next paragraph, submitters will be able to interact with the Committee during a specific portion of the public meeting. Any representatives joining remotely will be unmuted 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 remotely are encouraged to monitor the status of the meeting so that they will know when their proposal review is beginning. For meetings held in person, it is also recommended that representatives joining remotely 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 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 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 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 on the extent to which the proposal meets the Secretary's criteria, 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 the Committee scores the proposal on each criterion, **for Track 1 proposals**, PTAC members will also vote to place the proposal into one of the following recommendation categories:

> **PTAC RECOMMENDATION CATEGORIES**
> **(FOR TRACK 1 PROPOSALS ONLY)**
>
> **Recommended**
>
> **Recommend Full Proposal:** Proposal substantially meets the Secretary's criteria for PFPMs. PTAC recommends implementing proposal as a payment model as described in PTAC's comments.
>
> **Recommended Components**: Proposal includes attributes and/or components for attention by the Secretary as described by PTAC's comments.
>
> **Not Recommended**

A two-thirds majority of votes is required to determine the overall recommendation to the Secretary of HHS. After voting on the overall recommendation, Committee members will discuss their comments related to the overall recommendation.

**For Track 2 proposals**, the full Committee will not vote on an overall recommendation regarding the proposal because there is insufficient information for PTAC to be able to fully and comprehensively deliberate on the proposal.

**For Track 1 and Track 2 proposals,** if the PRT conducted any supplemental analyses, the findings from these analyses would be presented to the full Committee separately, and the Committee would determine whether any of these additional findings should be included in the report to the Secretary.

Recordings of past PTAC public 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.

### *j. 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 Committee's findings; the voting results regarding the extent to which the proposal meets the Secretary's criteria; and, for Track 1 proposals, the rationale for the vote on the overall 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, including information related to the findings of any supplemental analyses (which may be submitted as an Appendix to an existing report to the Secretary or in a separate report 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 extent to which the proposal meets 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 on the website.

MACRA requires the Secretary to review PTAC's comments and recommendations on proposals and to post a detailed response to PTAC's comments and 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 Proposals & Materials page of the ASPE PTAC website.

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 extent to which the proposal meets the criteria established by the Secretary in regulation.

### *k. 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 at the public meeting on the extent to which the proposal meets the Secretary's criteria. 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 the extent to which a proposal meets the Secretary's criteria, 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 30 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.

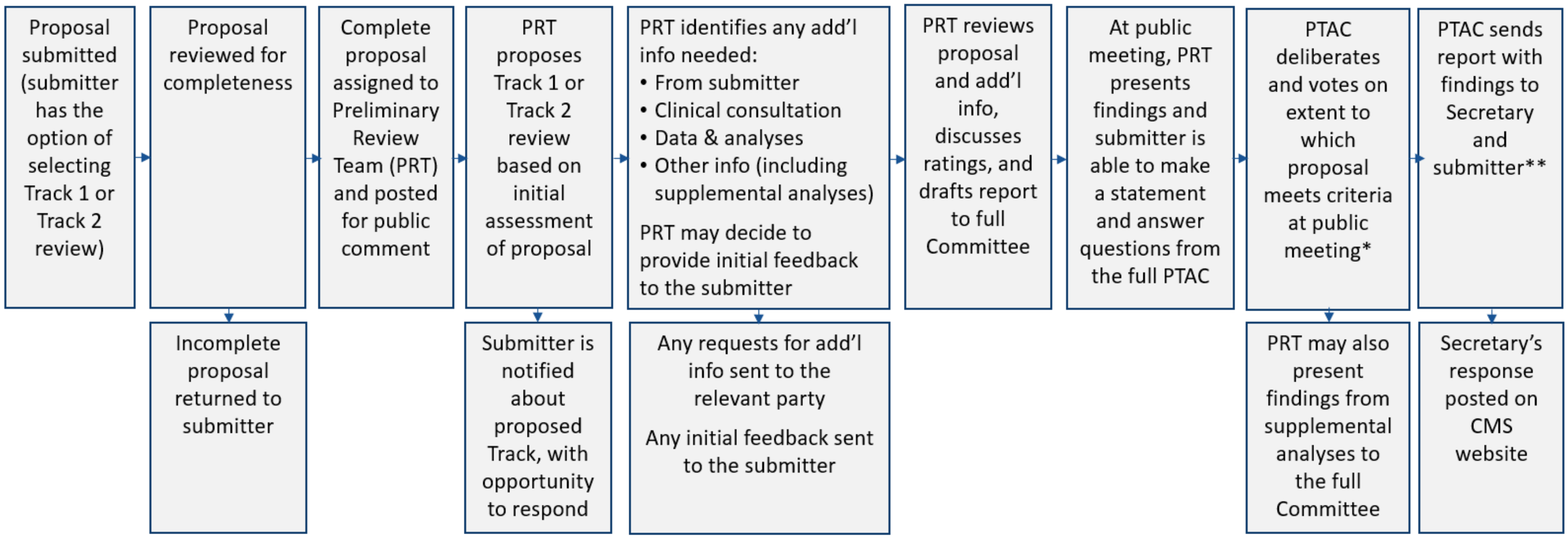
### *l. Appeals Process*

There is no appeal of PTAC determinations and recommendations to the Secretary provided for in statute. Additionally, PTAC does not re-deliberate on proposals that have already been deliberated and voted on by the full Committee. (As discussed in Section H, "After a Proposal Is Submitted," the Committee conducts an initial assessment to determine if a stakeholder's proposal is sufficiently distinct from a previous proposal that has already been deliberated and voted on by the full Committee before allowing the proposal to move forward to full Track 1 or Track 2 review.)

### *m. Detailed Summary*

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

## PTAC PROPOSAL RECEIPT AND EVALUATION PROCESSES




* For Track 1 proposals, the full PTAC will also vote on an overall recommendation.

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

## 4. 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 the ASPE PTAC website using the following links:

ASPE PTAC Website

- Frequently Asked Questions
- Resources for Submitters (which includes a *Common Alternative Payment Model (APM) Approaches: Reference Guide*)