Physician-Focused Payment Model Technical Advisory Committee

Physician-Focused Payment Models: PTAC Proposal Submission Instructions

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A. Introduction

1. MACRA Statute

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 creates incentives for physicians to participate in Alternative Payment Models (APMs), and it specifically encourages the development of physician-focused payment models (PFPMs).

2. Role of PTAC in Making Recommendations to Secretary

Section 101(e)(1) of MACRA created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to make comments and recommendations to the Secretary of the Department of Health and Human Services (the Secretary, HHS) on proposals for PFPMs submitted by individuals and stakeholder entities. The Secretary is required by MACRA to establish criteria for PFPMs and to respond to the recommendations of PTAC. Ten criteria were outlined in <u>regulations implementing Section 101(e)(1) of MACRA at 42 CFR §414.1465</u> published in the *Federal Register* on November 4, 2016. In addition, the <u>Bipartisan Budget Act of 2018</u> 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.

The Secretary's ten criteria are presented below in the Supporting Information section. The PTAC will deliberate in public meetings on (1) the extent to which the Secretary's criteria are applicable to submitted proposals for PFPMS and (2) whether the proposed PFPMs meet the applicable criteria. PTAC's expectations of characteristics of PFPMs likely to be recommended by PTAC are also described below.

3. APMs, PFPMs, and Advanced APMs Defined

<u>Regulations implementing MACRA</u> define an APM as a model under section 1115A of the Social Security Act (other than a health care innovation award), a model in the shared savings program under section 1899, a demonstration under section 1866C, or a demonstration required by federal law.

A PFPM is an APM

- In which Medicare is a payer;
- In which eligible clinicians that are eligible professionals as defined in section 1848(k)(3)(B) of the Social Security Act (SSA) are participants and play a core role in implementing the APM's payment methodology; and

• That targets the quality and costs of services that eligible professionals participating in the APM provide, order, or can significantly influence.

MACRA defines an Advanced APM as an APM that:

- 1. Requires participants to use certified electronic health record technology (CEHRT);
- 2. Provides for payment for covered professional services based on quality measures comparable to those in the quality performance category under the Merit-Based Incentive Payment System (MIPS); and
- 3. Requires either that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM or that participating APM Entities be a Medical Home Model expanded under section 1115A(c) of SSA.

A PFPM is not required to be an Advanced APM.

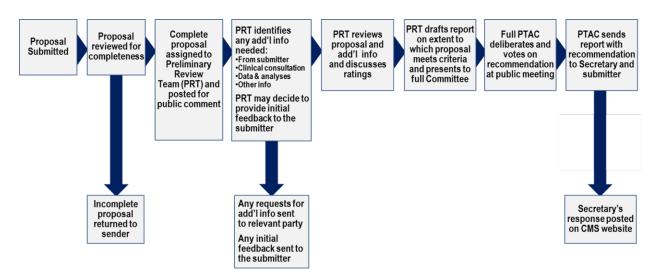
B. Guidance for Submitters

1. Eligibility

Any individual or organization may submit a proposal and there is no limit on the number of proposals stakeholders may submit. If the submitter is an organization, a letter of support from the governing board or responsible officer is required, unless the individual submitting on behalf of the organization clearly serves in that capacity (e.g., CEO). Stakeholders who are planning to submit a proposal to PTAC must submit a non-binding letter of intent at least 30 days in advance of submitting a proposal.

2. Proposal Review Process and Timeline

Stakeholders may submit proposals at any time and submissions will be accepted on an ongoing basis. PTAC's proposal receipt, review and recommendation process is summarized in the graphic below.



PTAC Proposal Review and Recommendation Process

As shown in the above graphic, once a proposal has been submitted and found to be complete (as per the checklist in Section F), it is assigned to a Preliminary Review Team (PRT) composed of 2-3 PTAC members. The PRT:

- Identifies any relevant data and information needed to thoroughly review the submitted proposal;
- Reviews the proposal, related information, and public comments;
- Requests any additional information needed from the submitter;
- Provides, at its discretion, initial feedback to the submitter; and

• To the extent that the PRT finds that the criteria for PFPMs specified by the Secretary are applicable to the proposal, sends a written report to the PTAC on the extent to which the PRT finds the proposal meets the Secretary's criteria. When a PRT finds that the Secretary's criteria do not apply to a submitted proposal, the PRT will also document this in a written report to the PTAC. The PRT's report will be posted for public review in advance of the PTAC meeting at which the proposal is scheduled for deliberation.

Informed by the PRT's report, the full PTAC then deliberates on the PFPM, and votes on (1) the extent to which the Secretary's criteria are applicable to the proposal and (2) whether the proposal meets the applicable criteria. The PTAC also deliberates and votes on a formal recommendation to the Secretary about the proposal. PTAC's complete proposal receipt and review process is discussed in detail in Section G.

PTAC will review and act on proposals as quickly as possible, but the time necessary to evaluate a proposal will be affected by the volume of proposals received and the completeness of those proposals. PTAC intends to hold public meetings no less frequently than quarterly.

3. Initial Feedback

The <u>Bipartisan Budget Act of 2018</u> 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. This new authority will be implemented consistent with the policies below. These policies will be revised as the Committee gains experience with providing initial feedback:

- a) Initial feedback may be given only to stakeholders who submit written proposals that meet PTAC's existing proposal completeness criteria. See Section F for the completeness checklist.
- b) The PTAC Preliminary Review Teams (PRT) that is reviewing a proposal will determine, at its discretion, whether to provide initial feedback on a proposal. No initial feedback will be provided by the PTAC other than through this PRT.
- c) Consistent with the statutory authority above, initial feedback will consist of (1) the extent to which a proposed model meets the Secretary's criteria and (2) "an explanation of the basis for the feedback." As such, initial feedback may identify (at the discretion of each PRT) shortcomings, strengths, or both of submitted models relative to the Secretary's criteria for PFPMs.
- d) 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; or
- Technical assistance in the development of the proposed model.
- e) Initial feedback might not always represent the unanimous conclusions of the PRT. When PRT members hold diverse opinions, the initial feedback will convey these differences.
- f) Initial feedback will be provided in writing and will be posted to the PTAC section of the Assistant Secretary for Planning and Evaluation (ASPE) 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.
- g) Initial feedback will carry a disclaimer that:
 - "Initial feedback represents the opinions of a Preliminary Review Team (PRT) subcommittee of the PTAC and does not represent the consensus or position of the full PTAC;
 - Initial feedback is not binding on the full Committee. PTAC may reach different conclusions from that communicated from the PRT as initial feedback; and
 - 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 Health and Human Services (HHS).*"
- h) 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; or
 - Revise and resubmit the proposal to PTAC.
- i) Submitters who choose to respond to the initial feedback or formally revise and resubmit their proposal to PTAC should be aware that these actions may lengthen the amount of time it takes for PTAC to review, deliberate on, and vote on the submitted proposal. PTAC encourages submitters to revise and resubmit proposals when key elements of the proposal are changed following submission or when the proposal would benefit from significant clarification. Revising the proposal ensures that PRT

and PTAC members act on a complete submission. PTAC discourages submitters from proposing changes at the public meeting or immediately prior to the public meeting. Because PTAC members need sufficient time to review and reflect upon the final proposal prior to deliberation and voting, and because PTAC would be unable to obtain public comments on such changes prior to its vote, PTAC may choose to base its vote on the proposal as it was originally submitted (i.e., without the proposed changes).

4. Transparency

PTAC is governed by the Federal Advisory Committee Act (FACA) which requires that,

"Subject to section 522 of Title 5, United States Code [The Freedom of Information Act] the records, reports, transcripts, minutes, appendices, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection . . . until the advisory committee ceases to exist."

PTAC adheres to these requirements and seeks to make its work as transparent and open as possible. Further, PTAC does not want to make a recommendation regarding a PFPM based on information that the public is not permitted to see. PTAC believes that the input of all types of stakeholders — consumers and their advocates, clinicians and practitioners, health care organizations, health plans and insurers, and purchasers and regulators — will ensure that the information used by PTAC in making its recommendations is as accurate and complete as possible.

Proposals submitted to the Committee will be posted on the PTAC <u>website</u> for public review and comment. Proposal-related information including the LOI, the submitter's answers to questions from PTAC on the submitter's proposal, and comments submitted to PTAC from the public also will be posted to the PTAC website. Therefore, a party submitting a proposal, comments on a proposal, or other information to the PTAC should not submit information that it considers confidential or proprietary or does not otherwise want publicly disclosed. In addition, it is the responsibility of the submitter or other party submitting material to PTAC to obtain any permission that may be necessary to reproduce and redistribute any copyrighted articles they may want to include in their proposal or other submission to the PTAC.

5. Resources for Submitters

From time to time PTAC will provide public education sessions and informational materials, such as webinars and FAQs, regarding the requirements of the Proposal Submission Instructions and the proposal review process. The PTAC <u>website</u> includes:

• instructions for submitting a letter of intent and proposal to PTAC;

- a description of the process PTAC uses to review proposals; all proposals received by PTAC, public comments on these proposals and copies of the PTAC's reports to the Secretary on these proposals;
- responses to Frequently Asked Questions (FAQs);
- a "Guide for Navigating Publicly Available Files for Those Developing Physician-Focused Payment Models;"
- numerous tables presenting data on Medicare beneficiaries, utilization of Medicare services, and Medicare payment; and
- reports on issues related to PTAC work such as, "*Examples of Health Care Payment Models Being Used in the Public and Private Sectors.*"

C. Letter of Intent

A non-binding letter of intent (LOI) must be submitted to PTAC at least 30 days prior to submission of a proposal. An LOI should be two pages or less, single-spaced, and include the following information (a <u>template</u> is available on the PTAC website):

- 1. Expected participants: (1) the types of patients expected to participate in the proposed payment model; and (2) the estimated number and types of physicians and other providers expected to participate in the proposed payment model
- 2. Goals of the payment model: the improvements in clinical quality, patient outcomes, and/or health care spending that would result from the proposed payment model compared to the current payment system
- 3. Model overview: a description of the basic structure of the payment model (e.g., creating payments for currently unpaid services, bundling of current payments for specific patients in a defined episode, risk adjusted global capitation for specific patients, etc.
- 4. Implementation strategy: a brief description of the organization submitting the proposal, and if the submitting organization is not a provider organization, the names of any provider organizations that are committed to implementing the proposed payment model
- 5. Timeline: the date that the organization expects to submit the proposal.

All LOIs will be posted on the PTAC website.

D. Proposal Format

1. Cover

The Proposal must include the name and address of the submitting individual or organization as well as the name, mailing address, phone number, and e-mail for the primary point of contact. This information will not count against the page limit discussed below.

2. Transmittal Letter

The proposal must also 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 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.

3. Title Page, Table of Contents, and Abstract

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

4. Main Body

Submitters must use paper size no larger than standard letter paper size (8.5" x 11"). All text should be Times New Roman font, no less than 12 point, with one-inch margins and single-spaced lines. Pages should be numbered. Graphics and tables may be included.

The main body of the proposal must be organized according to the outline below and must not exceed 25 pages, excluding citations. Citations may be included as endnotes; any style that enables clear identification of the source material is acceptable. More details on the type of information the Committee expects is addressed in the Supporting Information section.

Outline:

- I. Model Description
 - 1. Background and Model Overview
 - 2. How the model would work from the patient's perspective
 - 3. How the model would work from the perspective of participating eligible professionals, the patient's primary care provider, and other providers (including hospitals, post-acute care providers, etc.) who would participate in or be affected by the model

II. Response to Criteria

- 1. Scope (High Priority Criterion^{*})
- 2. Quality and Cost (High Priority Criterion)
- 3. Payment Methodology (High Priority Criterion)
- 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

5. Appendices

Essential information must be covered in the main body of the proposal. Supplemental information and information that is useful in elaboration 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 PTAC members may review material that is not included in the main body of the proposal. Letters of support (if included) and the submission checklist should be placed in appendices.

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

E. Supporting Information

PTAC will assess the extent to which criteria for PFPMs established by the Secretary of HHS in regulations at 42 CFR §414.1465 are applicable to each submitted proposal, and if the Secretary's criteria are applicable, the extent to which the proposal meets these criteria. The Secretary was required by MACRA to establish these PFPM criteria. MACRA also requires PTAC to review proposed models and submit comments and recommendations to the Secretary regarding whether each model meets the Secretary's criteria. PTAC will do so by reviewing information submitted as part of each proposal.

For each of the Secretary's criteria (copied below), PTAC has considered the types of information that it could use to evaluate the extent to which submitted PFPMs meet the Secretary's criteria. Under each criterion, a series of information items are listed showing what types of information might be useful in showing how a model meets the Secretary's criteria. Not all of these items will be relevant for every proposal. Please note:

- A. If an information item is relevant to your proposal, please provide it, if possible.
- B. You may include other information items not listed below that explain how the proposed model meets the Secretary's criteria.
- C. PTAC recognizes that not every information item may be relevant to your proposal. If an item of information does not apply to your proposed PFPM, you do not need to address it. If you believe it will help PTAC better evaluate your proposal, you may provide a brief explanation of why the information item does not apply.
- D. PTAC recognizes that an "Optional Information Item if Relevant" may apply to more than one criterion (although for economy PTAC has listed it only under one criterion). When any submitted information applies to more than one criterion, a proposal need not submit the information twice. A cross reference to information presented under another criterion will be sufficient.

For each criterion, PTAC will use the information it receives to determine the extent to which either:

- A. The Secretary's criterion is not applicable to the proposal; or
- B. If the Secretary's criterion is applicable to the proposal, the extent to which the proposal:
 - Does not meet the criterion;
 - Meets the criterion; or
 - > Meets the criterion and deserves priority consideration.

Based upon the extent to which a proposed PFPM meets the criteria, PTAC will assign the proposal to one of four categories of recommendation to the Secretary:

- 1. Do not recommend proposed payment model to the Secretary; or
- 2. Recommend proposed payment model to the Secretary for:

- Limited-scale testing of the proposed payment model. This category may be used when the PTAC determines a proposal meets all or most of the Secretary's criteria but lacks sufficient data to (1) estimate potential costs, savings, or other impacts of the payment model and/or (2) specify key parameters in the payment model (such as risk adjustment or stratification), and the PTAC believes the only effective way to obtain those data would be through implementation of the payment model in a limited number of settings.
- Implementation of the proposed payment model; or
- Implementation of the proposed payment model as a high priority. High priority models will be those that are rated as "meets the criterion and deserves priority consideration" on multiple criteria, particularly the criteria designated by the PTAC as "high priority" criteria.

Please note that PTAC has designated the first three criteria below as "High Priority Criteria." The PTAC is more likely to recommend to the Secretary proposals that meet each of the "High Priority Criteria.

<u>Criterion 1 of 10. Scope (High Priority Criterion[†])</u>: 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 explain the scope of the PFPM by providing PTAC with a sense of the overall potential impact of the proposed model on physicians or other eligible professionals and beneficiary participation. Please describe the scope and span of the payment model and discuss practice-level feasibility of implementing this model as well as clinical and financial risks. In your description, please also describe:

- Related to physician or other eligible professionals' practices:
 - What types of physician or other eligible professionals' practices would be able to participate in this payment model?
 - How many physician or other eligible professionals' practices or numbers of physicians or other eligible professionals have expressed interest and willingness to participate in the model if it is approved?
 - How many physicians or other eligible professionals and patients could participate if the model was expanded to scale?
 - How would the payment model work for physicians or other eligible professionals who are employed and for those that are independent, and what

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

changes in compensation might be necessary for employed physicians or other eligible professionals, if applicable?

- Has the model been implemented by other payers, and if so, what was the experience?
- Are the costs or financial risks associated with the payment model feasible for small practices?
- Related to patient population(s):
 - What is the size of the population anticipated to benefit from the model in its initial stages and if the model were expanded to scale?
 - How are patients expected to benefit and how would they be protected against unintended consequences? For example, what protections would be in place to protect against the denial of needed care, overutilization, or less than optimal patient outcomes?
- What are the overall anticipated impacts on Medicare spending?
- What are the expected spillover effects on Medicaid, CHIP, TRICARE/VA, or private health spending, or on those beneficiaries/enrollees, if any?

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

The goal of this section is to better understand the "value proposition" that will be addressed by the proposed PFPM. Please describe how the components of the value proposition will be achieved. For example, how will clinical quality, health outcomes, patient experience, and health care cost management be addressed within the model and how will performance be measured? Please describe any current barriers to achieving desired value/quality goals and how they would be overcome by the payment model. Please identify any novel clinical quality and health outcome measures that will be included in this proposed model. In particular, measures related to outcomes and beneficiary experience should be noted.

- How is care delivery expected to improve in order to achieve savings or improve quality, including:
 - Where and by how much will health care services or costs be reduced, and/or
 - If quality will be improved beyond a baseline, how (and by how much) will quality be improved? If quality will not be improved, how will quality be maintained?
- What are the nature and magnitude of barriers and risks to the model's success and how will they be overcome?

- What metrics will be used to assess performance under the model including the impact of the model on total cost of care, and will any of the metrics include patient-reported outcome measures or measures of beneficiary experience of care?
- What approach will be used to develop any innovative metrics proposed for inclusion in the model, such as specialty-specific measures or patient-reported outcome measures, and how will this approach leverage existing measures, standards, value sets, etc.?
- What approach will be used to incorporate data from multiple sources to support total cost of care, resource utilization, or clinical quality metrics?
- What approach to electronic reporting of and timely feedback on performance measures will be used? How will the approach take into account capturing and sharing data from the EHRs of all clinicians who provide relevant care for the attributed patient population, aggregation and calculation of measures, and provision of timely feedback to support performance improvement?
- What level of monitoring or auditing will be required?
- Are there any prior or planned statistical analyses to estimate the impact of the model on spending and quality of care?

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

The goal of this section is to better understand the payment methodology for the proposed model, including how it differs from both existing payment methodologies and current alternative payment models. Please include a diagram and description of the flow of Medicare payments under the proposed model from CMS to any intermediary recipients of Medicare payments and to all individual physicians and individual eligible professionals. Please also describe:

- *how the proposed PFPM will incorporate the performance results in the payment methodology;*
- the role of physicians or other eligible professionals in setting and achieving the PFPM objectives
- *b* the financial risk that the entity/physicians will bear in the model.

Please also differentiate between how services will be reimbursed by Medicare versus how individual physicians or other eligible professionals might be compensated for being a part of this model. Finally, a goal of this section is to better understand any regulatory barriers at local, state, or federal levels that might affect implementation of the proposed model.

Optional Information Items if Relevant:

- Payment methodology:
 - How would entities be paid under the proposed model, including the amount of new payments (e.g., per beneficiary per month, shared savings payments, etc.), and what is the methodology for calculating such payments?
 - Will the proposed model include other payers in addition to Medicare, and if so, is a different payment methodology needed for those payers?
 - How will the model enable entities to sustain the expected changes in care delivery over time?
 - How are the targets for success defined, and what are the penalties for failure?
 - What methodology will be used for risk adjustment (if relevant)?
- How does the payment methodology differ from current Medicare payment methodologies/Center for Medicare and Medicaid Innovation (CMMI) models for physicians or other eligible professionals and why cannot it be tested under current payment methodologies/CMMI models?
- What degree of financial risk will the entity and its physicians or other eligible professionals bear as a consequence of this proposed model (i.e., will physicians be at financial risk for their portion of care within the framework of the model, and how will this be determined)?
- Where relevant, how will the model address:
 - Establishing the accuracy and consistency of identification/coding of diagnoses/conditions?
 - Clinical appropriateness of the payment unit (e.g., procedure or other treatment for which payment would be made)?
 - Accurately assigning claims for payment to particular episodes of care?
- Barriers that make a new payment methodology necessary:
 - Are there any barriers in the current payment system that prevent or discourage the change in care delivery?
 - Are you aware of any barriers that exist in state or federal laws or regulations (such as current coverage limitations in Medicare or state-specific scope of practice limitations)?
 - If no barriers exist, why is the proposed model the appropriate solution?
 - Will the proposed model have an impact if regulatory barriers (if present) are not addressed?

• If a PFPM requires that the payment be made to an entity other than a physician practice or entity that is owned by physicians or other eligible professionals, information should be submitted explaining:

The role that physicians or other eligible professionals will play in implementing the PFPM payment methodology;

- What requirements there would be as to how the physicians and other eligible professionals who will be compensated through the PFPM will be involved in the governance of the organization or entity;
- How the payments or incentives for the individual physicians and other eligible professionals who are part of the organization or entity would change; and
- How the payments or incentives for individual physicians and other eligible professionals would 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 towards value, including financial and nonfinancial ones; please describe any unique and innovative approaches to promote the pursuit of value including nonfinancial incentives such as unique staffing arrangements, patient incentives, etc.

- What financial incentives will be provided to encourage physicians and other eligible professionals to deliver high-value health care?
 - How will these incentives influence physician or other eligible professionals' behavior? Please be clear about how you expect changing incentives to be manifested throughout the delivery system.
 - Has the submitter had prior experience with the use of these incentives? If yes, what have been the effects (both salutary and adverse)? Were there any unintended consequences of the use of these incentives?
- Will non-financial incentives (e.g., use of behavioral incentives) be used to promote physicians and other eligible professionals' delivery of high-value health care? If yes, please describe them.
 - How will these incentives influence practitioner behavior? Please be clear about how you expect changing incentives to be manifested throughout the delivery system.
 - Has the submitter had prior experience with the use of these incentives? If yes, what have been the effects (both salutary and adverse)? Were there any unintended consequences of the use of these incentives?

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

The goal of this section is to better understand (1) how the proposed payment model could accommodate different types of practice settings and different patient populations, (2) the level of flexibility incorporated into the model to include novel therapies and technologies, and (3) any infrastructure changes that might be necessary for a physician or other eligible professionals to succeed in the proposed model.

Optional Information Items if Relevant:

- Can the proposed model be adapted to accommodate the breadth and depth of differences in clinical settings and patient subgroups (e.g., rural physicians and/or patients, physicians in a tertiary/quaternary setting, specific subgroups of patients, etc.)?
- How can the proposed model be adapted to account for changing technology, including new drug therapies or devices?
- To what extent will practitioners have to adapt to operational burdens and reporting requirements that result from the proposed payment model?
- How will model participants prepare and build the infrastructure to implement the proposed model?

<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 or the care changes to be supported by the model can be evaluated and what, if any, evaluations are currently under way that identify evaluable goals for individuals or entities in the model. If there are inherent difficulties in conducting a full evaluation, please identify such difficulties and how they are being addressed.

- Is the impact of the PFPM on metrics that are included as part of the proposed model able to be evaluated? If so please describe how.
- What are the evaluable goals at various levels (e.g., for a population, for a provider entity, for individual physicians, etc.)?
- Are there any evaluations of the proposed model under development, underway or that have been conducted and that have not been referenced in other sections? If yes, please identify them and state whether findings from those evaluations can be shared.
- Are there other questions beyond the impact on core metrics which the evaluation should focus on, including through the use of qualitative methods?

<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 describe the full range of personnel and institutional resources that would need to be deployed to accomplish the proposed model's objectives. Please describe how such deployment might alter traditional relationships in the delivery system, enhance care integration, and improve care coordination for patients.

Optional Information Items if Relevant:

- What types of physicians, non-physicians, and other eligible professionals would likely be included in the implementation of this model in order to achieve desired outcomes?
- How would the model support integration and care coordination among practitioners and across settings?
- To what extent would the proposed model result in changes in workforce requirements compared to more traditional arrangements?
- How will the model address coordination with care team members that are not financially accountable (e.g., through program requirements around care processes or voluntary agreements to share in savings/losses)?

<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. Describe how differences among patient needs will be accommodated and how any current disparities in outcomes might be reduced. For example, please share how the demographics of the patient population and social determinants of care may be addressed.

- How is patient choice preserved under the model by accommodating individual differences in patient characteristics (including social needs, etc.), conditions, and health-related preferences while furthering population health outcomes?
- How would the payment model affect disparities among Medicare beneficiaries by race, ethnicity, gender, disability, and geography?
- How would the payment model expand the demographic, clinical, or geographic diversity of participation in alternative payment models beyond existing CMS models (e.g., would the proposed payment model address populations which are not currently addressed in current CMMI models)?

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

The goal of this section is to describe how patients would be protected from potential disruptions in health care delivery brought about by the changes in payment methodology and provider incentives. Please describe how disruptions in care transitions and care continuity will be addressed. Safety in this instance should be interpreted to be all-inclusive and not just facility-based.

Optional Information Items if Relevant:

- How would the proposed model ensure that patients are not harmed by efforts to achieve savings or to improve specific aspects of quality/outcomes?
- What measures would be used to ensure the provision of necessary care and monitor for any potential stinting of care?
- To what degree will the proposed model ensure the integrity of its intended benefits and what embedded monitoring and potential adjustments are under consideration, should unintended or other incongruent behaviors occur?

<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. In this section please describe how information technology will be utilized to accomplish the model's objectives with an emphasis on any innovations that improve outcomes, improve the consumer experience and enhance the efficiency of the care delivery process. Please also describe goals for better data sharing, reduced information blocking and overall improved interoperability to facilitate the goals of the payment model.

- How would patients' privacy be protected if new providers or caregivers will have access to personal health information (PHI)?
- How would the model facilitate or encourage transparency related to cost and quality of care to patients and other stakeholders?
- Will interoperability of electronic health records be needed to guide better decisionmaking?
- Will any information technology innovations be used to support improved outcomes, improve the consumer experience, or enhance the efficiency of the care delivery process?
- How will any health IT requirements included in the model ensure that clinicians have the flexibility to choose from a variety of solutions to meet their needs and leverage existing technology assets where possible?

Supplemental Information

- If the entity submitting the proposal wishes to serve as a recipient of the proposed payment, please describe the proposed governance structure for the entity.
- If known, please describe any infrastructure investments that might need to be made by CMS, in addition to changes in the payment model (e.g., different mechanisms for claims processing, data flows, quality reporting, etc.).

F. Submission

1. Letter of Intent Submission

LOIs should be uploaded to the PTAC submission system <u>website</u> in MS Word or PDF Format. A <u>guide</u> on how to upload to the system is available on the PTAC website. Submitters may contact PTAC@hhs.gov with any problems uploading their LOI. All LOIs will be posted on the PTAC's website for availability to the public.

2. Proposal Submission

Complete proposals should be uploaded to the PTAC submission system <u>website</u>. MS Word, MS Excel (appendices), or PDF formats are acceptable. A <u>guide</u> on how to upload to the system is available on the PTAC website. Submitters may contact PTAC@hhs.gov with any problems uploading their proposal. Once received, all proposals will be posted on the PTAC website for availability to the public.

3. Submission Checklist

The submission checklist is intended to aid submitters in reviewing their proposals for completeness and adherence to requirements. The submitter must complete and submit the checklist with the proposal. The completed checklist should be included in an appendix.

Requirement	Checkbox	Pages			
Letter of intent submitted 30 days before the proposal					
Name and address of the submitter (individual or organization)					
Name, address, phone number, and e-mail address for the primary point of contact					
Title Page					
Table of Contents					
Abstract					
If the submitter is an organization, a letter of support from the governing board or responsible officer is included.					
Main body of the proposal is ordered by and includes the following sections:					
Model Description					
Background and Model Overview					
How the model would work from the patient's perspective					
How the model would work from the perspective of participating eligible professionals, the patient's					

primary care provider, and other providers (including hospitals, post-acute care providers, etc.) who would participate in or be affected by the model	
Response to Criteria	
Scope	
Quality and Cost	
Payment Methodology	
Value over Volume	
Flexibility	
Ability to be Evaluated	
Integration and Care Coordination	
Patient Choice	
Patient Safety	
Health Information Technology	
Main body of the proposal does not exceed 25 pages and formatting requirements are met.	

4. Withdrawal of a Submitted Payment Model

A submitter may withdraw a PFPM submitted to PTAC at any time prior to the PTAC's vote on the proposal. The PTAC will not send any comments or a recommendation to the Secretary on any proposal that is withdrawn prior to PTAC's deliberation. 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.

5. Resubmission of a Withdrawn Submission

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

6. Appeals Process

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

G.PTAC Proposal Review Process

PTAC will use the process described below to review and evaluate PFPMs and develop its comments and recommendations to the Secretary with respect to each submitted PFPM.

I. Preliminary Review

- A. Completeness Review
 - 1. Staff from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) will review the submitted proposal to determine its completeness using the Submission Checklist in the Submission section.
 - 2. Incomplete proposals will be returned to submitters. The PTAC Chair/Vice Chair (or their designee) will confirm the need to return the proposal due to incompleteness and approve the statement to the submitter giving the reason for the incompleteness.
 - 3. Complete proposals will be
 - a. Posted on the PTAC website in order to provide the public with the opportunity to comment on the proposed PFPM. In general 3 weeks will be allowed for submission of public comments on a proposal.
 - b. Assigned to a Preliminary Review Team appointed by the Chair/Vice-Chair, and consisting of two to three PTAC members, at least one of whom will be a physician.
- B. Preliminary Review Team (PRT)
 - 1. The PRT, at its discretion, may provide initial feedback to the submitter. Initial feedback will consist of (1) the extent to which a proposed model meets the Secretary's criteria and (2) "an explanation of the basis for the feedback." As such, initial feedback may identify (at the discretion of each PRT) shortcomings, strengths, or both of submitted models relative to the Secretary's criteria for PFPMs. Initial Feedback will be provided in writing. 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.
 - 2. The PRT will identify any additional information needed from the submitter relevant to the proposal. PRT staff will draft the information request which will be finalized by the PRT and approved by the lead reviewer. Information needed from the submitter will be communicated via an email from the PTAC. The PRT will decide on a case-by-case basis the most efficient and effective way of obtaining additional information and responses to questions (e.g., a written response, a telephone discussion, an in-person discussion with the submitter. Verbal discussion will be transcribed in order to create a written record of information provided, and posted to the PTAC website.
 - 3. The PRT will determine to what extent any additional resources (e.g., medical specialty expertise) are required for the review.

- 4. The PRT will determine to what extent any additional analyses (e.g., actuarial analysis to confirm proposal estimates of total cost of care reductions) are needed for the review.
 - a. The PRT and ASPE staff and contractors will arrange any needed analyses so as to minimize the extra time required to review the proposal.
 - b. The PRT may be faced with a trade-off between time and thoroughness and will exercise judgment on weighing them.
- 5. Individual PTAC members may send requests for additional information from the submitter, resources, and analyses to the PRT.
- 6. 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 evaluation will address the extent to which the proposal:
 - a. Does not meet the criterion,
 - b. Meets the criterion, or
 - c. Meets the criterion and deserves priority consideration.

The PRT will identify areas of consensus on the evaluation of each of the ten criteria and areas of disagreement.

- 7. With staff assistance, the PRT will prepare a report on each PFPM submitted to PTAC for consideration by the full Committee. The report will:
 - a. If the PRT determines that the Secretary's criteria do not apply to the submitted proposal, provide an explanation for this conclusion;
 - b. If the PRT determines that the Secretary's criteria do apply to the submitted proposal:
 - > Contain a qualitative rating for each of the ten criteria;
 - Provide the rationale for the qualitative rating given by the PRT for each of the ten criteria; and
 - > Highlight the overall strengths and weaknesses of the proposal.

II. Full Committee Review, Deliberation, and Voting

- A. Full Committee Review
 - 1. The Chair/Vice-Chair will determine when PTAC will deliberate on the proposal at a public meeting.
 - 2. Each PTAC member will receive and independently review the proposal and related materials prior to the Committee's deliberation on the proposal at the public meeting.
 - 3. The submitter will receive a copy of the PRT report at least three weeks prior to the public meeting. The submitter may provide a written response to the PRT

report. All responses to the PRT report must be received at least five business days prior to the public meeting to ensure that Committee members have sufficient time for review. Any information received from the submitter later than five days prior to PTAC's deliberative meeting may not be able to be considered by PTAC in its deliberations.

- 4. The PRT report will be posted to the PTAC website at least three weeks prior to the public meeting.
- 5. At the public meeting, the PRT will present its findings to the full Committee.
- 6. The submitter will be provided the opportunity to make a public statement at the Committee meeting.
- 7. The Committee will hear comments from the public.
- 8. After the PRT presentation and any comments from the submitter or the public, the Chair will ask the Committee whether they are ready to vote.
 - a. Any Committee member who is not ready to vote may make a motion to postpone voting until the next public meeting of PTAC. If the motion receives a second, the Chair will ask for a voice vote.
 - A simple majority of those present and voting is needed for the motion to carry.
 - If there is no second or the motion does not carry, members who are not ready to vote may abstain from voting.
 - b. After absences, abstentions, and recusals are taken into account, there must be at least 6 voting members of PTAC in order for voting to commence.
- B. Full Committee Deliberation and Voting using Secretary's Criteria
 - 1. At the public meeting, the full Committee will deliberate and vote on whether the Secretary's criteria apply to the submitted proposal. For those proposals to which PTAC finds the Secretary's criteria are applicable, the PTAC will deliberate and score the proposal on each criterion established by the Secretary using electronic voting technology to compile and display scores. Committee members participating remotely may vote with assistance from ASPE staff.
 - a. After discussion of each criterion, each member will cast an electronic vote on the extent to which either the criterion does not apply to the proposal or the proposal meets the criterion. For a proposal to which the criterion applies, the vote will use a whole number between 1 and 6, where 1-2 means "does not meet the criterion," 3-4 means "meets the criterion," and 5-6 means "meets the criterion and deserves priority consideration."
 - b. For each criterion, the distribution of the Committee members' votes will be calculated. Individual Committee members' scores will not be displayed or made public.
 - c. If all or nearly all of the Committee members' votes fall in the same numeric range (i.e., 1-2, 3-4, or 5-6), the Committee may choose to accept the vote as its decision on the criterion without further discussion unless a

Committee member requests additional discussion. Committee members will have the opportunity to discuss how to score a proposal on an individual criterion when the Committee members' scoring shows substantial disagreement.

- d. A second "round" of voting may be used at the end of Committee discussion to ascertain if there are any changes among Committee members' scores.
- e. For each criterion, the final rating will be based on the point range in which a majority of votes fall:
 - If the majority of votes are 1 or 2, the proposal does not meet the criterion.
 - If the majority of votes are 5 or 6, the proposal meets the criterion and deserves priority consideration.
 - If the majority of votes is 3 or 4, or if the majority of votes is 3 or greater but a majority is not 5 or 6, the proposal meets the criterion (but does not deserve priority consideration).
- C. Full Committee Deliberation and Voting on Recommendation to the Secretary
 - 1. After rating each proposal on the individual criteria, each Committee member will vote to place the proposal into one of the following Secretarial recommendation categories:
 - a. Secretary's criteria do not apply to the proposal; i.e., a vote of "Not Applicable."
 - b. Do not recommend proposed payment model to the Secretary.
 - c. Recommend proposed payment model to the Secretary for
 - Limited-scale testing. (This category may be used when the PTAC determines a proposal meets all or most of the Secretary's criteria but lacks sufficient data to (1) estimate potential costs, savings, or other impacts of the payment model and/or (2) specify key parameters in the payment model (such as risk adjustment or stratification), and the PTAC believes the only effective way to obtain those data would be through implementation of the payment model in a limited number of settings.)
 - Implementation.
 - Implementation as a high priority. (High priority models will be those that are rated as "meets the criterion and deserves priority consideration" on multiple criteria, particularly the criteria designated by the PTAC as "high priority" criteria.)
 - 2. A two-thirds majority of voting will be required to determine the recommendation to the Secretary.
 - 3. If two-thirds of the Committee members' votes fall in the same recommendation category (i.e., not applicable, do not recommend, recommend for limited scale

testing, recommend for implementation, or recommend for implementation as a high priority), this will be the Committee's recommendation to the Secretary.

- 4. If two-thirds of the Committee members' votes do not fall in the same recommendation category, Committee members will have the opportunity to further discuss the proposal. Additional "rounds" of voting may be used at the end of Committee discussion to ascertain if there are any changes among Committee members' scores.
- 5. The final recommendation will be determined as follows:
 - a. If two thirds of the votes cast are for "Not Applicable," the Committee will adopt this recommendation.
 - b. If two thirds of the votes cast are for "Do not recommend proposed payment model to the Secretary," the Committee will adopt this recommendation.
 - c. If two-thirds of the votes cast are for one or more of the three categories of recommending the model to the Secretary, the Committee shall determine which of the three recommendations shall be made to the Secretary by aggregating votes cast for the following categories in the following order:

First: Implementation as a high priority.

Second: Implementation.

Third: Limited-scale testing.

As soon as the aggregation of votes cast in the order above reaches a twothirds majority of votes cast, the recommendation level at which the twothirds majority is reached shall be the Committee's recommendation.

III. Production of Report to the Secretary

- A. At the deliberative meeting and after completion of the voting, the Chair will ask if any Committee member(s) want any specific comment(s) to be included in the PTAC's report to the Secretary. Any such comment(s) will also be included in the minutes of the meeting.
- B. PTAC staff will prepare the draft final report and recommendations to the Secretary, incorporating material content of the full Committee's deliberations.
- C. The PRT and then all voting Committee members will be given the opportunity to review the draft final report and propose changes.
- D. The Chair/Vice-Chair will determine when the report is finished.
- E. The Chair will forward the finished final report and recommendations to the Secretary.
- F. The PTAC's report to the Secretary will be posted on the PTAC website.

Appendix. Characteristics of PFPMs Likely to Be Recommended by PTAC

In order to assist stakeholders who are considering submitting proposals for PFPMs and to facilitate its own deliberations, PTAC has developed the guidance below describing the kinds of payment models that are more likely to receive favorable recommendations. However, PTAC will consider all proposals on their merits, and it reserves the right to make decisions on individual proposals that differ from this guidance. It also reserves the right to modify this guidance as necessary based on experience in reviewing proposals, based on comments and recommendations offered by stakeholders, and based on the regulations governing PFPMs that are issued by the Secretary.

PTAC will use the information submitted in a proposal, a submitter's responses to questions from PTAC members, analyses conducted to support the proposal review, and comments from the public to determine whether a PFPM <u>meets the Secretary's criteria</u>. The information needed to make this determination is defined in detail under each of the Secretary's Criteria in the Supporting Information section.

1. Goals and Focus of PFPMs

PFPM proposals may include, but are not limited to:

- Payments designed to enable individual eligible professionals[‡] or groups of eligible professionals to improve care for patients who are receiving a specific treatment or procedure. These "treatment-based payments" could focus only on services delivered on the day(s) of treatment or on services delivered during a longer episode of care.
- Payments designed to enable individual eligible professionals or groups of eligible professionals to improve care during a period of time for patients who have a specific health condition or combination of conditions. These "condition-based payments" could focus on either acute conditions or chronic conditions.
- Payments designed to enable teams of eligible professionals to deliver more coordinated, efficient care for patients who have a specific condition or are receiving a specific treatment or procedure.
- Payments designed to improve the efficiency of care and/or outcomes for patients receiving both services delivered by physicians or other eligible professionals and related services ordered by eligible professionals that are delivered by other providers.
- Payments designed to enable physicians or other eligible professionals to improve care for particular subgroups of patients (e.g., patients with a severe form of a condition, patients who have an early stage of a condition where progression can be more easily

^{*} As defined in MACRA and the regulations issued by HHS, an "eligible professional" is a physician, physician assistant, nurse practitioner, clinical nurse specialist, physical therapist, occupational therapist, qualified speechlanguage pathologist, qualified audiologist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist, or registered dietitian or nutrition professional.

prevented, patients who need special services after treatment, or patients living in frontier or rural communities.)

- Payments designed to enable a primary care physician or a multi-specialty group of eligible professionals to improve care for most or all of the health conditions of a population of patients, or to prevent the development of health problems in a population of patients with particular risk factors.
- Revisions to the codes and fee levels for a broad range of services delivered by physicians and other eligible professionals that are designed to support delivery of a different mix of services in conjunction with accountability for measures of utilization, spending, or outcomes for a group of patients.
- Payments in which the amount of payment depends on patient outcomes, with or without changes to the units of payment for individual physicians or other eligible professionals.
 PTAC will consider PFPMs in which the amount of financial risk during an initial period of time is smaller than the amount of risk in later periods.

PTAC is not likely to recommend to the Secretary a payment model that is targeted to a single health care provider, facility, institution, or system. Parties submitting proposed PFPMs to PTAC should present information in their proposal explaining how the PFPM submitted to PTAC would be feasible for implementation by multiple health care providers, facilities, institutions, or systems, as appropriate.

2. Services Supported by a PFPM

In general, PTAC will only recommend PFPMs that directly affect the method and/or amount of payments for one or more services delivered, ordered, managed, or coordinated by one or more types of physicians or other eligible professionals.

If a proposed payment model changes the method and/or amount of payments to both eligible professionals and other types of health care providers (e.g., hospitals, home health agencies, skilled nursing facilities), PTAC will be more likely to recommend the model as a PFPM if a substantial portion of the payment supports services that are delivered or ordered by physicians or other eligible professionals.

3. How the Method of Payment Differs from the Physician Fee Schedule

Payment for Individual Services Not Billable under the Physician Fee Schedule

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

Payments for Packages and Bundles of Services

If a proposed PFPM would create a new payment for physicians or other eligible professionals that replaces or includes the payments for two or more services that are currently paid for separately under the Physician Fee Schedule, PTAC will be more likely to recommend the proposed PFPM if the new payment replaces all or most of the eligible professional's current payments for individual services that are related to (1) a specific health condition or risk factor, or combination of conditions and risk factors; (2) a specific treatment; or (3) all of the health care needs of a population of patients (e.g., a monthly payment that covers all office visits, phone calls, emails, and office-based procedures needed by a patient, replacing separate payments for Evaluation and Management services and procedures). The new payment could allow flexibility to deliver services that are not currently billable in addition to services that are billable, and the amount of the payment could be stratified or adjusted based on characteristics of the patients, rather than based on the number or types of services delivered.

If the physician or other eligible professional would continue to be paid separately for any individual services related to a condition, risk factor, or treatment covered by the new payment, the PFPM proposal should explain why those services cannot or should not be included in the new payment. In these cases, PTAC will be more likely to recommend the PFPM if it also includes a mechanism for accountability for spending on the services that are not included in the new payment. For example, the PFPM might include a performance-based payment component using a measure of total spending on all services related to the condition, risk factor, or treatment (both the services that are included in the new payment and those that are still paid separately) or a measure of total spending on all aspects of the patient's care.

PTAC will be more likely to recommend a PFPM if it defines a process for updating the definitions of what is included and excluded in a new payment and updating the amount of the new payment as changes in technology and evidence occur over time.

4. Relationship of Eligible Professionals to Entity Receiving the Payment

PTAC recognizes that there are many different organizational structures through which physicians and other eligible professionals deliver services to patients and through which eligible professionals are paid for those services. PTAC will not limit the types of entities that can submit proposed PFPMs and it will consider proposals for PFPMs that would need to be implemented through entities other than practices or groups consisting of one or more physicians or other eligible professionals. PTAC encourages submission of proposals that could be successfully implemented by small, independent physician practices.

5. Accountability for Spending and Quality

Measures of Utilization, Spending, Quality, and/or Outcomes

PTAC will be more likely to recommend a PFPM that is focused on a condition, risk factor, or treatment if the PFPM requires the eligible professionals or the entity receiving the payment to take accountability for (1) controlling total Medicare spending on all services the patients receive that are related to the condition, risk factor, or treatment, (2) controlling total Medicare spending on all services the patients receive, or (3) improving performance on measures of spending, utilization, and/or quality that are primary drivers of total Medicare spending or of the spending related to the condition, risk factor, or treatment.

PTAC will be more likely to recommend a PFPM if it appears that the projected savings for the Medicare program are sustainable without any increases in spending by other payers.

PTAC will be more likely to recommend a PFPM that changes payment related to a treatment if the eligible professionals or the entity receiving the payment take accountability for ensuring that the treatment is appropriate for the patient.

PTAC will be more likely to recommend a PFPM that changes payment related to a health condition if the payment model defines a consistent method of identifying the condition for which payment would be made and if the eligible professionals or the entity receiving the payment take accountability for ensuring the accuracy of the diagnosis of the condition.

PTAC will be more likely to recommend a PFPM that changes payment related to a health condition if it addresses how care will be delivered to patients who have health conditions in addition to the condition on which the PFPM is focused.

PTAC will be more likely to recommend a PFPM if it includes specific mechanisms for ensuring that patients receive evidence-based services for the health condition(s) or for the delivery of the preventive or treatment service(s) that are the focus of the PFPM.

PTAC will be more likely to recommend a PFPM if the eligible professionals or the entity receiving the payment take accountability for some or all of the outcomes of the care delivered.

PTAC will be more likely to recommend a PFPM if it proposes evidence-based quality measures that are feasible to collect and use to monitor performance, or, if such quality measures are not available, if the proposal presents a compelling case for how quality would be maintained or improved and how research or periodic monitoring could be used to demonstrate positive quality outcomes.

PTAC will be more likely to recommend a PFPM if it specifically identifies potential unintended consequences and includes mechanisms for preventing or mitigating them.

If a PFPM is designed to support services that would prevent future health problems, slow the progression of disease, or achieve other outcomes that will occur over a multi-year period, and if additional spending is needed in the short run to achieve savings in the future, PTAC will be more likely to recommend the PFPM if it (1) requires accountability for improving a current clinical measure that has been shown to have a close direct linkage to the long-term outcome, and (2) requires accountability for ensuring spending does not increase more than the amount projected to be needed to achieve the improved outcome.

Financial Risk

PTAC will be more likely to recommend a PFPM in which the eligible professionals or the entity receiving the payment accept more than nominal financial risk for achieving the desired results on the measures of spending and quality/outcomes. PTAC may recommend PFPMs that do not meet the specific requirements for financial risk or other requirements for qualification as an "Advanced Alternative Payment Model" under the regulations issued by HHS. The fact that the financial risk components or other characteristics of a PFPM lead to a recommendation by PTAC does not necessarily mean that the PFPM will be approved as an Advanced Alternative Payment Model by the Secretary.

PTAC will consider proposals for PFPMs that define financial risk in different ways, including, but not limited to:

- The amount of payment that could be lost by the eligible professionals or the entity if the desired results are not achieved;
- The increase in unreimbursed costs the eligible professionals or entity would incur if the desired results are not achieved; or
- The amount that the eligible professionals or entity would be expected to pay to the Centers for Medicare & Medicaid Services (CMS) if the desired results are not achieved.

PTAC will be more likely to recommend a PFPM in which the amount of financial risk and the way in which the risk is structured are (1) likely to be financially feasible for physicians and eligible professionals to accept, including small practices, and (2) likely to adequately encourage changes in care delivery needed to achieve the desired results on the measures of spending and quality/outcomes. This includes, but is not limited to, PFPMs that have one of the following characteristics:

- When the desired results are not achieved, the potential reduction in payments to a participating eligible professional practice is at least as great as the maximum penalty the practice would face if it were being paid under current Medicare payment systems rather than under the PFPM; or
- When the desired results are not achieved, payments to the eligible professional practice or entity could be reduced by more than any increase in payments the practice or entity received compared to the standard amounts it would have received under current Medicare payment systems; or

Payments to the eligible professional practice or entity could be reduced by an amount sufficient to ensure there is no net increase in Medicare spending for the condition(s) or treatment(s) that are the focus of the payment model.

PTAC will be more likely to recommend a PFPM that includes a method of adjusting payments, measures, and financial risk based on the differences in the needs of patients.