Preliminary Review Team Findings on:

Incident ESRD Clinical Episode Payment Model

Submitted by Renal Physicians Association (RPA)

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December 18, 2017

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.
Presentation Overview

- Preliminary Review Team (PRT) Composition and Role
- Proposal Overview
- Summary of the PRT Review
- PRT Evaluation Using the Secretary’s Criteria
- Key Issues Identified by the PRT
PTAC Chair/Vice Chair assigns two to three PTAC members who have no conflicts of interest (including at least one physician) to serve as the PRT for each complete proposal. One PRT member is tapped to serve as Lead Reviewer.

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Focus on optimal transition to dialysis; some modalities (e.g., catheters) are associated with higher costs, infections, and hospitalizations. Advance preparation is required for less costly modalities.

Eligible population: patients with incident ESRD who are enrolled in Medicare when they begin dialysis.

Episode length: 6 months, beginning the first day of the month during which dialysis begins (unless after 16th of the month).

Major components:
1. Shared savings/losses based on total cost of care during episode and performance on quality metrics
2. Transplant bonuses ($3,000 pre-dialysis and $1,500 during episode)
### Summary of the PRT Review

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Criterion 1. Scope (High Priority). 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: Proposal Meets the Criterion

Strengths:

• The only APM currently focused on high-cost ESRD patients (Comprehensive ESRD Care or CEC Model) has limited participation of ~10% nephrologists; this model expands access to APMs to more nephrologists and their patients.

• This model does not include the requirements for minimum # cases and other geographic considerations that make participation in CEC difficult for many nephrologists.

Concern:

• Potential role of random variation in spending for savings/losses calculations, particularly for small nephrology practices.
Criterion 2. Quality and Cost (High Priority). 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: Proposal Meets the Criterion

**Strengths:**

- Model addresses high annual spending for incident ESRD patients, including potentially preventable hospitalizations related in part to suboptimal transition to dialysis.
- The model makes shared savings payments contingent on a number of important quality metrics.

**Concerns:**

- Biggest opportunities for improvement need to occur prior to dialysis, but episode begins at dialysis initiation. The PRT is concerned about the ability of nephrologists to influence upstream care given treatment patterns.
- Minimum quality score for shared savings is 30, which is achievable merely by reporting performance. The PRT would like to see greater emphasis on patient experiences in the quality score threshold.
- Difficult to evaluate the impact of transplant bonus on quality and cost.
Criterion 3. Payment Methodology (High Priority). 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: Proposal Meets the Criterion, Except for Transplant Bonus

Strength:
• Model is designed to direct higher payments to nephrologists who achieve better results for patients in the first six months of dialysis, a time of particularly high costs and poor outcomes.

Concerns:
• Methodology does not include upfront payments to providers to support enhanced education and care management.
• Shared savings payments are based on risk-adjusted spending and regional benchmarks, but small numbers could hinder effective risk adjustment.
• Weighting of quality measures should place more emphasis on patient experience.
• Kidney transplant bonus is area of major concern:
  – Unlikely to change net number of kidney transplants due to organ supply constraints.
  – Factors determining transplant are largely out of a nephrologist’s control; encouraging transplant referral and education could more accurately reflect nephrologist actions.
Criterion 4. Value over Volume. Provide incentives to practitioners to deliver high-quality health care.

PRT Conclusion: Proposal Meets the Criterion

Strength:
• This model provides incentives to reduce the total cost of care for incident dialysis patients, in part by reducing the rate of hospitalizations and other avoidable complications of treatment.

Concern:
• By beginning the episode with a procedure, this model could create an incentive to start dialysis earlier in the disease process when patients are healthier and less likely to have complications.
Criterion 5. Flexibility. Provide the flexibility needed for practitioners to deliver high-quality health care

PRT Conclusion: Proposal Meets the Criterion

Strength:

• The model provides greater flexibility than fee-for-service Medicare or the CEC Model in the types of activities physicians could undertake to deliver high-quality health care. Providers could use shared savings payments to support a range of activities to improve quality.

Concern:

• Model requires providers to make upfront investments that they hope to recoup during reconciliation; this could discourage practices, particularly small practices, from making expensive but valuable investments.
PRT Conclusion: Proposal Meets the Criterion

Strength:

• The PRT believed it is feasible to assess changes in spending and quality associated with model implementation; the goals of the model, the quality measures, and potential impact on health care costs are clear and can be evaluated.

Concern:

• For assessment of quality outcomes, there may be challenges in reporting some of the quality measures through the EHR, particularly the patient experience (PROMIS) if a nephrologist does not participate in the RPA-sponsored Kidney Quality Improvement Registry.
Criterion 7. Integration and Care Coordination. 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: Proposal Does Not Meet the Criterion

Strengths:
• The model would indirectly encourage nephrologists to establish better mechanisms for communication with other providers in the community regarding patients with CKD who are likely to need dialysis in the near future.
• The model would also implicitly encourage nephrologists to improve care coordination with the patients’ other physicians.

Concern:
• The proposal does not provide clarity about how providers would achieve better coordination both prior to and during dialysis. There is no indication as to whether or how nephrologists would involve other physicians in the APM Entity or share savings and losses with other providers.
Criterion 8. Patient Choice. Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.

PRT Conclusion: Proposal Meets the Criterion

Strengths:
• This proposal has the potential to expand the range of treatment options available to patients with incident ESRD by encouraging earlier education and preparation for the transition to dialysis.
• This proposal also could encourage providers to identify patients unlikely to benefit from dialysis and educate patients about the alternative of conservative management of CKD.

Concerns:
• The model may incentivize providers to start dialysis earlier in the disease process when patients are healthier.
• The transplant bonus may encourage patient choice by providing a pathway to overcome existing barriers, but the large size of bonus may influence the role of patient preferences.

PRT Conclusion: Proposal Meets the Criterion

Strength:
• This proposal has a clear focus on avoiding hospitalizations, reducing infection rates, etc. for patients during the first six months of dialysis.

PRT Conclusion: Proposal Meets the Criterion

Strengths:
• All providers would be required to use CEHRT.
• Nephrologists and other participating providers would be encouraged to coordinate care prior to and during dialysis with the aid of health information technology.
• The proposal notes that the RPA Qualified Clinical Data Registry (QCDR) would be available to model participants and would facilitate the collection of patient and disease data.

Concerns:
• This proposal does not provide specific information about how it encourages use of health information technology.
Key Issues Identified by the PRT

The PRT supports the proposal’s goal of improving the transition to dialysis for patients with incident ESRD. The PRT’s major concerns are:

1. **Upstream activities:** The model has potential to improve quality and reduce costs, but it relies on the assumption that the same nephrologist (or group) is involved in the care of the patient for an extended time prior to and then after dialysis initiation.

2. **Upfront investments:** The model’s payment methodology requires upfront investments from providers for patient education, care management, and other services that could be returned to providers during reconciliation. Small providers are particularly vulnerable to random variation that could put their investments at risk.

3. **Transplant bonus:** The PRT supports efforts to increase transplants, but paying bonuses in this model is problematic and an unnecessary component of the model.
Overview of Performance-Based Payments

• APM Entities receive FFS reimbursements during the clinical episode
• One-sided (upside only) or two-sided options for participation
• Compares episode-adjusted patient cost to risk-adjusted regional benchmark
  – Adjusted patient cost: sum Part A and B expenditures (with some constraints), divide by # patients, divide by average normalized HCC score.
  – Regional Benchmark: two most recent years of Part A and B expenditures for incident ESRD patients in APM’s HRR, divided by normalized HCC scores.
• Shared savings/losses depend on quality performance
  – Minimum savings rate to receive payments: 3% (1% in 2-sided model); minimum quality score is 30. Savings split 75% participant/25% CMS, then 75% is multiplied by quality performance (e.g., 0.3-1.0).
  – The 2-sided model includes a 4% minimum loss rate for participants to share in losses. Participants are responsible for 50-75% of losses, depending on quality performance. Downside risk is capped at 8% of estimated part B revenues during episode for attributed patients.
• Quality measures: dialysis modality measures (55), advanced care planning (15), referral to transplant (10, reporting), patient centeredness (10, reporting), patient experience (10, reporting).
Multi-provider, bundled episode-of-care payment model for treatment of chronic hepatitis C virus (HCV) using care coordination by employed physicians in hospital outpatient clinics

Submitted by the New York City Department of Health and Mental Hygiene (NYC DOHMH)

Robert Berenson, MD (Lead Reviewer)
Jeffrey Bailet, MD
Grace Terrell, MD, MMM

December 18, 2017
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The proposal is based on a Health Care Innovation Award (HCIA) Round Two demonstration project, Project INSPIRE. The proposal focuses on integrated care coordination of patients, particularly higher-need patients (e.g., dual-eligible patients, patients with behavioral health and substance abuse disorders, etc.) with HCV to ready them to initiate and adhere to pharmacotherapy.

**Intervention**

- Patients would undergo a comprehensive psychosocial evaluation to identify barriers to care and medical evaluation to determine the complexity of liver disease.
- The care team would then assist patients in overcoming barriers through various means such as:
  - Referrals for psychosocial issues or other comorbid conditions;
  - Direct counseling services (except those separately billed for by the provider), including health promotion, alcohol counseling and treatment readiness assessment and counseling, or medication adherence measurement and counseling;
  - Helping patients navigate appointments; and
  - Assistance with prior authorization for costly pharmacotherapy.
- Primary care physicians (PCPs) would take on a greater role in managing patients with HCV. PCPs will be trained by hepatologists/other gastroenterologists through tele-mentoring (less emphasis was placed on tele-mentoring in the proposal compared to the HCIA project).
- Non-clinical care coordinators would also play a key role (non-clinical staff time cannot be billed using the chronic care management codes).
Payment

• Expected participants are employed physicians in hospital outpatient clinics who treat HCV.

• The APM Entity would receive a bundled episode payment ($760) for each eligible patient that agrees to participate (eligibility and attribution are unclear). The episode is comprised of three phases: (1) pretreatment assessment involving care coordination, (2) the treatment period, and (3) the report of sustained virological response at 12 weeks posttreatment (SVR12). The episode is not expected to exceed 10 months.

• The APM Entity would be eligible for bonus payments/at risk of paying penalties based on its (risk-adjusted) SVR rate, the proportion of participating patients who complete a full course of antiviral treatment and have undetectable HCV ribonucleic acid 12 weeks after treatment cessation.
  
  – The APM Entity’s SVR rate would be compared to a benchmark set by CMS. An APM Entity with an SVR rate at or above the benchmark would receive a bonus payment for each patient that achieved SVR. An APM Entity with a rate below the benchmark would be required to pay back a penalty for each patient who did not achieve SVR.

  – Bonus payments for each patient who achieved SVR would be calculated by applying a CMS-determined shared savings rate or rates to the product of the following formula:

  \[
  \text{Expected annual cost (from continued HCV infection) avoided} \times \text{Life years gained with SVR}
  \]

• How penalties would be calculated is unclear, but only the episode payment amount would be at risk.
## Summary of the PRT Review

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(at 42 CFR §414.1465)

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<td>Majority</td>
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Key Issues Identified by the PRT

- Care coordination of higher-need patients with HCV is important and has the potential to improve quality and reduce costs.
- The efficacy of pharmacotherapy for HCV enables payment to be tied to a meaningful outcome measure.
- The PRT is not convinced that a new payment model is necessary to support the care model. The PRT believes the proposal could be accommodated within current payment methods.
- The PRT has specific concerns regarding the payment methodology, including the shared-risk arrangement, attribution methodology, and lack of risk adjustment.
Key Issues Identified by the PRT (continued)

• Shared savings are based on expected annual costs from continued HCV infection avoided and number of life years gained with SVR. The approach is untested, unprecedented in Medicare, and imprecise. To the extent that it has merit, it should first be tested in a manner that is specifically designed to study the feasibility of such an approach and how to incorporate this methodology within an APM.

• The shared savings rate or rates have not yet been determined, but rewarding facilities for practicing high standards of care with potentially huge bonuses based on savings that are not attributable, in large part, to these high standards of care is problematic; such a precedent would likely lead other parties, including drug manufacturers and other providers, to advance similar claims to a share of these savings.

• Physician-determined attribution and a lack of adequate risk adjustment could lead to patient selection imbalances that would undermine accurate evaluation. Beneficiaries with HCV frequently have substantial comorbidities, including behavioral and mental health conditions, but there does not seem to be continuity between care coordination for purposes of accomplishing HCV treatment and what should be ongoing care coordination for HCV patients with comorbidities.
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
Unanimous

• HCV is a high-impact condition, affecting nearly a quarter of a million beneficiaries in 2016. Many of these beneficiaries have substantial comorbidities, and this patient population is high cost.

• There are issues in payment policy regarding HCV, particularly due to the high cost of pharmacotherapy.

• However, the PRT believes that care coordination can be accommodated under current payment methodologies.

• While the proposal could in theory be generalizable, it is designed for employed physicians in hospital outpatient clinics, not all physicians providing care for patients with HCV, and seems rather specific to the large integrated health systems in New York City and to circumstances specific to the New York practice environment.
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**
Unanimous

- Coordinating care for higher-need patients with HCV in a careful and concentrated way, and providing health education, appointment navigation, and connection to supports and services seem likely to increase the proportion of patients who achieve SVR.

- Activities that increase the number of patients who are treated and cured would reduce costs associated with complications. Higher cure rates would reduce disease transmission and subsequent costs.

- Medicare beneficiaries with HCV frequently have substantial comorbidities, including behavioral and mental health conditions, and are high cost. Focusing on this patient population seems likely to reduce certain costs, such as those associated with avoidable emergency department visits for comorbid conditions.

- The final HCIA evaluation would help the PRT better understand the model’s potential impact on quality and cost.
## Criterion 3. Payment Methodology (High Priority)

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- The proposal directly ties payment to a meaningful outcome measure and uses a straight-forward episode-based approach for providing care coordination funding.

- Billing the current complex chronic care management codes would seem to provide payment in line with the proposed episode payment. The PRT recognizes that there are some restrictions on how the current codes can be used, suggesting that fixes to the predominant fee schedule-based payment model are worthy of consideration.

- Patient eligibility and attribution are unclear and there does not appear to be any risk adjustment to the episode payment. Physician-determined attribution and a lack of adequate risk adjustment could lead to imbalances in patient selection.

- Shared savings are based on expected annual costs from continued HCV infection avoided and number of life years gained with SVR. The approach is untested, unprecedented in Medicare, and imprecise. To the extent that it has merit, it should first be tested in a manner that is specifically designed to study the feasibility of such an approach and how to incorporate this methodology within an APM.

- The shared savings rate or rates have not yet been determined, but rewarding facilities for practicing high standards of care with potentially huge bonuses based on savings that are not attributable, in large part, to these high standards of care is problematic; such a precedent would likely lead other parties, including drug manufacturers and other providers, to advance similar claims to a share of these savings.
Criterion 4. Value over Volume

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- The proposal is focused on and provides incentives for practitioners to deliver high-quality health care, increasing the number of patients who are treated and cured, reducing utilization and cost associated with continued HCV infection, and reducing the possible risk of further spreading of the disease.

- Physician-determined attribution, especially in the absence of adequate risk adjustment, could lead to the avoidance of patients who are more complex and high cost.
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

- The care team appears to have broad flexibility in meeting the unique needs of each patient. The model places emphasis on the outcome measure rather than inputs and processes.
- The delivery model supports tele-mentoring of PCPs to enable them to take on a greater role in managing patients with HCV.
Criterion 6. Ability to be Evaluated

- The proposal incorporates a meaningful outcome measure: the proportion of patients who complete treatment and achieve SVR.
- Physician-determined attribution and a lack of adequate risk adjustment could lead to patient selection imbalances that would undermine accurate evaluation.
- Shared savings are based on expected annual costs from continued HCV infection avoided and number of life years gained with SVR. However, given the relative newness of the use of HCV drugs, the initial modeling may prove to be inaccurate.
The proposal focuses on integrated care coordination of patients, particularly higher-need patients, with HCV.

The proposal supports tele-mentoring of PCPs to enable them to take on a greater role in managing patients with HCV.

The submitter notes that an advantage of implementing the model in hospital-based clinics is the ability for care coordinators to make referrals to other diagnostic and treatment services within the same facility. These facilities are also likely to have integrated electronic health record (EHR) systems.

Beneficiaries with HCV frequently have substantial comorbidities and would likely benefit from care coordination before, during, and after their HCV-related treatment, yet the proposal does not address how care coordination occurs across outpatient department settings and with other providers.
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

- Patients have a choice of whether or not to participate in the model.
- The proposed model would provide greater attention to the health of a high-cost patient population.
- The proposal considers patients’ unique needs and preferences. For example, patients would receive referrals for conditions, such as substance abuse, that may interfere with their readiness to initiate and adhere to pharmacotherapy for HCV.
Criterion 9. Patient Safety

Aim to maintain or improve standards of patient safety.

Meets criterion

Unanimous or Majority Conclusion

Unanimous

Helping patients complete treatment and achieve SVR would reduce risks of complication from continued HCV infection.

The model targets a patient population with high rates of mental and behavioral health issues. Coordinating care for these patients and helping them overcome issues that may interfere with their readiness to initiate and adhere to pharmacotherapy for HCV would improve patient safety.
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

- Participants include employed physicians in hospital outpatient clinics. Therefore, the participants are more likely to have EHR systems that are integrated across the facility.

- The proposal does not adequately describe coordination with non-participating providers outside of the facility, and it seems likely that there could be interoperability challenges with these providers.
Preliminary Review Team Findings on:

Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP)

Submitted by Zhou Yang, PhD, MPH

Bruce Steinwald, MBA (Lead Reviewer)
Robert Berenson, MD
Elizabeth Mitchell

December 18, 2017

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1. **Enrollment.** Community-dwelling beneficiaries age 85 or younger, without cognitive disability or severe mental illness choose between traditional Medicare fee-for-service (FFS) plan or joining 3VBPP which would provide Medicare services through several defined-contribution plans.

2. **Spending Accounts.** Each 3VBPP participant given a Medicare Account to spend on covered services over 3 years. Starting account balance = 3x average annual Medicare expenditures of FFS patients adjusted by inflation, age, gender, chronic diseases, geographic area.

3. **Plan Selection.** Each participant chooses one of several CMS-approved plan types and plans provided by private carriers or physician groups:
   
   a. **Capitated HMO plan.** Medicare Account used to contribute to the capitation. Reimbursement rates for care negotiated between carriers and providers.
   
   b. **PPO plan.** Medicare Account used to contribute to premium. Reimbursement rates for care negotiated between carriers and providers. Private carriers may charge out-of-pocket copayment, deductibles, or coinsurance for all care.
   
   c. **High deductible PPO plan.** Medicare Account used to pay for a low premium (e.g., $1,000 – $1,500) and costs above deductible with a low copayment rate; e.g., at 5 – 10%. No annual limit on Medicare contribution to the high deductible plan.
   
   d. **Low premium FFS plan.** Reimbursement rates for services negotiated between providers and patients. Account could be used to contribute to premiums and reimbursement of Part A and B services. Beneficiaries share out-of-pocket copayment or coinsurance. No annual limitation on Medicare contribution.
4. **Covered Services.** All plans to cover Part A and B services. 3VBPP participants could choose either a plan providing prescription drug (Part D) benefits or a stand-alone Part D carrier. Annual physical examination and wellness counseling session covered without out-of-pocket copayment. All wellness care prescribed by primary care doctors or wellness counselors fully covered by benefit carriers; however CMS to regulate inclusion criteria for wellness care.

5. **Option to waive some premiums and deductibles.** To incentivize beneficiary participation, there would be an option to waive out-of-pocket Part B premiums and/or Part A deductibles for all participating plans.

6. **Financial reward for wellness care.** If a beneficiary uses the free annual physical and wellness counseling session and pursues the preventive or wellness care prescribed by a primary care physician or counselor, beneficiary is rewarded with an age-adjusted credit to the Medicare Account per year. All the preventive and wellness care will be fully covered by the Medicare benefit carriers without copayment or coinsurance from the beneficiaries.

7. **Reduced Medicare contribution to premiums or reimbursement after initial Account balance is exhausted.** If a beneficiary exhausts the balance of the initial Medicare Account before the end of the 3rd year, and would like to remain in the demonstration, Medicare will continue to contribute to the premiums and reimbursement to clinical care, but at a lower %. Wellness care would still be fully covered by the carriers. However, beneficiaries would be responsible for a higher % of means-tested, out-of-pocket contributions to the premiums for HMO, PPO plans, as well as for the copayment for clinical services under low premium PPO FFS & High Deductible plans.
8. **Catastrophic coverage.** Instead of annual catastrophic coverage, 3VBPP will provide catastrophic coverage over 3 years if the three-year total exceeds certain amounts during the demonstration period. Beneficiaries’ out-of-pocket responsibility of premiums, copayment, and coinsurance will all be waived above the catastrophic coverage cap.

9. **Handling of plan balances.** If there is balance left within the lower cap of the Account by the end of the 3rd year, savings will be credited to beneficiaries to pay for premiums, copayment, or deductibles of their Medicare-covered services under FFS or Medicare MA financing plan in the future. The remaining balance on the Account will not be deemed as cash to be paid to the patients, the providers, or the Medicare benefit carriers. If the beneficiary dies before the lower cap of Medicare Account is exhausted, the remaining balance will be paid back to Medicare.

10. **Opt-Out provisions.** Participants would be able to opt out of the payment models at any time and return to traditional FFS without any financial or legal obligations. To prevent fraud or abuse of Medicare contribution, for all participants who choose to switch back to FFS or Medicare MA before exhausting the lower cap of the Medicare Account, the remaining balance will not be credited to the beneficiaries, but paid back to Medicare.

11. **Financial reward for postponing Medicare initiation until after age 65.** The proposal identifies this as one of its major parts, but does not otherwise elaborate on it.
### Summary of the PRT Review

<table>
<thead>
<tr>
<th>Criteria Specified by the Secretary (at 42 CFR §414.1465)</th>
<th>PRT Conclusion</th>
<th>Unanimous or Majority Conclusion</th>
</tr>
</thead>
<tbody>
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<td>1. Scope (High Priority)</td>
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<td>Unanimous</td>
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<td>2. Quality and Cost (High Priority)</td>
<td>Not Applicable</td>
<td>Unanimous</td>
</tr>
<tr>
<td>3. Payment Methodology (High Priority)*</td>
<td>Not Applicable</td>
<td>Unanimous</td>
</tr>
<tr>
<td>4. Value over Volume</td>
<td>Not Applicable</td>
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<td>5. Flexibility</td>
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<tr>
<td>10. Health Information Technology</td>
<td>Not Applicable</td>
<td>Unanimous</td>
</tr>
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</table>

* The PRT’s rationale for its conclusions is discussed under this criterion
The PRT concluded that it would be inappropriate for the PRT and PTAC to evaluate Medicare 3VBPP as a proposed change in Medicare payment methodology because:

- The 3VBPP proposal focuses on Medicare coverage and benefits rather than on payment methodology by:
  1. restructuring the Medicare program to be a defined contribution benefit, supported by creation of health spending accounts, and in doing so altering the statutory framework for Medicare Parts A, B, and C;
  2. substantially changing the package of Medicare benefits available to beneficiaries;
  3. deploying expenditure thresholds that would trigger changes in copayments or coinsurance payments by beneficiaries; and
  4. changing Medicare eligibility rules to provide a financial reward for postponing Medicare initiation after age 65.

- The PRT does not consider the 3VBPP proposal a physician payment model and so rated each of the Secretary’s criteria as “Not Applicable” to this proposal.
• PRT conclusions are not meant to imply any qualitative opinion about the merits of the proposal.

• While the PRT concluded that PTAC is not an appropriate vehicle for responding to such a proposal, the concepts and approaches articulated in this proposal may receive attention from other more appropriate entities that are working to improve the Medicare program.
Preliminary Review Team Findings on

Annual Wellness Visit Billing at Rural Health Clinics

Submitted by the Mercy Accountable Care Organization (ACO)

Robert Berenson, MD (Lead Reviewer)
Tim Ferris, MD MPH
Len Nichols, PhD

December 18, 2017
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.

• 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.
Rural Health Clinics (RHCs)

- Facilities in non-urban areas or areas with shortage designations that receive CMS certification to provide primary care services to beneficiaries delivered by practitioners and incident-to services and supplies.
- The Medicare RHC benefit includes only services delivered in these clinics by “practitioners” (physicians, nurse practitioners, physician assistants, certified nurse midwives, clinical psychologists and clinical social workers) and services and supplies incident to these services.
- In 2015, there were about 4,000 RHCs in operation, which received $847 million in Medicare payments.

All-Inclusive Rate (AIR)

- Each beneficiary encounter, regardless of the number or intensity of services provided, is paid a single rate.
- The AIR is calculated for each RHC annually by the Medicare Administrative Contractor based upon each RHC’s cost report.
- The RHC’s AIR is subject to a national payment limit updated annually through statute ($82.30 in 2017).
- There are a few exceptions to the AIR, such as the Welcome to Medicare exam, which prompts a second AIR payment if performed on the same date as another covered service.
- The Annual Wellness Visit is not an exception to the AIR.
Proposal Overview

This proposal follows upon Mercy Medical Center’s HCIA Round Two project related to rural critical access hospitals. Mercy proposes “that Annual Wellness Visits be eligible for an additional encounter payment at the All-Inclusive Rate, similar to the Initial Preventative Physical Examination (IPPE) for patients who are new to Medicare” and that “Annual Wellness Visits be categorized as an Incident To carve-out so that RNs are able to provide the AWV under direct supervision of a physician at the clinic.”

Through these changes, they hypothesize that more AWVs would be conducted, and eventually cost savings would be realized by identifying health risks that can be mitigated.

Proposal Summary:

1: Make an Additional Payment for Providing the Annual Wellness Visit

- Under current payment policy, Medicare makes one All-Inclusive Rate (AIR) payment to an RHC for all services delivered to a beneficiary on a date of service
- Separate payment of an additional AIR for the same date of service is only made in a few circumstances, including the Initial Physical and Preventive Exam (IPPE, a.k.a. the Welcome to Medicare exam)

2: Allow for Non-Practitioners to Provide an Annual Wellness Visit

This document is 508 Compliant according to the U.S. Department of Health & Human Services Section 508 Accessibility guidelines.
## Summary of the PRT Review

### Criteria Specified by the Secretary (at 42 CFR §414.1465)

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<tr>
<td>2. Quality and Cost (High Priority)</td>
<td>Not applicable</td>
<td>Unanimous</td>
</tr>
<tr>
<td>3. Payment Methodology (High Priority)</td>
<td>Does not meet criterion</td>
<td>Unanimous</td>
</tr>
<tr>
<td>4. Value over Volume</td>
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<td>Not applicable</td>
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</table>
Key Issues Identified by the PRT

• The PRT unanimously and unequivocally did not consider the proposal to represent an alternative, physician payment model that PTAC should be reviewing, but rather rules changes within a well-established payment methodology. The Secretary may wish to consider the merits of the proposal as part of CMS’s ongoing supervision of rural health clinics.

• The PRT had a lengthy discussion before arriving at its recommendation, concluding that it lacked the expertise or standing to consider technical modifications of an existing payment methodology, such that any recommendations it would make regarding this proposal could have unforeseen and unintended consequences.

• At the same time, so that the public and future submitters more clearly understand the scope of PTAC’s work, the PRT suggests that the PTAC develop criteria that distinguish proposals that meet tests of meriting review as alternative physician payment models and those that seek modifications in established payment methodologies, such as the all-inclusive rate approach for rural health clinics.
Criterion 1. Scope (High Priority)

<table>
<thead>
<tr>
<th>Criterion Description</th>
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<tbody>
<tr>
<td>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.</td>
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</table>

- The PRT did not discuss the merits of this criterion.

<table>
<thead>
<tr>
<th>PRT Conclusion</th>
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<tbody>
<tr>
<td>Not applicable</td>
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<tr>
<td>Unanimous</td>
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</table>
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
Not applicable

Unanimous or Majority Conclusion
Unanimous

• The PRT did not discuss the merits of this criterion.
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 PRT considers this proposal a recommendation for changing existing payment policy for RHCs, rather than an Alternative Payment Model (APM).
- The PRT finds that the proposal merely seeks modifications in existing rules that govern the current payment model for rural health clinics and as such does not represent a physician payment model that PTAC should deliberate over.
- Two of the PRT members point out that the proposed modifications do not include accountability for either quality or spending associated with the rule changes, and as such the proposal does not meet what they consider hallmark expectations for PFPMs.
## Criterion 4. Value over Volume

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<tbody>
<tr>
<td>Provide incentives to practitioners to deliver high-quality health care.</td>
<td>Not applicable</td>
<td>Unanimous</td>
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</tbody>
</table>

- The PRT did not discuss the merits of this criterion.
**Criterion 5. Flexibility**

<table>
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</thead>
<tbody>
<tr>
<td>Provide the flexibility needed for practitioners to deliver high-quality health care.</td>
<td>Not applicable</td>
<td>Unanimous</td>
</tr>
</tbody>
</table>

- The PRT did not discuss the merits of this criterion.
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**

Not applicable

**Unanimous or Majority Conclusion**

Unanimous

- The PRT did not discuss the merits of this criterion.
## Criterion 7. Integration and Care Coordination

<table>
<thead>
<tr>
<th><strong>Criterion Description</strong></th>
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<tbody>
<tr>
<td>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.</td>
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</table>

<table>
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<tr>
<th><strong>PRT Conclusion</strong></th>
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<tbody>
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### Criterion 8. Patient Choice

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<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.</td>
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</table>

- The PRT did not discuss the merits of this criterion.

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## Criterion 9. Patient Safety

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</tr>
</thead>
<tbody>
<tr>
<td>Aim to maintain or improve standards of patient safety.</td>
<td>Not applicable</td>
<td>Unanimous</td>
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</tbody>
</table>

- The PRT did not discuss the merits of this criterion.
Criterion 10. Health Information Technology

<table>
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<tbody>
<tr>
<td>Encourage use of health information technology to inform care.</td>
<td>Not applicable</td>
<td>Unanimous</td>
</tr>
</tbody>
</table>

- The PRT did not discuss the merits of this criterion.