

# Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Findings on

## **The Acute Unscheduled Care Model (AUCM): Enhancing Appropriate Admissions**

Submitted by American College of Emergency Physicians

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# Presentation Overview

- Preliminary Review Team (PRT) Composition and Role
- Proposal Overview
- Summary of the PRT Review
- Key Issues Identified by the PRT
- PRT Evaluation Using the Secretary's Criteria

# Preliminary Review Team Composition and Role

- The PTAC Chair/Vice Chair assigns two to three PTAC members, including at least one physician, to each complete proposal to serve as the PRT. One PRT member is tapped to serve as the Lead Reviewer.
- The PRT identifies additional information needed from the submitter and determines to what extent any additional resources and/or analyses are needed for the review. ASPE staff and contractors support the PRT in obtaining these additional materials.
- The PRT determines, at its discretion, whether to provide initial feedback on a proposal.
- After reviewing the proposal, additional materials gathered, and public comments received, the PRT prepares a report of its findings to the full PTAC. The report is posted to the PTAC website at least three weeks prior to public deliberation by the full Committee.
- The PRT report is not binding on PTAC; PTAC may reach different conclusions from those contained in the PRT report.

# Proposal Overview

**Goals** – The proposed model centers on incentivizing improved quality and decreased cost associated with the discharge disposition decisions made by emergency department (ED) physicians for defined episodes of care.

- Areas for potential Medicare spending reductions and improved quality of care focus on reducing avoidable hospital inpatient admissions and observation stays, providing the ability for ED physicians to coordinate and manage post-discharge home services, avoiding return ED visits, and other patient safety events.

**Episode Framework** – The proposal uses an episode framework or bundled payment methodology with retrospective reconciliation, a target price, and a quality reporting or performance component for eligible participants.

**Episode Definition** - The episode starts with a qualifying ED visit. All Medicare services that occur in the 30 day post discharge period are included in the episode for purposes of monitoring costs and quality. The episode ends at patient's death or 30 days after the qualifying ED event.

**Qualifying Diagnoses** – The initial performance years of the proposed model focuses on four high-volume ED conditions (abdominal pain, chest pain, altered mental status, and syncope). Additional conditions would be added that do not result in greater than 90% of inpatient admissions in subsequent performance years.

**Risk Bearing Entity** – Risk bearing entity is an independent physician group, the faculty practice plan in academic settings, or the hospital in the case of employed physicians.

# Proposal Overview- *Continued*

## Qualifying ED Case is an ED visit that results in:

- Discharge home to the community
- ED observation stay followed by discharge home to the community
- Non-ED observation followed by discharge
- Inpatient admission followed by discharge (This includes stays where patients admitted to non-ED observation are ultimately discharged from inpatient status.)
- **ED observation as compared to non-ED observation:** The proposal makes a distinction between observation stays that are under the care of an ED physician in the location of the ED as compared to observation stays that take place in hospital locations other than the ED under the care of non-ED physicians.
  - **Episode Target Price:** For purposes of calculating a target price, non-ED observation stays that take place in hospital locations other than the ED are considered equivalent to inpatient admissions in the calculation of the episode target price.
  - **Quality Metrics:** Inpatient admissions and observation stays that take place in locations other than the ED do not appear to qualify for participation in the model intervention in terms of the cases or the physicians who would be accountable for those cases since the quality metrics that determine eligibility for reconciliation payments do not apply to them.

# Proposal Overview- *Continued*

**Episode Target Price** – A facility-specific target episode price for each qualifying condition would be calculated based on three years of historical claims data for the initial ED visit plus all costs incurred 30 days post-discharge including new services associated with proposed waivers in the model.

- Savings in the model would be generated when actual Medicare episode spending for selected conditions is below a facility-specific, historical cost for the episode. Reduced admissions for the target condition would provide the greatest opportunity for savings.

**Discount to Episode Target Price** – A discount to the episode target price of 1.5%- 3% would guarantee savings and amount of the discount depends upon a participant's performance on quality metrics.

- Participants in higher quality performance categories would have a lower discount (e.g., 1.5%) to the episode target price or the potential to receive higher reconciliation payments.
- Lower scores on quality metrics would have a higher discount threshold or receive lower reconciliation payments.
- If participants have a quality score considered unacceptable, they are not eligible for a reconciliation payment.

**Updates to Target Price** – In order to adjust for temporal changes in average severity, the episode target price would be updated annually using the CMS-Hierarchical Condition Categories or other methodology determined by CMS

# Proposal Overview- *Continued*

**Options for Participants** – The proposed model includes three options for participants to choose different tracks of *quality reporting* versus *quality performance* which correspond to different options for risk sharing, stop gain/stop loss thresholds, and other parameters.

- Pay for reporting transition to pay for performance with downside risk starting in performance year three
- Pay for performance with stop gain/loss of 10% with downside risk starting in performance year one
- Pay for performance with progressive stop gain/loss capped at 20% with downside risk starting in performance year one

**Performance Measures** – The proposed model includes three performance measure domains:

- Patient engagement/experience - % of eligible cases in which shared decision making about discharge plan occurred is reported– minimum threshold 40%
- Process/care coordination - % of eligible cases in which a shared discharge assessment was completed and reviewed by a physician is reported – minimum threshold 40%
- Outcomes - % of eligible cases where an unscheduled ED revisit, hospitalization, or death did not occur within 30 days compared to the prior reference period (event-free post discharge period) – calculated at the facility level

# Proposal Overview- *Continued*

**Final Assessment for Safe Discharge Home** – ED physician is responsible for final patient assessment for safe discharge home. Proposal includes examples of possible patient assessment tools.

**ED physician Communication at Discharge** – Requires ED physician to communicate with a follow-up care provider (primary care physician, specialist, or designee). Proposal suggests an ED-based care coordinator will assist scheduling follow-up care to facilitate handoff of patient at discharge.

**Medicare Program Waivers-** 1) Authorize ED physicians to bill for transitional management codes, 2) allow ED physicians to provide telehealth services, and 3) allow licensed clinical staff to provide home visits under general supervision of an ED physician.



# Summary of the PRT Review

Criteria Specified by the Secretary (at 42 CFR §414.1465)	PRT Conclusion	Unanimous or Majority Conclusion
1. Scope (High Priority)	Meets Criterion	Unanimous
2. Quality and Cost (High Priority)	Meets Criterion	Majority Conclusion
3. Payment Methodology (High Priority)	Does Not Meet Criterion	Majority Conclusion
4. Value over Volume	Meets Criterion	Unanimous
5. Flexibility	Meets Criterion	Unanimous
6. Ability to be Evaluated	Meets Criterion	Unanimous
7. Integration and Care Coordination	Does Not Meet Criterion	Majority Conclusion
8. Patient Choice	Meets Criterion	Unanimous
9. Patient Safety	Meets Criterion	Unanimous
10. Health Information Technology	Meets Criterion	Unanimous

# Key Issues Identified by the PRT

- The model both approaches ED payment policy in a new way, conceptually aligned with value over volume, and provides an opportunity for a new group of physicians, ED physicians, to participate in an APM. The PRT was impressed with the data-driven selection of eligible conditions, the sizing and structure of the incentives, and the attention to patient safety.
- The PRT has concerns with the model in terms of:
  - the exclusion of non-ED physicians caring for observation patients admitted through the ED,
  - the lack of process quality metrics that would permit sharing of best practices,
  - use of a facility-specific approach to pricing without including a regional or national benchmark, and
  - challenges with the feedback loop of communication among participating providers.

# Criterion 1. Scope (High Priority)

## Criterion Description

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.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- Proposal aims to provide a Medicare payment model whereby ED physicians currently not able to participate in APMs could do so through an episode framework in alignment with other CMS initiatives.
- Patient-centered approach would identify qualifying ED patients at potential risk for post-discharge events and provide financial incentives that enhance discharge planning and support patient and family engagement.
- Current variation in treatment of these types of patients (including especially variation in admission rates) supports the finding that this type of payment model is a potential candidate to advance the progression of best practices of care for patients in this care trajectory.
- Additional strength of this model is it could be adopted by commercial payers, states, and even accountable care organizations (ACOs) could use a similar approach internal to their organization.

# Criterion 2. Quality and Cost (High Priority)

## Criterion Description

Are 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.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Majority Conclusion

- The episodic approach to care delivery shifts the focus from a volume of individual services to a more patient-centered approach focused on decision making in the ED and thus the value of care delivered.
- The proposed model includes three options for participants to choose different tracks of increasing risk/reward that moves through stages of quality reporting to performance-based which correspond to different options for risk sharing, stop gain/stop loss thresholds, and other parameters.
- The proposal is anticipated to improve quality by supporting appropriate discharge from the ED while ensuring beneficiaries are safe from harm by relying on both the professionalism of the care team and through monitoring of post-discharge events including hospital admission, death, and return to the ED within 30 days of the qualifying ED visit.
- The most important quality concern related to changing payment for ED services is the possibility that patients who should be admitted will not be. The PRT found the model addresses this concern in three ways: 1) focus on diagnoses where evidence suggests there is considerable opportunity to reduce hospitalization, 2) uses historical controls, and 3) proposes to measure post-discharge mortality and include performance on this metric in the assessment of the program.
- While the key issues related to quality are addressed (patient experience, care coordination, outcome), PRT raised concerns with the lack of available process quality measures that would permit greater ability to understand improvement opportunities.

# Criterion 3. Payment Methodology (High Priority)

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Majority Conclusion

- The proposal uses an episode framework or bundled payment methodology with retrospective reconciliation, a target price, and a quality reporting or performance component for eligible participants.
- The model includes three options for participants to choose different tracks of quality reporting versus performance which correspond to different options for downside risk. The PRT was concerned with option one which permits pay for reporting with upside opportunity for two years. One year was considered more appropriate given the short feedback cycle time.
- The distinction between patients cared for in ED observation and those cared under observation by other departments is a result of the submitter's desire to constrain accountability to only the providers practicing within the risk accountability unit (ED physicians).
  - This model feature is imposed in an identical way to all potential risk bearing entities. If the rationale for exclusion of non-ED observation patients from the bundles is lack of alignment between the at-risk physicians and the control of the discharge of the included patients, then the PRT thought this exclusion should be applied to only independent physician associations. Even with this adjustment, the PRT had concerns about the possibility that this distinction could result in different pt mgmt.

# Criterion 3. Payment Methodology (High Priority) – Continued

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Majority Conclusion

- The PRT viewed the other two types of risk bearing entities (i.e., the faculty practice plan in academic settings and the hospital in the case of employed physicians) as having institution/hospital-wide responsibility for handoffs and discharges. In these cases, all observation cases regardless of the type of physician managing the patient, should be handled similarly in the model.
- ED observation patients and non-ED observation patients would have different attending physicians of record who may or may not be in the same risk group. These distinctions are unimportant from the patient or payer’s perspective.
- The PRT was concerned where ED observation and non-ED observation co-exist in the same hospital, changes in the types of patients going to each could confound the estimates of performance or potentially used to game the assessment.
- The PRT also had concerns with the sole reliance on a historical, facility-specific target price without consideration of a process to include a regional, national, or blended approach. The PRT was concerned that the exclusive reliance on a historical, facility-specific target may end up rewarding improvements based on relatively poor starting performance while those facilities starting off with better baseline performance would be disadvantaged.

# Criterion 4. Value over Volume

## Criterion Description

Provide incentives to practitioners to deliver high-quality health care.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- The focus of the model is to incorporate an episode of care triggered by an ED event. The current Medicare fee-for-service structure focuses on individual service delivery.
- Model provides incentives to inform the ED physician's decision making on the included patient populations.
- Design of the model focuses on diagnoses with high variability in admissions and returns to the ED.
- The shift toward incentivizing decisions in the ED focuses on opportunities to obtain value in the purchase and delivery of health care to beneficiaries.

# Criterion 5. Flexibility

## Criterion Description

Provide the flexibility needed for practitioners to deliver high-quality health care.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- Model is designed to include nearly all practice types found in the ED.
- Model does not specify how the target price will be achieved by participants and therefore provides adequate flexibility to providers to deliver care they consider appropriate and innovative.
- Model provides a platform that could be extended to more diagnoses in the ED which by definition provides flexibility.
- Provides flexibility in options for quality performance strategies as well as paths towards two-sided risk based on the readiness of participants.



# Criterion 6. Ability to be Evaluated

## Criterion Description

Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- Evaluation could be performed by comparing changes in spending under the model for participants vs. non-participating practices.
- Patient, provider, and geographic characteristics of participants vs. non-participants could be constructed using CMS administrative data sets.

# Criterion 7. Integration and Care Coordination

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Majority Conclusion

- The model incentivizes greater communication and coordination between the ED and all ambulatory physicians who are planned to follow-up with the patient.
- ACEP’s distinction between ED visits with observation stays as compared to observation stays in locations other than the ED could be viewed as a barrier to communication and coordination among these different parts of the hospital that should be providing the same level of care.
- The model does define the first hand-off by the participant at the time of initial discharge home by requiring physician-physician communication with the primary care physician, physician, or designee who will provide follow-up care and includes an ED based coordinator who will assist in scheduling follow-up care.
- The proposal includes the potential for Medicare payment waivers to provide home visits, telehealth, and transitional care payments.
- PRT found the model did not adequately address the feedback loop of patient information that would likely be necessary during the 30-day post discharge period beyond the initial hand-off at ED discharge. The PRT raised concerns about the lack of specificity on the features and how the patient information will be provided to the accountable entity to ensure care coordination during the 30-day post-ED discharge episode.

# Criterion 8. Patient Choice

## Criterion Description

Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- The PRT found the model meets the criterion because protecting patient choices in the ED is in an ED physician’s rubric in which patient’s interests are being considered.
- The payment incentives included in this model are unlikely to negatively impact patient choices.
- In theory, some concern that individual financial incentives on participating ED physicians could provide an incentive for the physician to advise patients to pursue a course that was not in the patient’s best interests. The PRT thought the checks and balances included in the proposal were sufficient to negate this potential concern (see criteria 9, patient safety). On the other hand, patients who would otherwise be admitted without benefit would have the opportunity to go home.

# Criterion 9. Patient Safety

## Criterion Description

Aim to maintain or improve standards of patient safety.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- The model incentives will hold ED physicians accountable for post-discharge complications in the scoring of quality and costs in the post-discharge 30-day episode period. The magnitude of the required discount appears appropriate so should not unduly incent injudicious decision making. Combined with the quality measures, the model builds in sufficient checks for patient safety.
- The model's quality measures include:
  - patient engagement/experience defined as % of eligible cases in which shared decision making about the discharge plan occurred is reported,
  - process/care coordination defined as % of eligible cases in which a shared discharge assessment was completed and reviewed by physician is reported, and
  - outcomes defined as % of eligible cases where an unscheduled ED revisit, hospitalization, or death did not occur within 30 days compared to the prior reference period.

# Criterion 10. Health Information Technology

## Criterion Description

Encourage use of health information technology to inform care.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- The model does not restrict current health information integration efforts and may incentivize use of technology such as registries to provide information on model discharges.
- Shared discharge assessment and shared decision making measures could be submitted through the use of certified electronic health record technology (CEHRT).
- The model also includes the possible use of ACEP's clinical emergency data registry (CEDR) or other registries to provide benchmarks and enable ED group participation in the model using CEHRT.

# Physician-Focused Payment Model Technical Advisory Committee

Preliminary Review Team Findings on the

## **“An Innovative Model for Primary Care Office Payment” Payment Model (IMPC-APM)**

Submitted by Jean Antonucci, MD

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September 6, 2018

# Presentation Overview

- Preliminary Review Team (PRT) Composition and Role
- Proposal Overview
- Summary of the PRT Review
- Key Issues Identified by the PRT
- PRT Evaluation Using the Secretary's Criteria

# Preliminary Review Team Composition and Role

- The PTAC Chair and Vice Chair assigned three PTAC members (Ferris, Miller, and Patel), including two physicians (Ferris and Patel), to serve as the PRT. Miller was assigned as the Lead Reviewer.
- The PRT requested and received additional information from the submitter. ASPE staff and contractors assisted the PRT in obtaining additional information needed for its review.
- The PRT decided to provide initial feedback on the proposal to the submitter, and it held a conference call with the submitter.
- Based on its review of the proposal and of the additional information that it received, the PRT prepared a report of its findings to the full PTAC. The report was posted to the PTAC website for public review prior to this meeting. The full PTAC Committee has not previously discussed the proposal or the PRT report.
- The PRT report is not binding on PTAC; the full PTAC Committee may reach different conclusions from those contained in the PRT report.



# Proposal Overview

**Goals:** The goals of the Innovative Model for Primary Care Office Payment (IMPC-APM) are to provide additional financial resources to support primary care practices; reduce administrative burden on primary care practices; and increase the flexibility of primary care practices to deliver more and different services to patients than under traditional office visits. It is intended to be simpler and easier for small, independent, office-based practices to participate in than other alternative payment models (APMs) for primary care practices.

**Eligible Participants:** Primary care physicians and independent primary care nurse practitioners would be eligible to participate. The model is not specifically designed to apply to pediatricians.

**Payment Methodology:** The proposal contains two payment components.

## 1: Risk-Stratified PBPM Payments

- A practice would receive a risk-stratified per beneficiary per month (PBPM) payment instead of virtually all current fees (including Evaluation and Management (E/M) services, minor procedures, and most office-based tests). The payment could be used for services other than office visits.
- The submitter proposes the following payment amounts: \$60 per month for low / medium risk patients, and \$90 per month for high risk patients.

## 2: Performance-Based Payment

- A performance-based payment would be created by withholding 15% of the PBPM payment, and the practice would receive the withhold only if it meets a performance standard based on quality and utilization of hospital services. The specific performance standard is not defined in the proposal.
- A practice could also appeal to have the withhold paid in extenuating circumstances.

# Proposal Overview – *Continued*

**Quality Standards:** Participating practices would be required to have an annual visit with every patient and to maintain office hours, staffing, and phone access.

**Quality Measurement:** Quality of care would be measured using information reported by patients in the 15-minute online “How’s Your Health” (HYH) survey.

- The survey would be available free of charge to participating practices at [www.HowsYourHealth.org](http://www.HowsYourHealth.org).
- The physician would receive a report about the patient’s “function, diagnosis, symptoms, health habits, preventive needs, capacity to self-manage chronic conditions, and their experiences of care.”
- The practice could compare data for its patients with benchmarks based on other participating practices.
- The submitter indicates it would likely not be feasible to get 100 percent of the patients to complete the survey; the submitter asserts that a practice would need 60 to 100 surveys completed per year to get statistically valid data.

**Risk Stratification of Payments:** Monthly payments would be higher for patients classified as High Risk based on the “What Matters Index” (WMI). WMI is based on five factors derived from HYH (e.g., pain, emotional issues, polypharmacy, adverse medication effects, and low confidence in managing health problems) that the submitter indicates are predictive of rates of hospital admissions and patients’ use of primary care services.

**Patient Attribution:** Patients who explicitly choose to use a participating practice would be assigned to the practice. Patients could also be attributed to the practice based on how often they visit the practice. Practices would be limited to 1,500 patients per physician.

# Proposal Overview – *Continued*

## Examples of Quality Measures From the “How’s Your Health” Tool That Can Be Monitored and Benchmarked

- No Hospital or Emergency Department (ED) Use for Chronic Disease
- Medications not making ill
- Measures Often Requested by Regulators
- Efficiency of Care (Does not waste time)
- Any Sick Day in 3 Months
- Any Stay in Hospital in One Year
- Wellness Activities
- Continuity (Personal Doctor or Nurse)
- Any Current Specialist Care
- One Clinician in Charge
- Medical Care Perfect (Nothing needs improvement)
- Very Easy Access

# Proposal Overview – Continued

**Comparison to Payment Methodologies in Other APMs** – The following are key similarities and differences between the payment methodologies in the Comprehensive Primary Care Plus (CPC) APM that is currently being tested by CMMI, the APC-APM that PTAC recommended for implementation at its December 2017 meeting, and the IMPC-APM.

## CPC+

- Available in only 18 regions; practices must apply and be selected by CMS.
- 3-4 Components to Payment:
  - Track 1 practices continue receiving Medicare FFS payment.
  - Track 2 practices receive quarterly Comprehensive Primary Care Payments + reduced Medicare FFS.
  - All practices receive a quarterly risk-adjusted Care Management Fee for each patient to support non-visit-based services.
  - All practices receive a Performance-Based Incentive Payment (PBIP) at the beginning of each year which may be recouped based on performance.

## APC-APM

- Would be available nationally.
- 4 Components to Payment:
  - A risk-adjusted Per Beneficiary Per Month (PBPM) payment in place of some E/M services.
  - Continued FFS payment for non-E/M services and for E/M services not included in PBPM.
  - A risk-adjusted PBPM payment for non-face-to-face care management services delivered by the practice.
  - Prospectively awarded quarterly performance incentive payments which may be recouped based on performance.

## IMPC-APM

- Would be available nationally.
- 2 Components to Payment:
  - A risk-stratified Per Beneficiary Per Month (PBPM) payment in place of virtually all current fees (E/M services, minor procedures, and most office-based tests).
  - 15% of PBPM payment is withheld and would be forfeited if the practice fails to meet annual quality targets (which are not specified in the proposal).

# Proposal Overview – Continued

**Comparison to Other APMs on Quality Measures and Risk Adjustment** – The following are key similarities and differences between the Comprehensive Primary Care Plus (CPC) APM that is currently being tested by CMMI, the APC-APM that PTAC recommended for implementation at its December 2017 meeting, and the IMPC-APM.

## CPC+

- Half of the Performance-Based Incentive Payment is based on quality measures (CAHPS and eQMs), and half is based on hospital service utilization.
- Practices must report at least 9 of the 14 CPC+ eQMs (including 2 of 3 outcomes measures, 2 of 4 complex care measures, and any 5 of the remaining measures).
- The CMS-HCC risk score is used for risk stratification.

## APC-APM

- Fewer measures and a different mix of measures are used than CPC+ (APM Entity would select 6 quality measures, including 1 outcome measure from the ACO and PCMH Primary Care Measures Set).
- The Minnesota Complexity Assessment Model is proposed for risk stratification.

## IMPC-APM

- Patient-reported measures from the free, proprietary “How’s Your Health” Tool (HYH) would be used for quality measurement. The exact measures and performance benchmarks are not specified.
- The “What Matters Index” based on HYH would be used for risk stratification of patients.
- Not all patients would complete the HYH.

# Summary of the PRT Review

Criteria Specified by the Secretary (at 42 CFR §414.1465)	PRT Conclusion	Unanimous or Majority Conclusion
1. Scope (High Priority)	Does Not Meet	Majority
2. Quality and Cost (High Priority)	Does Not Meet	Unanimous
3. Payment Methodology (High Priority)	Does Not Meet	Unanimous
4. Value over Volume	Meets	Unanimous
5. Flexibility	Meets	Unanimous
6. Ability to be Evaluated	Does Not Meet	Majority
7. Integration and Care Coordination	Does Not Meet	Unanimous
8. Patient Choice	Does Not Meet	Unanimous
9. Patient Safety	Does Not Meet	Unanimous
10. Health Information Technology	Meets	Unanimous

# Key Issues Identified by the PRT

- The IMPC-APM payment model has some similarities to the APC-APM that PTAC recommended for implementation at its December 2017 public meeting, but it also has some important differences.
- The IMPC-APM model's payment structure is significantly simpler than the APC-APM, which could make it easier for primary care practices to implement, particularly solo and small practices.
- The use of monthly payments in place of all current payments for visits and services creates greater flexibility for practices, but also a risk that patients could be undertreated.
- Quality accountability would be based on the "How's Your Health" (HYH) survey instrument. Using patient-reported measures could be desirable for reducing physician burden and ensuring attention to what matters to patients. However, in order to use the HYH results as part of a performance-based payment, a standardized sampling frame and mode of administration would be needed, and no method for doing this is described in the proposal.
- The proposal does not explain which specific quality measures would be used and what performance levels would need to be met in order for a practice to receive the 15% withhold payment.
- Because of the large payment amounts proposed, the PRT was unable to conclude that Medicare spending would be maintained or decreased.
- The PRT believes the proposal has many desirable features and potentially important innovations in quality measurement, but it would need considerable further development in order to be tested on a broad scale. The PRT believes it would be desirable to further develop and test this approach as an option within other primary care models or ACOs, rather than as a completely separate model.

# Criterion 1. Scope (High Priority)

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Majority

- The IMPC-APM is significantly different than the payment models that have previously been tested by CMMI and that are currently being tested in CMMI's Comprehensive Primary Care Plus (CPC+) model.
- IMPC-APM uses a completely different approach to risk stratification of payments and quality measurement than any other CMS payment model and any other PFPM proposal that PTAC has previously recommended.
- The structure of the payment model is specifically designed to be less complex and more administratively feasible for solo and very small primary care practices.
- However, the majority of the PRT is concerned that:
  - This proposal has many similarities to other primary care medical home payment models, and it is not clear how many primary care practices would be interested in participating in this model or how many would prefer it over other approaches.
  - Because of the innovative nature of the quality measurement approach, additional development work would be needed to implement this with a large number of practices.
- The PRT believes that it would be desirable to find a way to further develop and test this approach as an option within other primary care models or ACOs, rather than as a completely separate model.



## Criterion 2. Quality and Cost (High Priority)

### Criterion Description

Are 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.

### PRT Conclusion

Does Not Meet Criterion

### Unanimous or Majority Conclusion

Unanimous

- The proposal has strengths relating to delivering quality care:
  - Participating practices would have more flexibility and more resources to deliver more and different services to patients.
  - The proposed quality and risk stratification tool is more directly tied to patient characteristics and issues that a primary care practice can directly address (including barriers to adherence and social determinants of health) than typical diagnosis-based risk tools and quality measures.
- However, the proposal also has weaknesses relating to quality:
  - Because the monthly PBPM payment would replace all payments that would otherwise be made for minor procedures and office-based tests, some practices could send patients to specialists or urgent care centers for these services rather than performing them directly, and no mechanisms are specified for avoiding this.
  - Using a completely different quality metric for practices participating in this model will make it difficult for patients and CMS to determine whether the quality of care is better than in non-participating practices.
  - It is not clear what level of quality the participants will be expected to achieve.

## Criterion 2. Quality and Cost (High Priority) – Continued

### Criterion Description

Are 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.

### PRT Conclusion

Does Not Meet Criterion

### Unanimous or Majority Conclusion

Unanimous

- The proposal also has weaknesses relating to cost:
  - The proposed payment amounts would represent almost a tripling of Medicare payments for participating practices compared to what they would receive under the current system. The only justification provided for this is to increase earnings for primary care physicians, rather than to cover costs of explicitly identified additional services for patients.
  - Evidence is unclear as to how much savings can be achieved by changing or increasing payments to primary care practices. Participation is not limited to practices that care for patients who have a high risk of hospital admission, and there is no requirement that participating practices would have to use evidence-based approaches for reducing avoidable hospitalizations or other expensive services.
  - Past experience with practice capitation payments indicates that some practices could be less responsive to patients who need to be seen by the physician, and there is no explicit mechanism to prevent that.
  - In order to use the results of the How's Your Health Tool as part of a performance-based payment, a standardized sampling frame and mode of administration would be needed in order to insure consistency and comparability of results and to avoid the possibility of manipulation of results, and this would be very different than the proposed method of data collection for use in quality improvement and patient care.

# Criterion 3. Payment Methodology (High Priority)

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- The proposed payment methodology would provide more resources and greater flexibility for primary care practices to deliver higher-quality, more efficient care for Medicare beneficiaries.
- The risk-stratification structure would help assure that higher payments are made for patients who need more services and for whom there may be greater opportunities for savings from reducing avoidable spending.
- However, the methodology could enable practices to deliver lower-quality, less efficient care with no immediate/short-run impact on the practice's revenues.
- No information was provided showing that the proposed payment amounts are needed to cover specific costs of additional staff or services required to deliver high-quality care.
- Due to significant differences in the way quality is measured compared to current methods, it would be challenging for CMS to ensure that quality of care was being maintained or improved, particularly if the participating practices are not also reporting data for standard MIPS quality measures.
- The penalty for any shortfall in quality would be complete loss of the 15% withhold, rather than a more graduated penalty based on relative levels of performance. This could make it difficult to set high goals for quality.
- Specific criteria for awarding the 15% withhold are not defined.

# Criterion 4. Value over Volume

## Criterion Description

Provide incentives to practitioners to deliver high-quality health care.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- Payments to participating practices would no longer be based on the number or type of services delivered, but would instead be based on:
  - The number of patients managed,
  - The level of need for those patients, and
  - The practice’s performance on quality measures and rates of emergency department visits and hospital admissions.
- A significant portion (15%) of the practice’s revenues would be at risk based on quality performance.
- The lack of a direct connection between payments and services could lead to stinting on aspects of care that would not be readily detectable through the proposed quality measures.
- The proposed cap on patient panel size would discourage taking on an excessive number of patients without being able to adequately serve them. However, the higher payments for higher-risk patients, combined with the proposed cap on panel size, could discourage a practice from accepting healthier patients.

# Criterion 5. Flexibility

## Criterion Description

Provide the flexibility needed for practitioners to deliver high-quality health care.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- Under the proposed model, participating primary care practices would have complete flexibility regarding which services they deliver to patients.
- The proposed payments are much higher than what primary care practices receive under the current payment system, which could enable the delivery of many more or different services to patients.
- The higher PBPM payment for patients with higher-need/risk characteristics would provide the flexibility to deliver additional services to those patients.
- However, each practice's flexibility would be limited to the services that it could deliver itself; there would be no changes in payment for any services delivered by other providers.
- Additionally, there is no assurance that higher payments would be used to deliver more or different services to patients, rather than simply increasing physicians' income for the same services they are currently delivering.

# Criterion 6. Ability to be Evaluated

## Criterion Description

Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Majority

- It would be straightforward to compare utilization and spending of non-primary care services for patients assigned to the practices in the model and patients attributed to non-participating practices.
- However, because the practices would be using a different tool for measuring quality, it would be difficult to assess the differences in quality between participating and non-participating practices. If participating practices were required to report standard MIPS quality measures as well as the proposed patient-reported measures in order to facilitate evaluation, it would increase the practices' administrative burden rather than reducing it.
- It would be difficult to separately measure differences in utilization and spending for patients in each of the risk tiers because risk stratification is based on a tool that would only be used by practices participating in the model.
- It would be difficult to evaluate the extent to which favorable impacts on cost and quality resulted because of: (1) the more effective ability to identify patient problems due to use of the HYH tool, or (2) the different services that could be provided due to the increased payments and greater flexibility.
- A minority view was that more innovative payment models will inherently be more difficult to evaluate.

# Criterion 7. Integration and Care Coordination

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- The payment model would provide more resources and flexibility to a primary care practice to enable it to carry out care coordination activities for its patients. However, there are no specific mechanisms defined for assuring that it would do so.
- Use of the “How's Your Health” survey would help the practice to identify patients who do not feel their care is being effectively coordinated, and to measure whether the practice's services had resulted in improved coordination from the patient's perspective.
- While the proposed payment model would provide more resources and flexibility to the primary care practice to support care coordination activities, it does not directly affect the willingness or ability of other providers to support coordinated services. The proposal does not establish any specific standards or goals related to care coordination.

# Criterion 8. Patient Choice

## Criterion Description

Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- The payment model could encourage more physicians to enter or remain in primary care, thereby increasing access and choice of primary care practices, particularly in rural areas. However, the higher payments per patient and the proposed limits on practice size could also reduce access to primary care in the short run.
- The payment model would enable primary care practices to deliver services in different ways based on their patient's needs. However, depending on the types of changes a practice makes, the changes could be harmful to patients as well as beneficial.
- The proposal does not describe how patients would be informed about the differences between the proposed payment model and the current payment system, nor does it describe what information and assurances patients would receive about the types of services and the quality of the care they would receive. Consequently, the PRT was unable to say for sure that the model would improve the patient's choices.



# Criterion 9. Patient Safety

## Criterion Description

Aim to maintain or improve standards of patient safety.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- The “How's Your Health” survey and the What Matters Index would help participating primary care practices to identify patients with potential medication safety issues and other safety issues.
- However, there is no assurance that individual patients would receive the care they need:
  - The practice would be paid the same amount regardless of how many face-to-face visits and/or other services were provided, as long as an annual assessment was conducted.
  - There is no requirement for the “How's Your Health” survey to be completed by all patients, and the highest-risk patients may be the least able or willing to complete an online survey. Consequently, it is possible that the practice could receive its full payment for every patient even if a subset of patients is receiving poor-quality care.

# Criterion 10. Health Information Technology

## Criterion Description

Encourage use of health information technology to inform care.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- The model is premised on the use of an online system ([www.HowsYourHealth.com](http://www.HowsYourHealth.com)) for collecting patient-reported outcomes and for analysis of practice performance.
- The proposal says that at least “50% of qualifying participants are expected to use CEHRT” (Certified Electronic Health Records Technology), but the proposal does not include a mechanism for assuring that this will occur.

# Physician-Focused Payment Model Technical Advisory Committee

## Preliminary Review Team Findings on **Alternative Payment Model for Improved Quality and Cost in Providing Home Hemodialysis to Geriatric Patients Residing in Skilled Nursing Facilities**

Submitted by Dialyze Direct

Harold D. Miller (Lead Reviewer)  
Jeffrey Bailet, MD  
Rhonda Medows, MD

September 6, 2018

# Presentation Overview

- Preliminary Review Team (PRT) Composition and Role
- Proposal Overview
- Summary of the PRT Review
- Key Issues Identified by the PRT
- PRT Evaluation Using the Secretary's Criteria

# Preliminary Review Team Composition and Role

- The PTAC Chair and Vice Chair assigned three PTAC members (Bailet, Medows, and Miller), including two physicians (Bailet and Medows), to serve as the PRT. Miller was assigned as the Lead Reviewer.
- The PRT requested and received additional information from the submitter. The PRT also determined that additional information and data were needed for the review, and ASPE staff and contractors supported the PRT in obtaining this information. Public comments received on the proposal were reviewed by the PRT.
- The PRT decided to provide initial feedback on the proposal to the submitter and it held a conference call with the submitter.
- Based on its review of the proposal and of the additional information it received, the PRT prepared a report of its findings to the full PTAC. The report was posted to the PTAC website for public review prior to this meeting. The full PTAC Committee has not previously discussed the proposal or the PRT report.
- The PRT report is not binding on PTAC; the full PTAC Committee may reach different conclusions from those contained in the PRT report.

# Proposal Overview

**Goals:** The goal of the proposal is to encourage the delivery of on-site dialysis and more frequent dialysis (MFD) to patients with end-stage renal disease (ESRD) who are short-term patients or long-term residents of skilled nursing facilities (SNFs).

**Eligible Patients and Services:** Patients with ESRD who are patients or residents of a SNF, if they meet Medicare medical necessity criteria for more frequent dialysis (5 days per week instead of 3 days per week), would receive daily staff-supported home hemodialysis at the SNF, rather than being transported (typically by ambulance) to an offsite dialysis center for standard dialysis treatments.

## **Payment Model:**

- There would be no change to current Medicare payments for the dialysis treatments.
- The nephrologist would receive two new payments in addition to all current Medicare payments:
  - A one-time bonus payment of \$500 for providing education to a patient regarding the service;
  - A payment equal to 90% of any savings resulting from avoided patient transportation costs if the nephrologist sees the patient in the SNF rather than in the nephrologist's office.
- There would be no downside risk or other accountability for assuring savings or higher quality. Savings would be determined through a retrospective evaluation.

# Summary of the PRT Review

Criteria Specified by the Secretary (at 42 CFR §414.1465)	PRT Conclusion	Unanimous or Majority Conclusion
1. Scope (High Priority)	Does Not Meet	Majority
2. Quality and Cost (High Priority)	Does Not Meet	Unanimous
3. Payment Methodology (High Priority)	Does Not Meet	Unanimous
4. Value over Volume	Meets	Unanimous
5. Flexibility	Does Not Meet	Unanimous
6. Ability to be Evaluated	Meets	Unanimous
7. Integration and Care Coordination	Does Not Meet	Unanimous
8. Patient Choice	Meets	Unanimous
9. Patient Safety	Does Not Meet	Unanimous
10. Health Information Technology	Does Not Meet	Unanimous

## Key Issues Identified by the PRT

- The goals of the proposal are meritorious: ESRD patients in SNFs would benefit from not having to be transported to an offsite dialysis center, and many would benefit from more frequent dialysis.
- Medicare pays for each dialysis session, so if more patients receive more frequent dialysis (MFD), Medicare spending will increase unless there are offsetting savings from other changes in services.
- The proposal assumes, but does not assure, that offsetting savings will be achieved by reducing Medicare spending on ambulance transportation to dialysis centers. However, this depends on which types of patients are participating:
  - Medicare *does* pay for medically necessary ambulance transportation to offsite dialysis centers for *long-term residents* of SNFs who have ESRD, and savings from avoiding such transportation could offset higher Medicare spending for more frequent dialysis treatments.
  - Medicare does *not* make *additional* payments for transportation to dialysis centers for patients in *Medicare-covered (short-term) SNF stays*, so any savings from avoiding such transportation would accrue to the SNF, not to Medicare. It appears that most of the participating patients would be in this category.
- Additional Medicare savings might be possible through reductions in hospitalizations, shorter SNF stays, etc., but there is no mechanism in the proposal for assuring this will occur.
- The proposed payment model does not address the barriers that exist in the current payment system to delivering the service. In particular, it does not appear that the proposed service would be financially sustainable at current Medicare payment rates at most nursing facilities.
- The model encourages one approach to dialysis, even if that is not the best approach for an individual patient, and there is no mechanism for assuring that patient outcomes will improve.



# Criterion 1. Scope (High Priority)

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Majority

- There are no current CMS alternative payment models specifically designed to encourage home dialysis or to improve dialysis care for patients who reside in nursing facilities.
- The proposed payment model is designed to support a specific approach to staff-assisted home hemodialysis, which may not be the best option for all patients in nursing facilities.
- It appears that only a small proportion of nursing facilities (less than 1%) would currently have the minimum number of eight eligible patients that the applicant indicates is necessary to make the proposed staff-supported home dialysis model economically viable.
- The proposed payment model does not address some of the important disincentives to home dialysis care that exist in the current payment system.
- Organizations participating in CMS's Comprehensive ESRD Care Model could presumably pursue similar efforts to increase on-site dialysis for ESRD patients residing in nursing facilities and capture the savings from reduced transportation costs and any reductions in complications.

## Criterion 2. Quality and Cost (High Priority)

### Criterion Description

Are 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.

### PRT Conclusion

Does Not Meet Criterion

### Unanimous or Majority Conclusion

Unanimous

- For long-term residents of nursing facilities who have ESRD:
  - The residents would likely benefit both from receiving more frequent dialysis and not having to be transported to an offsite dialysis center.
  - Savings to Medicare from reduced transportation would likely offset higher Medicare spending on more frequent dialysis.
- For patients with ESRD who are receiving Medicare-paid SNF care:
  - The patients would likely benefit from not having to be transported to an offsite dialysis center.
  - Many patients would only be able to receive more frequent dialysis during the time they are in the SNF, and changes in the frequency of dialysis could potentially harm the patients.
  - Medicare does not pay extra for transportation to dialysis centers, so there would be no Medicare savings for avoiding transportation.
  - There may be additional savings to Medicare from reduced hospital admissions, shorter SNF stays, etc., but there is no assurance of this.
- It appears that the majority of participants would be patients in Medicare-paid SNF stays, so Medicare spending could increase and some patients could be harmed.

# Criterion 3. Payment Methodology (High Priority)

## Criterion Description

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.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- No changes are proposed to the methods or amounts by which Medicare pays for the actual dialysis services.
  - It does not appear that current payments would be sufficient to cover the cost of the staff-supported home hemodialysis services.
  - The services depend on the willingness and ability of a SNF to provide a “dialysis den,” but there is no payment to support that.
- The nephrologist would receive 90% of any savings from avoiding ambulance transportation to the nephrologist’s office, but Medicare does not pay separately for this, so there would not be any savings. Also, it is unclear that avoiding patient visits to the nephrologist’s office is necessary to the success of the proposed approach.
- The proposed payment to the nephrologist appears to create a financial incentive to recommend more frequent dialysis even if other approaches to dialysis would be better for the patient.
- The payments to the nephrologists would not be affected by poor quality care or poor outcomes for patients.
- The payment model does not require any accountability for achieving savings or for maintaining or improving quality/outcomes.

# Criterion 4. Value over Volume

## Criterion Description

Provide incentives to practitioners to deliver high-quality health care.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- More frequent dialysis at the nursing facility would be beneficial for long-term residents of nursing facilities who have multiple conditions and more advanced illnesses.
- Because of the need to have a minimum volume of patients and to receive more dialysis payments per patient in order to ensure financial viability of the service, there would be a financial incentive for the dialysis provider and nephrologist to encourage more frequent dialysis even if it was not the best option for the patients.

# Criterion 5. Flexibility

## Criterion Description

Provide the flexibility needed for practitioners to deliver high-quality health care.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- It is currently difficult for nephrologists to recommend more frequent dialysis for most nursing home patients because of the challenges of off-site transportation, so having an option for more frequent dialysis without requiring transportation would be desirable.
- However, the ability of nephrologists to use this option would be limited because:
  - it would likely only be available in a limited number of sites;
  - for patients in a short SNF stay, the transition to and from more frequent dialysis would create additional risks for the patient and care management challenges for the nephrologist; and
  - the nephrologist would still be paid less if the patient received home dialysis in the nursing facility than if the patient received dialysis in a separate dialysis center.

# Criterion 6. Ability to be Evaluated

## Criterion Description

Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- Because the proposed approach would only be tested in a limited number of facilities, it should be feasible to find a comparison group and to collect comparative information on standard quality and utilization measures.
- However, it would be difficult to measure many important outcomes or to risk-adjust the results unless both the participants and the comparison group were submitting appropriate quality measures to a patient registry.
- Moreover, with a small number of participants, it would be difficult to draw conclusions about the results unless there were very large changes in the outcome measures, and it would also be more difficult to risk-adjust the findings.

# Criterion 7. Integration and Care Coordination

## Criterion Description

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.

- Patients would be able to receive more of their care in the same facility and spend less time in transportation, which could improve the ability for patients to receive both dialysis and nursing home services and reduce conflicts in services.
- However, there is no explicit process proposed for ensuring that care would be coordinated with the patient's primary care provider, other specialists, and with the nursing facility staff.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

# Criterion 8. Patient Choice

## Criterion Description

Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

## PRT Conclusion

Meets Criterion

## Unanimous or Majority Conclusion

Unanimous

- The proposed approach could give many nursing facility residents a new and better option for receiving dialysis.
- The proposed financial incentives for physicians based on patient participation and the need for the dialysis provider to achieve a minimum level of patient participation could result in patients not receiving objective information on the risks associated with the proposed approach.
- The more frequent dialysis service could be denied by Medicare contractors even if the patient could benefit from the service and want to receive it.
- Patients who are not long-term nursing facility residents would only have access to this option during the time that they were in a SNF following a hospital stay.



# Criterion 9. Patient Safety

## Criterion Description

Aim to maintain or improve standards of patient safety.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- There are risks to patients from more frequent dialysis, including higher risks of infection and access failure from more frequent vascular access.
- Most patients who are not long-term nursing facility residents would have to transition to (or return to) less frequent dialysis. This would require changes in their medications which could potentially have negative impacts on their health.
- It would likely be more difficult for nephrologists to see patients as frequently in the nursing facilities as they do in a dialysis center. The patient's nephrologist would likely have less oversight than if the patient were receiving center dialysis.
- The proposed payment methodology does not include any explicit mechanism for assuring that patients receive high-quality care or achieve better outcomes than they would under the current delivery and payment system.

# Criterion 10. Health Information Technology

## Criterion Description

Encourage use of health information technology to inform care.

## PRT Conclusion

Does Not Meet Criterion

## Unanimous or Majority Conclusion

Unanimous

- There is no discussion of the specific kinds of data that would be collected and how they would be used.