

EARLY IMPLEMENTATION REVIEW: CMS's MANAGEMENT OF THE QUALITY PAYMENT PROGRAM

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Why OIG Did This Review

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) enacted clinician payment reforms designed to promote quality and value of care. These reforms, known as the Quality Payment Program (QPP), are a significant shift in how Medicare calculates compensation for clinicians and require the Centers for Medicare & Medicaid Services (CMS) to develop a complex system for measuring, reporting, and scoring the value and quality of care. CMS issued final regulations on October 14, 2016, and the first performance year will begin January 1, 2017, with the first payment adjustments taking effect on January 1, 2019. Clinicians may participate in one of two QPP tracks: the Merit-Based Incentive Payment System (MIPS) or Advanced **Alternative Payment Models** (Advanced APMs).

Given the importance and complexity of these reforms and the tight timeline, OIG conducted an early implementation review of CMS's management of the QPP. We did not assess the extent to which the QPP will be successful in meeting program requirements and goals.

How OIG Did This Review

We interviewed CMS staff and reviewed internal CMS documents as well as publicly available information. We conducted qualitative analysis to identify key milestones (both those achieved and those yet to come), priorities, and challenges related to QPP implementation.

Early Implementation Review: CMS's Management of the Quality Payment Program

What OIG Found

From our analysis, we identified CMS's five key management priorities regarding the agency's planning and early implementation of the QPP. Early on, CMS staff decided that clinicians' acceptance of the QPP, and readiness to participate in it, would be the most critical factor to ensuring the program's success. This focus on clinicians informed CMS's decisionmaking regarding its other management priorities, including:

- adopting integrated internal business practices to accommodate a flexible, user-centric approach;
- developing information technology (IT) systems that support and streamline clinician participation;
- developing flexible and transparent MIPS policies; and
- facilitating participation in Advanced APMs.

Key Takeaway

CMS has made significant progress towards implementing the QPP. Although many milestones remain before the QPP payment adjustments in 2019, OIG identified two vulnerabilities that are critical for CMS to address in 2017, because of their potential impact on the program's success:

- (1) providing sufficient guidance and technical assistance to ensure that clinicians are ready to participate in the QPP, and
- (2) developing IT systems to support data reporting, scoring, and payment adjustment.

As of December 2016, CMS had finalized key policies to implement the QPP, including issuing final regulations and identifying Medicare models that qualify as Advanced APMs for the first performance period. CMS had also initiated engagement and outreach activities to clinicians, launched a public-facing informational website, and awarded various contracts for technical assistance and training.

CMS must still expand its technical assistance efforts, issue promised subregulatory guidance, award and oversee key contracts, and complete development of backend IT systems necessary to support critical QPP operations.

Background

o improve care for Medicare beneficiaries, the Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act of 2015 (MACRA) moves Medicare from a volume-based payment system to one that rewards value.¹ The Centers for Medicare & Medicaid Services (CMS) is implementing core provisions of MACRA as the Quality Payment Program (QPP), a set of clinician payment reforms designed to put increased focus on the quality and value of care.² The QPP is a significant shift in how Medicare calculates payment for clinicians and requires CMS to develop a complex system for measuring, reporting, and scoring the value and quality of care. MACRA mandated that the first payment adjustments based on QPP performance measures go into effect on January 1, 2019. To meet this statutory deadline, CMS issued final regulations implementing the QPP on October 14, 2016, and determined that the first performance year for clinicians will begin January 1, 2017.^{3, 4}

Given the importance and complexity of the new payment system and the tight timeline to launch the QPP, OIG conducted an early implementation review of CMS's management of the program. The objective of this review was to assess CMS's progress and identify key challenges and potential vulnerabilities that CMS faces as it implements the QPP.

CLINICIAN PAYMENT UNDER MEDICARE PART B

Medicare pays clinicians (such as physicians and nurse practitioners) for their services through the Part B benefit. Clinician services include office visits and surgical, diagnostic, and therapeutic procedures. CMS bases its payment rates for over 7,000 clinician services on the Medicare Physician Fee Schedule. Fee Schedule. Fee Prior to the passage of MACRA, these payment rates were intended to be updated annually using the sustainable growth rate (SGR) formula. The SGR was designed by Congress to control Medicare spending by either reducing or increasing Part B payment rates when spending fell above or below a set target. However, many stakeholders criticized the projected annual payment rate reductions under the SGR as being too severe. As a result, Congress overrode the SGR payment rate reduction each year from 2003 to 2015 and opted to either maintain or increase payment rates, an annual process that came to be known as the "doc fix." Under this system, Medicare reimbursed clinicians based on the volume of services provided.

To begin linking payment to value, Congress created multiple programs between 2006 and 2010 that established incentives and penalties related to quality reporting and performance. ^{11, 12, 13, 14, 15} These included the Physician Quality Reporting System (PQRS), the Value-Based Payment Modifier (VBM), and the Electronic Health Record (EHR) incentive programs.

- The PQRS initially provided incentive payments to clinicians who reported specific quality measures; since 2015, however, clinicians no longer receive incentives and instead receive a negative payment adjustment if they fail to report these data.¹⁶
- The VBM adjusts clinician payment up or down based on the quality of care provided as compared with the cost of care during a performance period.¹⁷
- The Medicare physician EHR incentive program provides incentive payments to clinicians who adopt and meaningfully use health information technology to improve patient care and outcomes. In addition, beginning in 2015, eligible clinicians who did not demonstrate meaningful use could receive a negative payment adjustment.¹⁸

Under MACRA, CMS will phase out all three of these programs in favor of a new set of payment reforms built on these prior efforts.

OVERVIEW OF THE QUALITY PAYMENT PROGRAM

MACRA was enacted in April 2015 with bipartisan support. It repealed the SGR formula and increased Medicare Physician Fee Schedule rates 0.5 percent each year from 2016 through 2019. Additionally, MACRA phased out Medicare payment adjustments made under the PQRS, VBM, and Medicare physician EHR incentive programs. In place of these programs, MACRA required that CMS make quality- and value-based incentive payments to clinicians through one of two tracks: the Merit-Based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (Advanced APMs). CMS refers to these two tracks together as the QPP.

MERIT-BASED INCENTIVE PAYMENT SYSTEM

Using the Physician Fee Schedule as a base rate, MIPS will adjust clinicians' Medicare Part B payments up or down based on their performance in four categories, which consolidate elements of the existing programs that MIPS replaces. The four MIPS categories are:

- quality (replaces the PQRS),
- cost (replaces the VBM),
- advancing care information (replaces the Medicare physician EHR incentive program), and
- improvement activities (a new performance category).²¹

Within each category, CMS has defined a set of possible measures or activities. For the Cost category, CMS calculates certain measures based on claims data. For all other categories, clinicians select from a menu of CMS-approved measures and must report data to CMS. For example, in the Quality category, clinicians must select and report on 6 measures or a set of specialty measures defined by CMS. Clinicians may use a variety of options to report these data to CMS; the data can be reported via claims data, electronic health records, and qualified clinical data registries. Additionally, clinicians may report individually or as part of a group, and they may use vendors or surrogates (e.g., data registries or a group practice's administrator) to submit MIPS data on their behalf.

For each clinician, CMS calculates a MIPS "Final Score" based on the provider's performance in each of the four categories. The four areas do not carry equal weight; for example, in 2017, clinicians' performance on measures in the Quality category will account for 60% of their MIPS Final Score. (See Appendix A for further detail about MIPS scoring.)

CMS uses clinicians' MIPS scores for a given year to adjust Medicare Part B payments 2 years later—for example, CMS will use scores for 2017 to adjust payments in 2019. To determine payment adjustments, CMS compares each clinician's MIPS score to a "performance threshold." For 2017, CMS set the threshold such that any clinician who reports a minimum amount of data will avoid a negative payment adjustment in 2019. Beginning in the program's third year, CMS will set the threshold at the mean or median score of all MIPS-eligible clinicians for a prior period specified by the Secretary of Health and Human Services. Clinicians scoring further above or below the threshold receive larger adjustments. The maximum payment adjustment gradually increases from 4 percent (positive or negative) in 2019 to 9 percent (positive or negative) in 2022 and beyond. MACRA established MIPS as a budget-neutral program, so CMS may scale positive payment adjustments under MIPS as needed to ensure that they do not exceed penalties. In addition, MACRA provided \$500 million annually for CMS to distribute payments for exceptional performance to clinicians whose MIPS scores exceed a certain level.

Clinicians are exempted from MIPS reporting requirements if they (1) meet the "low-volume threshold" of having no more than \$30,000 in Medicare Part B charges or no more than 100 Medicare beneficiaries during the performance period²⁴, or (2) meet criteria for participation in the Advanced APM track (see below for further detail). Providers who are exempt from MIPS because they fall below the low-volume threshold will continue to be paid for Medicare Part B services at the Physician Fee Schedule rates without an additional QPP payment adjustment.

ADVANCED ALTERNATIVE PAYMENT MODELS

The Patient Protection and Affordable Care Act (ACA) established authorities to test several alternative payment models (APMs).²⁵ APMs are payment and care delivery models that are designed to financially reward high-quality and cost-efficient care. Some APMs seek to achieve this by providing incentive payments to high performers, while others require providers to bear additional risk, sharing in gains and/or losses based on the overall cost of care. Some APMs apply to specific clinical conditions (e.g., end-stage renal disease (ESRD)), others to a type of care episode (e.g., joint replacement), and others to a population (e.g., primary care patients).²⁶

Building on these initiatives, MACRA enabled providers who participate in Advanced APMs to be exempt from MIPS reporting and subject to a different set of incentive payments. MACRA established three criteria for determining which Medicare APMs will qualify as Advanced APMs in the QPP. Each Advanced APM must:

- (1) require participants to use certified EHR technology;
- (2) provide payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and
- (3) require APM Entities²⁷ to bear more than a nominal amount of financial risk, or be a Medical Home Model expanded under section 1115A(c) of the Act.²⁸

Providers with a certain proportion of patients or payments that are part of an Advanced APM are deemed "Qualifying APM Participants" for the QPP Advanced APM track. Qualifying APM Participants are excluded from MIPS reporting and payment adjustment, and instead receive a 5-percent annual bonus during payment years 2019 through 2024. Beginning in 2026, Qualifying APM Participants receive higher physician fee-schedule updates, compounded annually. These providers may receive additional bonuses specific to the Advanced APMs in which they participate.

TIMELINE

The performance periods for MIPS and for Advanced APMs are broadly aligned with each other. For both, the first performance period begins January 1, 2017. MIPS adjustments and Advanced APM bonuses based on the 2017 performance period will go into effect in 2019. The QPP will operate on an overlapping 3-year program cycle. The first year of each cycle is the performance period; the second year is for reporting data and calculating scores; and the third year is for adjusting payment. (See Appendix B.)

Figure 1. Overview of the Medicare Quality Payment Program

Merit-Based Incentive Payment System (MIPS) Track

- Components of MIPS Final Score:
 - Quality
 - Cost
 - Advancing Care Information
 - Improvement Activities
- Payment Adjustment: MIPS must be budget neutral, so CMS may scale positive payment adjustments as needed to achieve neutrality. High performers will be eligible for additional payments for exceptional performance.

Advanced Alternative Payment Models (Advanced APMs) Track

- CMS determines which models meet criteria for Advanced APMs.
- Qualifying APM Participants have a certain proportion of their Medicare payments or patients through the Advanced APM.
- Payment Adjustment: Qualifying APM
 Participants will receive an annual
 5% lump-sum bonus from 2019 through
 2024. Beginning in 2026, they will receive
 higher physician fee-schedule updates,
 compounded annually.



STAKEHOLDER CONCERNS

Providers, professional associations, and Members of Congress have expressed a variety of concerns about the QPP. CMS received over 4,000 comments on the proposed rule for the QPP published in May 2016,²⁹ and has continued to receive feedback after issuing the final rule in October 2016. Stakeholders' major concerns are summarized below:

- Too burdensome for solo, small-practice, and rural providers. Stakeholders questioned
 whether small and/or rural providers will succeed under the QPP. Unlike large practices, small
 providers may not have the resources to hire an administrator or third-party vendor to handle
 reporting.
- Too complex. Stakeholders raised concerns about the QPP's complexity—in particular, the
 complicated formula for calculating MIPS Final Scores and determining payment adjustments.
 Stakeholders also noted that if clinicians in Advanced APMs do not know until late in the
 performance period whether they have reached the threshold to be Qualifying APM
 Participants, they may still need to prepare for MIPS reporting—reducing one of the incentives
 for participation in the Advanced APM track.
- Applicability and validity of specific MIPS measures. Stakeholders offered feedback about the
 availability of MIPS measures relevant to different types of clinical practice and whether the
 measures will accurately reflect clinician performance.
- Paucity of Advanced APM opportunities currently available. Stakeholders stated that more
 Advanced APM opportunities for clinicians, particularly specialists, are needed. Some
 recommended that CMS simplify and lower the financial-risk standards for Advanced APMs.

LESSONS FROM HEALTHCARE.GOV

Implementing the QPP is a significant undertaking for CMS, requiring extensive policy and systems development within a relatively short timeframe. CMS has historically faced challenges when implementing complex initiatives of this size, such as the launch of the Medicare Part D program and the rollout of HealthCare.gov.

In a prior report, OIG examined CMS's management of HealthCare.gov from the time of its well-publicized initial failures to its improvements during the second enrollment period. ³⁰ OIG synthesized several lessons learned from CMS's management of that program, as outlined in the sidebar.

CMS staff reported that they drew on experiences from HealthCare.gov to rethink the agency's approach to launching complex initiatives such as the QPP. Like HealthCare.gov, the QPP requires coordination on policy, operational, and technological issues, as well as extensive collaboration across different components within CMS. In this report, we have noted points at which CMS staff reported applying the lessons learned from HealthCare.gov to CMS's management of the QPP.

"HealthCare.gov was a really low moment for the agency, but it was a learning moment, which allowed us to learn the lessons of how to build new muscles [from the turnaround of] HealthCare.gov and apply them to the MACRA program." — CMS official

METHODOLOGY

To describe progress that CMS has made towards implementing the QPP, we interviewed CMS staff and reviewed relevant internal CMS documents as well as publicly available information.

Scope. This review describes CMS's activities to implement the QPP. We did not review other HHS agencies involved in

QPP operations, such as the Office of the National Coordinator for Health Information Technology. Our review primarily describes CMS's activities through August 2016, with additional information that relates to regulations issued in October 2016.

Interviews. We interviewed CMS staff between June 2016 and November 2016. We asked about roles and responsibilities; resources; communication; and challenges. We also asked about CMS's approach

Lessons from HealthCare.gov

- Leadership: Assign clear project leadership to provide cohesion across tasks and a comprehensive view of progress.
- Alignment: Align project and organizational strategies with the resources and expertise available.
- Culture: Identify and address factors of organizational culture that may affect project success.
- **Simplification:** Seek to simplify processes, particularly for projects with a high risk of failure.
- Integration: Integrate policy and technological work to promote operational awareness.
- Communication: Promote acceptance of bad news and encourage staff to identify and communicate problems.
- Execution: Design clear strategies for disciplined execution, and continually measure progress.
- Oversight: Ensure effectiveness of IT contracts by promoting innovation, integration, and rigorous oversight.
- Planning: Develop contingency plans that are quickly actionable, such as redundant and scalable systems.
- Learning: Promote continuous learning to allow for flexibility and changing course quickly when needed.

to developing the QPP, including its overall strategy, priorities, progress made to date, and the timeline for remaining activities. Additionally, we conducted a focus group of CMS staff working on the QPP to better understand how the agency's overarching management priorities are carried out in practice. Finally, we received responses from the United States Digital Service (USDS)—a component of the Office of Management and Budget that provides IT consulting to Federal agencies—regarding its partnership with CMS on the QPP.

Documents. We requested and received from CMS a variety of documents related to its QPP implementation efforts. These included, but are not limited to, materials on operations and management activities; communications and outreach activities; IT development activities; and QPP organizational structures. We also reviewed publicly available information, such as congressional hearing transcripts, CMS public communications, and public comments that CMS received on the QPP proposed rule.

Analysis. We conducted a qualitative analysis of interview and focus group responses, USDS responses, CMS documents, and publicly available information to identify key milestones (both those achieved and those yet to come), priorities, and challenges related to QPP implementation. To identify vulnerabilities, we reviewed priorities and milestones yet to be achieved and identified those that (a) will require extensive, sustained CMS activity in 2017 to address, and (b) pose a significant risk to the QPP's success if insufficiently addressed.

Limitations. Our review focused on CMS's management of the QPP's early implementation. At this point in the program's development, we did not assess the extent to which CMS's management of the QPP, or the QPP itself, will be successful in meeting program requirements and goals. Our review relied on self-reported information from a purposively selected sample of CMS staff involved in QPP implementation. We did not interview all CMS staff involved in the QPP, nor did we interview any contractors or external entities (e.g., clinicians participating in user testing). We reviewed a selective set of CMS documents that we requested based on their relevance to our study objectives.

Standards. This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Key Management Priorities

From interviews with CMS leadership and staff and analysis of key documents, we identified CMS's five key management priorities regarding the agency's planning and early implementation of the QPP. Early on, CMS staff decided that clinicians' acceptance of the QPP, and readiness to participate in it, would be the most critical factor to ensuring the program's success. This focus on clinicians informed CMS's decisionmaking regarding its other management priorities, including:

- adopting integrated internal business practices to accommodate a flexible, user-centric approach;
- developing IT systems that support and streamline clinician participation;
- developing flexible and transparent MIPS policies; and
- facilitating participation in Advanced APMs.

In the following sections, we assess CMS's progress to date for each of its management priorities and describe what remains to be accomplished. Additionally, where appropriate, we identify key vulnerabilities that will require intensive activity from CMS during 2017 and could affect the program's success.

Facilitate
Advanced
APM
Participation

Acceptance
& Readiness

Acceptance

Business
Practices

Develop IT
Systems

Develop MIPS
Policies

Figure 2. CMS's Key Management Priorities for Implementing the QPP

Source: OIG analysis of CMS's implementation of the QPP, 2016.

CMS PRIORITY: FOSTER CLINICIAN ACCEPTANCE AND READINESS TO PARTICIPATE

STATUS: CMS initiated engagement and outreach activities to foster clinicians' acceptance of the QPP and readiness to participate in it. Moving forward, CMS plans to continue these activities and expand technical assistance. However, CMS faces challenges in ensuring that providers have the information and tools to participate in the QPP.

WHAT'S BEEN DONE

- ✓ Engaged clinicians and stakeholders
- ✓ Conducted user testing of the QPP Portal
- ✓ Established "Clinician Champions" and other partnerships
- ✓ Created a transition year
- ✓ Awarded contracts for direct education, support, and technical assistance

WHAT'S STILL TO COME

- Continue clinician engagement and outreach activities
- Oversee technical assistance contractors

VULNERABILITY:

 CMS must continue to expand its outreach and technical assistance efforts to ensure that providers—especially solo, small-practice, and rural providers—have the information and tools they need to participate in the QPP.

OVERVIEW

According to CMS staff, the QPP's success relies in large part on clinicians' acceptance of the program and readiness to participate. However, stakeholders have expressed concerns about whether providers—especially solo, small-practice, and rural providers, who historically have been less likely to take part in CMS quality initiatives—will be technically and logistically ready to participate in the QPP. To address these concerns, CMS engaged with clinicians of all practice types throughout the early

"The biggest goal and the biggest risk is the acceptance by the physician community."

– CMS Acting Administrator

implementation process, instituted policies designed to ease the transition to the QPP, and awarded contracts to provide direct support and technical assistance to clinicians participating in the QPP (although some of these activities have yet to begin).

WHAT'S BEEN DONE

Engaged clinicians and stakeholders. Through focus groups and listening sessions, CMS found that clinicians' lack of trust in CMS's management capabilities and concerns about the QPP posed a challenge to QPP implementation and success. Specifically, clinicians reported negative experiences with previous CMS quality programs; confusion over QPP requirements; and concerns about the program's complexity and potential technological

"(The CMS Acting Administrator) made it clear that we have to put the pens down and listen to the users. . . . We went across the country to hear providers' perceptions and their reality. . . . We recorded their 'pain points.'" —CMS official

obstacles. CMS staff also reported that some clinicians expressed skepticism about the QPP's stated purpose of improving care delivery and instead viewed the program as a vehicle to reduce clinician reimbursement. In response, CMS provided a variety of opportunities for clinicians to obtain information and submit feedback as the agency developed the QPP policies and systems. Specifically, CMS held webinars, listening sessions, focus groups, and solicited written comments throughout the rulemaking process. (See Figure 3.) As implementation moves forward, CMS is continuing to publicize the program and educate clinicians, using terminology that it has tested with clinician groups to align key messages with providers' concerns.

Figure 3. QPP Engagement, Outreach, and Education Activities

Engagement, Outreach, and Education Activities	Number of activities completed between 1/1/2016 and 10/28/2016
User Research	87
including focus groups and in-depth interviews	
Travel and Public Events	311
including speeches, conferences, and listening	
sessions/town halls	
Training	27
including national and regional trainings	
Channel and Partner Engagement	109
including monthly partner calls; emails and mailings;	
"open door" forums; and biweekly Clinician Champions	
meetings	

Source: CMS, CMS Official Response to OIG's Questionnaire, 2016.

Conducted user testing of the QPP Portal. CMS staff reported that as part of the agency's focus on clinicians, it adopted a user-centric approach to developing the QPP Portal that serves as clinicians' online gateway to the QPP. When fully operational, the Portal will provide everything from general information about the QPP to provider-specific feedback; it will also be the mechanism through which clinicians report MIPS data. In developing the Portal, CMS conducted extensive user testing to identify and address potential problems. For example, CMS showed early versions of the website to volunteer clinicians and gathered their feedback on the intuitiveness of the site, the clarity of the language, and the resonance of the site's content. As part of this user testing, CMS also observed as clinicians

attempted to navigate through the Portal, with the goal of identifying aspects of the site that may confuse or frustrate users. CMS staff reported incorporating this user feedback in subsequent iterations of the website. CMS is continuing to conduct user testing as it further develops the Portal.

"We need to prove to users that this system is for them and we are working for them.

Once we prove this, then we will get the buy-in." – CMS official

Established Clinician Champions and leveraged other partnerships. CMS staff reported leveraging new and existing partners to engage clinicians and provide them with information. Existing partners included frontline clinicians; medical societies and associations; qualified clinical data registries; and EHR vendors. Partners participated in national stakeholder calls, shared social media messages with their networks, led Learning and Action Network trainings, and provided feedback to CMS from these communications. Furthermore, CMS developed a new partnership named "Clinician Champions" to assist with QPP outreach. Clinician Champions are providers who are nominated by CMS and are trained to deliver QPP messages at the local level and provide peer-based education. This effort responds directly to feedback that CMS received in focus groups indicating that clinicians preferred to receive information from "people like me." CMS staff reported that the Clinician Champions have been meeting biweekly since July 2016.

Created a transition year. To give providers additional time to adjust to the QPP, CMS decided that 2017 would serve as a transition year for the program. In interviews, CMS staff described this approach as an "on-ramp" that would enable clinicians to gradually adapt to the QPP—particularly, to the MIPS reporting requirements—with little risk of penalty. Specifically, clinicians who need time to prepare their systems and learn about the program need report only a minimum amount of MIPS data in order to avoid a negative payment adjustment. Providers who are farther along in their preparations can opt to provide more MIPS data and qualify for a positive payment adjustment. The 2017 transition year will also enable clinicians who are interested in the Advanced APM track to determine which model would best suit their practice and prepare for participation. For the 2018 performance period, CMS envisions continuing the ramp-up of the program and its performance thresholds; rulemaking to finalize these policies for 2018 will occur in 2017.

Awarded contracts for direct education, support, and technical assistance. CMS developed a variety of technical assistance programs designed to meet the needs of different types of clinicians and practices. Technical assistance contractors will provide individualized education, support, and assistance that is appropriate to each provider type. For example, Congress allocated \$100 million for technical assistance to clinicians working in small practices with less than 15 professionals, with priority given to those practices located in areas that are rural, have shortages of health professionals, or are medically underserved. These funds will be disbursed to approved entities³¹ through the QPP-SURS (Small, Underserved and Rural Support) contracts. CMS plans to award the QPP-SURS contracts in early 2017, and awardees are expected to begin working with clinicians upon award. CMS also established similar initiatives to provide assistance for all types of practices, such as the Quality Innovation Network-Quality Improvement Organization contract program and the Transforming Clinical Practice Initiative contract program. These contracts have been awarded and outreach and assistance activities are underway.

WHAT'S STILL TO COME

Continue clinician engagement and outreach activities. As the first performance year begins, CMS will face both an increased demand for information as well as new feedback from clinicians who may not have engaged with the QPP earlier in the implementation process. Additionally, the first year of the QPP is a "transition year" that does not require full reporting. Although this is likely to initially encourage clinician participation, CMS may face resistance in future years as the program requirements become more stringent. To achieve its goals, CMS will need to sustain its clinician-engagement efforts.

Oversee technical assistance contractors. To ensure that clinicians receive timely assistance, CMS must monitor and oversee the performance and effectiveness of technical assistance contractors as direct support activities begin.

VULNERABILITY: CMS must ensure that providers—especially solo, small-practice, and rural providers—have the information and tools they need to participate in the QPP If providers lack the knowledge, tools, or skills to participate, they will struggle to meet the QPP reporting requirements. Frustrated providers may even opt not to participate in the QPP despite the payment penalty, limiting the program's ability to meet its goals. To mitigate this risk, CMS must continue to monitor clinician readiness—especially as the first reporting deadline approaches—to identify and address any problems early on. CMS has begun its technical assistance and training efforts, but these activities must quickly be ramped up to full scale and continued throughout 2017 to support Medicare clinicians' participation in the QPP.

CMS PRIORITY: ADOPT INTEGRATED, FLEXIBLE BUSINESS PRACTICES

STATUS: CMS established an integrated, flexible management approach to launch the QPP.

WHAT'S BEEN DONE

- ✓ Developed an overall QPP strategy
- ✓ Assigned executive leadership to each program component
- ✓ Established integrated project teams and shared office space
- ✓ Partnered with United States Digital Service to adopt agile IT development methods
- ✓ Adopted a new contracting approach
- ✓ Awarded a systems integrator contract

WHAT'S STILL TO COME

- Award QPP "sprint" contracts in a timely manner
- Expand oversight of contractors
- Hire qualified staff to sustain CMS's shift to agile practices

OVERVIEW

Implementing the QPP requires CMS to coordinate policy, technology, communications, and operations activities. Additionally, because the legacy programs on which the QPP is based are dispersed among various CMS components, staff with necessary expertise and experience are similarly dispersed. Staff working with many of the APMs, for example, report to the CMS Center for Medicare & Medicaid Innovation, while those involved in the Value-Based Payment Modifier program are located in the CMS Center for Medicare. To address this logistical and organizational complexity, CMS adopted an integrated, flexible approach to both program management and IT development. CMS staff reported that this new approach was informed by lessons it learned from HealthCare.gov, which was initially hampered by fragmentation, poor communication, and an inability to change course when problems arose. Based on that experience, CMS strove to implement the QPP with clear project leadership; to develop structures and processes that promote communication and integration of policy and technological work; and to promote a user-focused, change-oriented organizational culture.

WHAT'S BEEN DONE

Developed an overall QPP strategy. One of CMS's early steps in planning the QPP was to create an overarching strategy, which includes the following objectives:

- improve beneficiary outcomes and engage patients through patient-centered Advanced APM and MIPS policies;
- (2) enhance clinician experience through flexible and transparent program design and interactions with easy-to-use program tools;
- (3) increase the availability and adoption of robust Advanced APMs;
- (4) promote program understanding and maximize participation through customized communication, education, outreach, and support that meet the needs of the diversity of physician practices and patients, especially the unique needs of small practices;
- (5) improve data and information sharing to provide accurate, timely, and actionable feedback to clinicians and other stakeholders; and
- (6) ensure operational excellence in program implementation and ongoing development.³²

"From the beginning, we had a strategic plan with really clear goals that were informed by the user, clinician, and patient community." – CMS official CMS staff described this strategy as fundamental in guiding its daily management of the QPP. They reported that because the objectives clearly define the long-term goal, they have been able to be creative and flexible as they develop the QPP.

Assigned executive leadership to each program component. In February 2016, CMS established a QPP executive leadership team to guide staff and to coordinate decisionmaking. The Director of the Center for Clinical Standards and Quality was designated as the QPP Chief Executive Officer, with responsibility for leading the executive team and overseeing all QPP programmatic functions across CMS. QPP executives were drawn from

"[I]t . . . is much clearer to me where I need to go to fix a problem. I can get a much more rapid audience with higher leadership if problems arise and I can cross-talk with my peers . . . across workstreams." – CMS official

different CMS components to lead key aspects of implementation (e.g., Technology, Policy, Operations). Within each of these areas, CMS created "workstream" teams to create policy, build IT systems, plan operations, manage external communications, and address other major tasks. (See Appendix C for the organizational chart of the QPP Executive Leadership Team.) In this way, CMS sought to ensure that responsibility for each major element of QPP implementation would be clearly assigned and that the project would be overseen by a single executive with primary responsibility for coordinating the program as a whole. (See Appendix D for further detail about the roles and responsibilities assigned to each member of the QPP Executive Leadership Team.)

CMS staff reported that the QPP executive team meets multiple times each week and also meets regularly with CMS senior leaders. Meeting materials that we reviewed described progress on QPP activities; plans for upcoming activities; program risks and corresponding mitigation strategies; and issues requiring a decision from senior leaders. According to CMS staff, the QPP leadership structure and regular meetings have provided clear communication channels across CMS divisions to raise issues to the executive leadership team for input and resolution.

Established integrated project teams and shared office space. CMS created a shared office space for staff and contractors working on the QPP and staffed each workstream with personnel from various CMS divisions with relevant expertise. Contractors are also embedded in the CMS teams. Several staff described this as a new way of working within CMS and noted that the integrated project teams have increased transparency and communication. Additionally, CMS staff reported that being physically co-located with contractors has facilitated closer oversight of their work.

According to CMS staff, teams coordinate closely to ensure that interrelated decisions are informed by all relevant workstreams. For example, one CMS official reported that when CMS developed the final rule, it drafted some policies more generally to provide the IT team with greater flexibility for its operations. As another example, the communications team shared with the IT team feedback from office managers of group practices regarding how they preferred to use the Portal. In response to this feedback, the IT team developed a feature that enables users to download a list of quality measures for later discussion with colleagues.

Partnered with the United States Digital Service to adopt agile IT development methods. To develop the complex IT infrastructure necessary to support the QPP, CMS partnered with USDS.³³ USDS advised CMS to adopt an "agile" IT development methodology—an iterative approach in which the final product is created through a series of 1-week or 2-week "sprints" of work to complete smaller

components.³⁴ This allows the IT team to regularly adjust priorities; conduct user testing and security testing; and respond to user feedback.

CMS staff reported that using agile development has enabled closer monitoring of the work of both CMS staff and contractors. Additionally, because each component of the system is initially tested during the process—rather than waiting to test until the system is fully built—the team can detect and mitigate issues earlier.

"[The agile development approach is to] pilot small, move fast, fail fast, and have a backup plan." – CMS official

Adopted a new contracting approach. USDS staff also advised CMS staff to develop a Blanket Purchasing Agreement (BPA) for agile IT development because this method is better aligned with the iterative nature of agile IT development.³⁵ According to CMS procurement staff, using a BPA strategy for IT development is a new contracting strategy for the agency. CMS staff reported that the BPA will support the agile IT-development approach for the QPP by permitting the agency to procure in smaller increments based on each sprint, allowing more rapid procurement based on the speed of planning and executing each sprint, and establishing a fixed pricing structure for each sprint. Staff also noted that the agency "can walk away from a contactor that does not meet our needs" after a shorter period of time (e.g., at the end of a 6-month sprint contract). Finally, budget staff noted that this procurement approach has led to more efficient and precise budget estimates. In September 2016, CMS awarded the BPA to six IT firms.

Awarded a systems integrator contract. Following the initial, failed launch of HealthCare.gov, OIG reviewed CMS's IT procurement and recommended that CMS assess whether to assign a lead systems integrator for other complex IT projects.³⁶ In our interviews, CMS staff reported that the agency had decided to award a systems integration contract for the QPP. This contractor is responsible for "analysis of system development schedules and business and systems requirements; management and support of system changes; support for architecture design and development, capacity planning, integrated end-to-end and performance testing; and support for business operations and maintenance."³⁷ CMS awarded this contract on September 22, 2016, but work was delayed until a bid protest was withdrawn on November 9, 2016. CMS staff reported that the systems integration contractor began work shortly after the resolution of the bid protest. Ongoing systems integration will be critical as the QPP expands into a larger operation with new staff and contractors.

WHAT'S STILL TO COME

Award QPP sprint contracts in a timely manner. Having recently finalized the agile IT development BPA, CMS must now begin procuring specific contracts for the QPP sprints. Timely procurement is critical to ensuring that the QPP sprint schedule remains on course.

Expand oversight of contractors. With the finalization of the agile IT development BPA and the system integration contract, CMS will expand the pool of active contractors working on the QPP development and operation. With a larger pool of contractors working on the QPP, CMS will need to expand its oversight and monitoring of their activities.

Hire qualified staff to sustain CMS's shift to agile practices. CMS staff described USDS as a major driver of its ability to adopt agile practices. However, USDS's role in the QPP is time-limited. USDS staff stated that they are training CMS staff and contractors in preparation for USDS's eventual departure, and CMS staff noted that CMS's direct hiring authority for the QPP has been helpful in bringing qualified staff onboard. Nonetheless, both CMS and USDS staff reported that hiring staff with expertise in agile

"Implementing a major technical and operational program such as QPP requires interdisciplinary management, technical, and product management expertise. Hiring for those skills in government is difficult...."

— USDS correspondence

development poses a challenge. As new staff join the QPP, CMS will need to continue training in agile development and QPP internal processes to sustain its new business practices.

CMS PRIORITY: DEVELOP IT SYSTEMS

STATUS: In 2016, CMS prioritized developing the public-facing QPP website. Upcoming milestones include enabling individualized QPP accounts for clinicians and expanding a service desk. However, CMS faces challenges in building the complex backend IT systems required to receive clinicians' data, calculate their MIPS scores, and carry out other functions vital to the program's success.

WHAT'S BEEN DONE

✓ Developed informational website (launched on October 14, 2016)

WHAT'S STILL TO COME

- Enable individualized accounts for clinicians
- Expand the service desk
- Build backend IT systems

VULNERABILITY:

 CMS must build and test the backend IT systems necessary for data submission and validation, calculation of MIPS Final Scores, payment adjustment, and other key functions.

OVERVIEW

The QPP Portal consists of three major components (see Figure 4 on the next page):

- a public-facing informational website,
- individualized accounts for clinicians, and
- backend systems necessary to receive and validate clinicians' data, provide individualized performance feedback, calculate clinicians' MIPS scores, and adjust Part B payments accordingly.

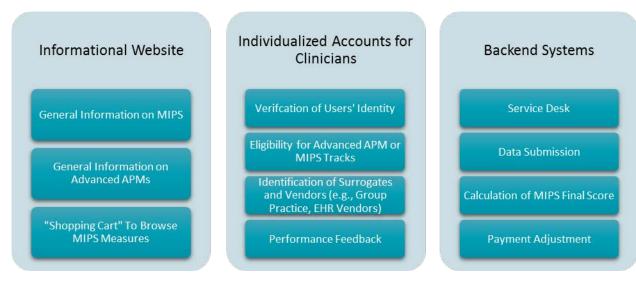
The informational website component was launched in October 2016, while the remaining components are still under development. CMS also plans to expand a service desk that will assist clinicians in using the Portal.

WHAT'S BEEN DONE

Developed and launched the informational website. The QPP informational website launched on October 14, 2016.³⁸ The website provides general information about the QPP, the MIPS track, and the Advanced APM track. It also clarifies clinicians' reporting options and how to qualify for either the MIPS or Advanced APM tracks. For the MIPS track, the website enables users to browse the various MIPS measures available for selection.

"We understood early on that the Portal was going to make or break the physician experience with the MIPS program. The way we communicate to them and how much of a hassle it is for them to communicate with us is important." – CMS official

Figure 4. Overview of the QPP Portal



Source: OIG analysis of CMS's implementation of the QPP, 2016.

WHAT'S STILL TO COME

Enable individualized accounts. For many clinicians, registering for and using their individualized QPP account will be their first significant interaction with the QPP. CMS staff reported that individualized accounts will be available in January 2017. These accounts will ultimately enable CMS to:

- verify the user's identity;
- inform clinicians of their eligibility for the Advanced APM track versus the MIPS track, so that clinicians know whether they must select and report MIPS measures; and
- provide individualized performance feedback.

CMS staff reported that, later in 2017, the QPP accounts will also be used to gather information on a clinician's network of surrogates and vendors (e.g., entities that may report data on the clinician's behalf).

CMS staff noted that CMS has, for the first time, contracted with a vendor to provide "identity as a service"—an approach in which a third party provides scalable identity-management services, rather than having those functions housed and managed onsite. CMS staff reported selecting this approach because it will provide flexibility in capacity, enabling CMS to pay for more capacity only at times of higher demand. CMS staff anticipated that such flexibility will prevent user access problems during peak use times—an issue that initially caused significant problems during the launch of HealthCare.gov—and will also prove cost-efficient, because CMS will pay only for the level of capacity actually needed each month.

CMS staff reported that CMS plans to pilot-test the security and reliability of this new service prior to fullscale deployment. Such testing is critical; a poorly functioning identity management service could impede clinicians' ability to successfully submit data, receive performance feedback reports, and conduct other QPP activities using the Portal. To mitigate this risk, CMS plans to encourage clinicians to voluntarily register for a QPP account several months prior to the first deadline for data submission. This "soft" rollout of individual accounts may allow CMS to identify and address problems that arise with the new identity management service prior to the peak registration period.

Expand the service desk. CMS has initiated a QPP service desk to answer questions and resolve problems. CMS staff reported that in the future, the service desk will not only provide IT support for the Portal, but will also offer broader program assistance. This will include sharing information about training opportunities and assisting providers who have filed requests to have their MIPS Final Scores reviewed. CMS staff reported that its goal is to eventually create a single integrated system across the currently separate service desks of the legacy systems (i.e., PQRS, VBM, and the Medicare physician EHR incentive program) and the new QPP portal. Achieving this milestone will require CMS to (1) modify service-desk contracts as they come up for renewal, and (2) develop new IT tools to share information across separate helpdesk functions (e.g., an integrated ticketing system for all incoming requests).

Build backend IT systems. With limited time between the passage of MACRA and the beginning of the first performance year, CMS focused its IT development on ensuring that the public-facing QPP website would be up and running when the final rule was issued. However, the agency must now build the backend systems that will enable CMS to:

- receive and validate clinician performance and attestation data;
- provide useful performance feedback to clinicians;
- calculate MIPS Final Scores for MIPS-eligible clinicians; and
- adjust future Part B payments.

VULNERABILITY: CMS must build and test the backend systems necessary to fully support the QPP

Building and testing the extensive IT systems necessary to support critical QPP operations will require significant and sustained effort over the forthcoming year. In the past, CMS has sometimes experienced delays and complications related to major IT initiatives, such as those required for the continued operation of Medicare Part D and HealthCare.gov. If the complex systems underlying the QPP are not operational on schedule, the program will struggle to meet its goal of improving value and quality.

CMS has sought to mitigate these risks by (1) planning to use legacy program systems (i.e., PQRS, VBM, and EHR) as a backup option for MIPS data submission, and (2) using 2017 as a "transition year" in which MIPS scores are calculated but—as long as the clinician submits a minimum of data—will not result in a negative payment adjustment. Nonetheless, the QPP is more likely to succeed if all IT infrastructure is ready when needed.

CMS PRIORITY: DEVELOP MIPS POLICIES

STATUS: CMS issued MIPS-related regulations that finalized key policies for the first performance year. Promised subregulatory guidance is still needed to ensure that providers have sufficient information as the first performance year begins.

WHAT'S BEEN DONE

✓ Published QPP final rule, including MIPS policies for 2017

WHAT'S STILL TO COME

- Issue promised subregulatory guidance
- Finalize policies for virtual groups
- Rulemaking in 2018 and beyond

OVERVIEW

CMS met challenging timeframes to issue final regulations implementing MIPS on October 14, 2016. These regulations finalize MIPS policies for the first performance year. Further rulemaking will be necessary in 2018 and beyond. Additionally, CMS has not yet issued promised subregulatory guidance for a variety of topics on which stakeholders have requested clarification.

WHAT'S BEEN DONE

Published final rule. On October 14, 2016, CMS issued a final rule with comment period. This final rule finalized MIPS policies for 2017, the first performance period. In developing the final rule, CMS staff reviewed over 4,000 comments received regarding the proposed rule that was published on May 9, 2016 and worked to develop MIPS policies that would address the numerous concerns raised by

stakeholders while remaining in compliance with the statute. Despite the complexity of the rulemaking process and a challenging timeframe, CMS was able to issue the final rule on schedule. (See Appendix E.)

"Getting the policy right is critical. This is new territory, and we need to get the program on the right glide path." — CMS Acting Administrator

Consistent with its strategic objectives of prioritizing "clinician experience" and "flexible and transparent

program design," CMS made numerous revisions from the proposed rule based on stakeholders' comments. Of these changes, two are particularly significant:

- Implementing the 2017 performance period as a transition year. The final rule reenvisioned the first performance year as a "transition year" with minimal or no negative impact on payments. Under the final regulations, providers can "pick their pace" and participate in the QPP to a smaller or greater extent in 2017 with little risk of penalty. This significant change from the proposed rule responded to numerous stakeholder comments requesting delayed MIPS implementation.
- Increasing the low-volume threshold. Many stakeholder comments on the proposed rule reflected concerns about the ability of solo and small-practice providers—particularly in rural areas—to successfully participate in MIPS. In response, CMS raised the low-volume threshold so that fewer clinicians will be required to participate in MIPS. Under the final regulations, clinicians are exempt from MIPS if they have no more than \$30,000 in Medicare Part B charges or serve no more than 100 beneficiaries during a 12-month period. CMS estimates that as compared to the proposed rule, the final rule exempts between approximately 150,000 and

200,000 additional clinicians from MIPS. CMS now estimates that in total, between 43 and 47 percent of all clinicians billing to Medicare Part B—between 592,000 and 642,000 clinicians—will be required to submit MIPS data in the first year. Of these, approximately 148,000 are solo or small-practice providers.³⁹ The clinicians required to participate in the first year represent between approximately 73 and 78 percent of total Medicare payments for Part B professional services.

WHAT'S STILL TO COME

Issue promised subregulatory guidance. MIPS reporting and scoring is complex and requires clinicians to adapt to significant changes in the Medicare Part B payment system. Clinicians have requested additional guidance and tools for compliance, and in the QPP final rule, CMS stated its intention to provide subregulatory guidance on a variety of topics, including:

- group reporting options;
- the form and manner of data submissions by clinicians, including standards that third-party vendors will need to follow;
- information and instructions regarding CMS data validation and auditing; and
- documentation expectations for the transition year.

However, with only weeks to go until the beginning of the 2017 performance year, CMS has yet to issue most of its planned subregulatory guidance. The earlier clinicians have this information, the better prepared they will be to fully and successfully participate in MIPS in 2017.

Finalize policies for virtual groups. Section 1848(q)(5)(I) of MACRA established voluntary "virtual groups" that would allow solo and small practitioners to report as a group with at least one other solo or small practitioner for a performance period. Clinicians who wish to report as a virtual group in this manner must elect to do so before the start of the relevant performance period. Stakeholders have expressed support for this option, but CMS was not able to implement it for the 2017 performance period because of "significant barriers" related to both technology and operations. CMS has stated that it intends to implement virtual groups for the 2018 performance period. To achieve this milestone, CMS must finalize the relevant policies promptly to ensure sufficient time for necessary IT infrastructure development, as well as for clinicians to plan for their participation.

Rulemaking in 2018 and beyond. The final rule issued in October 2016 sets MIPS policies for the first performance year, but additional rulemaking will be necessary for the 2018 performance year—for example, to finalize policies around virtual groups, to identify new quality measures, and to set the 2018 performance threshold. In addition, CMS will use future rulemaking to address comments received and concerns expressed in response to on the October 2016 final rule. As in 2017, CMS will face a challenging timeframe to finalize and issue the necessary regulations in sufficient time for clinicians, vendors, and other entities to be ready for the 2018 performance year.

CMS PRIORITY: FACILITATE PARTICIPATION IN ADVANCED APMS

STATUS: CMS identified Medicare models that qualify as Advanced APMs for the first performance period. Participation in Advanced APMs is expected to be limited in 2017; CMS has begun identifying ways to increase opportunities for clinicians to participate in this program track in the future.

WHAT'S BEEN DONE

- ✓ Identified which existing Medicare models meet criteria for Advanced APMs
- ✓ Established policy for determining Qualifying APM Participants
- ✓ Published QPP final rule, including Advanced APM policies for 2017
- ✓ Awarded contracts for technical assistance to prepare clinicians to participate in Advanced APMs

WHAT'S STILL TO COME

- Determine which clinicians are Qualifying APM Participants
- Increase Advanced APM opportunities
- Increase clinician participation in Advanced APMs over time

OVERVIEW

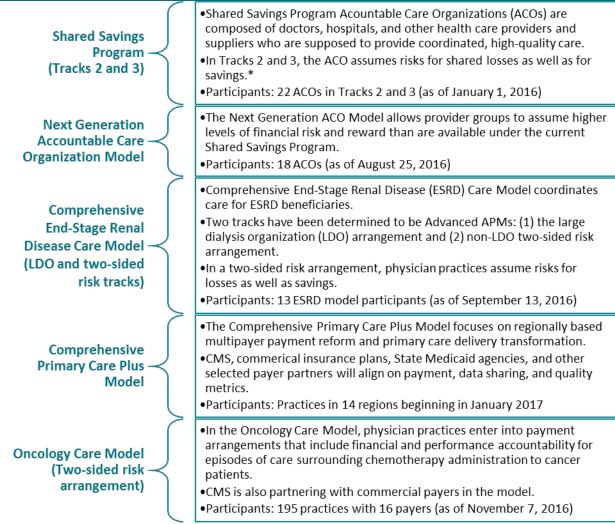
CMS issued regulations finalizing Advanced APM policies for the first performance year, including the initial list of Medicare models that qualify as Advanced APMs and the criteria CMS will use to identify additional models. (See Appendix E for key milestones in the rulemaking process.) In 2017, CMS will need to inform clinicians of whether they are Qualifying APM Participants or whether they will need to report MIPS measures. In the future, CMS will need to take steps to increase clinician participation in Advanced APMs in order to meet HHS goals.

WHAT'S BEEN DONE

Identified which existing Medicare models meet criteria for Advanced APMs. CMS reviewed its existing Medicare models with regard to the three criteria defined by MACRA⁴⁰ and identified models, demonstrations, or programs that currently qualify as Advanced APMs for the first performance period.⁴¹ See Figure 5 on the next page.

Established policy for determining Qualifying APM Participants. The final rule established that for the first performance period, clinicians are designated Qualifying APM Participants if they serve 20 percent of their Medicare patients or receive 25 percent of their Part B payments through an Advanced APM. ⁴² In 2016, CMS procured a contractor for APM program analysis whose main responsibility will be to identify clinicians participating in the Advanced APMs and determine which are meeting the threshold to be Qualifying APM Participants during the first performance period.

Figure 5: Overview of Advanced APMs Available in the first QPP Performance Period



Source: OIG analysis of CMS's implementation of the QPP, 2016.

*In Track 1 of the Shared Savings Program, the ACOs share in program savings. Without requiring ACOs to also assume risk for losses, Track 1 does not meet the criteria to be an Advanced APM in the QPP. Because ACOs in Tracks 2 and 3 of the Shared Savings Program are required to assume risks for both savings and losses, Tracks 2 and 3 qualify as Advanced APMs under the QPP.

Awarded contracts for technical assistance to facilitate clinician participation in Advanced APMs. In its final rule, CMS estimated that between 5 and 8 percent of all clinicians billing under Medicare Part B—between 70,000 and 120,000 clinicians—will be Qualifying APM Participants in the Advanced APM track during the first performance period. CMS's goal is to increase participation in subsequent program years by expanding the Advanced APM opportunities available to meet the needs of different types of clinicians. However, this goal will be met only if clinicians are interested in and prepared to participate in Advanced APMs.

To this end, CMS is investing in technical assistance and training opportunities to help clinicians prepare for Advanced APMs. In June 2016, CMS announced a new funding opportunity for Support and Alignment Networks 2.0, which is part of its larger Transforming Clinical Practice Initiative.⁴³ The goal of these networks is to increase the adoption of APMs on a large scale by providing tailored technical assistance, training, and other learning resources to primary care and specialty providers on how to

enhance the quality, efficiency, and coordination of the care they provide. CMS announced that it intended to make up to \$10 million available over the next 3 years to fund these networks. In September 2016, CMS announced that it had awarded two cooperative agreements—one to the American Psychological Association and the other to the Virginia Cardiac Services Quality Initiative.

WHAT'S STILL TO COME

Determining which clinicians are Qualifying APM Participants. In response to the proposed rule, some commenters expressed concern that if clinicians do not know until the end of the performance period whether they meet the threshold to be Qualifying APM Participants, they may also have to prepare for MIPS reporting. Preparing to participate in both QPP tracks—Advanced APMs and MIPS—would be burdensome and could be a disincentive to participate in the QPP.

CMS is planning to provide clinicians with information throughout the year about their likelihood of meeting the Qualifying APM Participant threshold. Specifically, during the first performance period, the contractor for APM program analysis will track which clinicians are providing Part B services through Advanced APMs and periodically estimate whether they are likely to meet the threshold to be Qualifying APM Participants. CMS anticipated that it will make three Qualifying APM Participant determinations—Quarter 1, Quarter 2, and Quarter 3—using data available through March 31, through June 30, and through August 31, respectively. CMS plans to share its early estimates of Qualifying APM Participant determinations with clinicians through their individualized QPP Portal accounts.

Increase Advanced APM opportunities. As noted above, there are a limited number of Advanced APM opportunities available during the first QPP performance year. Increasing the availability of Advanced APMs for clinicians is a significant undertaking, and CMS is planning a multiyear expansion effort. CMS staff described a range of options, including (1) modifying some current Medicare models to meet the criteria for Advanced APMs, (2) opening additional rounds of the existing Advanced APMs to new participants, and (3) developing new models. In considering which options to pursue, CMS staff reported that they plan to prioritize models

"For each model, we look at the savings opportunities and the magnitude of how many beneficiaries could be covered as we assess the likelihood of improvements to both cost and quality."

– CMS official

with the highest yield—those that provide the greatest number of opportunities for clinicians to participate. As CMS develops future Advanced APMs, it is also considering models that can meet the needs of specialists. As it seeks to expand Advanced APM options, CMS must also ensure that it meets statutory requirements to test only models that have the potential either to generate savings while maintaining quality, or to improve quality while not increasing spending.⁴⁴

In addition to the Advanced APM models developed by CMS, MACRA established an independent Physician-Focused Payment Model Technical Advisory Committee (PTAC) so that external stakeholders may propose new models for consideration. In 2016, the PTAC developed criteria for reviewing proposed models and making recommendations to the Secretary of Health and Human Services as to which models should be adopted. It anticipated that the submission of proposals would begin in December 2016. CMS staff reported ongoing communications with the PTAC, including providing it with requested resources on CMS's approach to planning Advanced APMs and developing savings estimates.

Increase clinician participation in Advanced APMs over time. In addition to increasing the number and variety of Advanced APM opportunities, CMS seeks to increase clinician adoption of these new care delivery models. Along with the steps that CMS is already planning—such as prioritizing high-yield models and funding technical assistance designed to facilitate clinician participation—CMS must monitor the interplay of MIPS and Advanced APM financial rewards to identify any unintended consequences that would affect clinician participation. Specifically, some policy analysts have speculated that there could be disincentives to participate in the Advanced APM track because in the early years of the program, high performers might gain more financially under the MIPS track. ⁴⁶ As CMS gains more experience with clinician participation in the two QPP tracks and how payment adjustments are distributed, it will need to identify and address any competing incentives that would impede the program's ability to meet its goals.

Conclusion

Since MACRA's enactment in April 2015, CMS has made significant progress towards implementing the QPP. During 2016, CMS focused on laying the groundwork for the QPP by fostering clinician acceptance and readiness to participate; adopting integrated business practices; building IT systems; developing MIPS policies; and facilitating participation in Advanced APMs. As the beginning of the first performance year approaches, CMS has finalized key policies, launched an informational website, and awarded a variety of contracts for technical assistance and training. Overall, CMS has worked to address many of the key lessons learned from the initial launch of HealthCare.gov, such as the need for clear leadership; integration of policy and technological work; clear and frequent communication; and flexibility to adapt to new information.

Although many milestones remain to be completed, two aspects of implementation merit particular attention in 2017, because they will be crucial in determining the QPP's success: (1) providing sufficient guidance and technical assistance to ensure that clinicians are ready to participate in the QPP, and (2) developing backend IT systems.

First, continued engagement with clinicians is essential to CMS's efforts to ensure that providers have the information and tools they need to meet the challenges of the QPP. CMS's technical assistance and training efforts must quickly be ramped up to full-scale, and the extensive subregulatory guidance promised in the final rule should be issued, to help Medicare clinicians:

- understand the QPP;
- take advantage of the transition year to familiarize themselves with the program;
- select the QPP participation option that best suits their practice; and
- use QPP performance feedback to improve their care delivery to Medicare beneficiaries.

Second, it is crucial that the backend IT systems are ready to securely and reliably support the QPP. Some key functions must be operational in 2017, with others required in 2018. These systems are necessary so that:

- clinicians can report QPP data to CMS accurately and with minimized burden;
- CMS can validate the data it receives and calculate MIPS Final Scores;
- CMS can provide useful performance feedback information to clinicians; and
- CMS can accurately adjust Part B payment based on clinicians' QPP participation.

CMS has built a promising foundation for managing the initial transition to the QPP. However, its ability to ensure clinicians' readiness to participate in the program and develop the necessary IT infrastructure will help determine whether the QPP succeeds in its goal to promote quality and value of care. OIG will continue to monitor CMS's progress in developing and operating the QPP and will conduct additional reviews as appropriate.

AGENCY COMMENTS AND OIG RESPONSE

In its comments on OIG's draft report, CMS reiterated its goal of providing patient-centered, high-quality care for Medicare beneficiaries. CMS described its prior and ongoing activities to engage clinicians through listening tours and other outreach and noted that a variety of technical assistance efforts are underway. CMS also said that it recognized the particular challenges faced by small and rural practices and described its efforts to support such practices. Regarding the two vulnerabilities

that OIG identified, CMS stated that as it implements the QPP, it is committed to continuing to engage with clinicians and provide them with assistance, and to optimize backend IT systems support. (See Appendix F for the full text of CMS's comments.)

Appendix A

OVERVIEW OF THE MIPS FINAL SCORE FOR PERFORMANCE YEAR 1, 2017

In the final rule, CMS finalized the following categories of MIPS measures and the proportion that each will contribute to the final score.⁴⁷

Quality:

60% in Year 1

- Measures: Clinicians must report on six measures or a defined set of specialty measures, which they may select from a variety of approved measures based on what is most applicable to their practice
- Reporting: Clinicians may use a variety of options, including claims data, electronic health records, and qualified clinical data registries
- Predecessor program: Physician Quality Reporting System (PQRS)

Cost:

0% in Year 1

- Measures: Two overall cost measures: (1) per-capita costs for all attributed beneficiaries and (2) Medicare spending per beneficiary, as well as 10 episode-based cost measures, as applicable to the clinician
- <u>Reporting</u>: Via claims data, so there are no additional reporting requirements for clinicians
- Predecessor program: Value-Based Modifier (VBM) Program

Advancing Care Information:

25% in Year 1

- <u>Measures</u>: Five required measures with additional optional measures, focusing on interoperability and the use of electronic health record technology to support healthcare delivery
- <u>Reporting</u>: Clinicians may use a variety of options, including electronic health records and qualified clinical data registries
- Predecessor program: Medicare physician EHR incentive program

Improvement Activities:

15% in Year 1

- Improvement activities are designed to improve health care delivery, including care coordination, beneficiary engagement, population management, and health equity
- CMS will annually publish an inventory list that will designate certain improvement activities as "high" or "medium" activities
- Measures: Most clinicians attest that they completed up to four improvement activities for a minimum of 90 days
- <u>Reporting</u>: Clinicians may use a variety of options, including claims data, electronic health records, and qualified clinical data registries
- Predecessor program: None

Appendix B

QPP TIMELINE: PERFORMANCE PERIODS, FEEDBACK, SCORING, AND PAYMENT ADJUSTMENT

The QPP will operate on an overlapping 3-year program cycle. The figure below shows the first three program cycles, which will begin in 2017, 2018, and 2019, respectively. Subject to future rulemaking, program cycle four will begin in 2020, program cycle five in 2021, and so on.

Program Cycle 1

2017

January – December:

MIPS performance period

January - August:

Advanced APM performance period

July:

Clinicians receive feedback reports

2018

March 31:

Clinicians send MIPS data to CMS

April – June:

CMS analysis and scoring

2019

January – December:

Payment adjustment period (based on 2017 data)

Program Cycle 2

2018

January – December:

MIPS performance period

January - August:

Advanced APM performance period

July:

Clinicians receive feedback reports

2019

March 31:

Clinicians send MIPS data to CMS

April – June:

CMS analysis and scoring

2019

Program Cycle 3

January – December:

MIPS performance period

January - August:

Advanced APM performance period

July:

Clinicians receive feedback reports

2020

January – December:

Payment adjustment period (based on 2018 data)

2020

March 31:

Clinicians send MIPS data to CMS

April - June:

CMS analysis and scoring

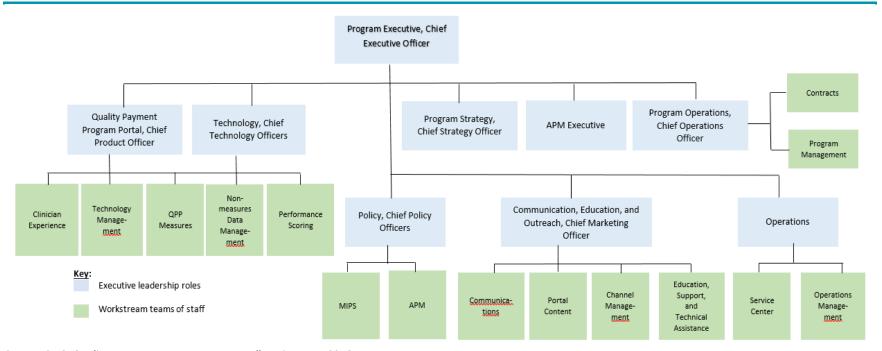
2021

January – December:

Payment adjustment period (based on 2019 data)

Appendix C

QPP EXECUTIVE **L**EADERSHIP **T**EAM — **S**TRUCTURE



Source: CMS, Quality Payment Program Resource Allocation, June 2016.

Appendix D

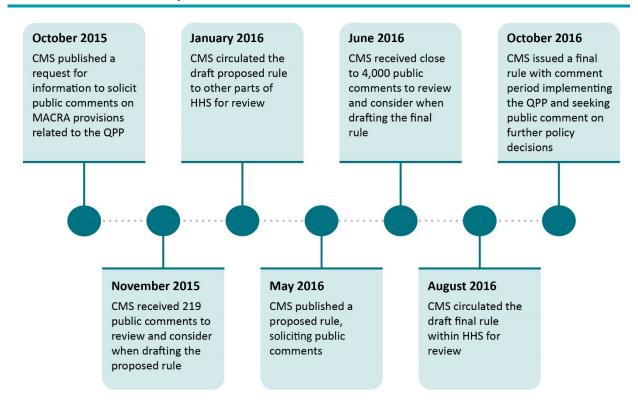
QPP EXECUTIVE LEADERSHIP TEAM – ROLES AND RESPONSIBILITIES

Roles	Responsibilities for the QPP
Chief Executive Officer	Oversees and directs all programmatic functions, including overarching program strategy and implementation; serves as internal and external authority for MACRA.
Chief Strategy Officer	Develops program strategy and measurement plan. Facilitates annual planning.
Chief Operating Officer	Manages program planning and operations, including program infrastructure, processes, human capital, budgets, and contracting. Implements and oversees program governance and reporting.
APM Executive	Leads development and implementation of APMs considering departmental, agency, and industry goals and constraints. Coordinates APM development and implementation closely within/across the organization working with counterparts to align/integrate implementation efforts and resolve challenges and barriers.
Chief Product Officer	Leads product strategy, design, and modification to achieve desired customer experience. Coordinates all product-related functions to produce an integrated customer experience. Leads customer analysis, user research, and product prioritization.
Chief Policy Officers	Lead policy development, coordinating with internal and external parties to achieve legislative requirements and the intent of MACRA. Lead impact analysis and facilitates implementation analysis. Coordinate policy development and implementation closely within/across the organization.
Chief Technology Officers	Develop technology alternatives analysis and target architecture for implementing the policy and achieving the desired customer experience goals across infrastructure, systems, and applications. Determine development approach and standards and oversee development and enhancements.
Chief Marketing Officer	Develops program narrative, branding, messaging, content, and education materials to inform and respond to the needs of the customers and critical audiences. Develops and maintains partnership and channel strategies to engage customers and audiences and provide critical program-feedback loops. Leads content development, review, and publication.

Source: CMS, Quality Payment Program Resource Allocation, June 2016.

Appendix E

KEY MILESTONES IN THE QPP RULEMAKING PROCESS



Appendix F

COMMENTS FROM THE CENTERS FOR MEDICARE & MEDICAID SERVICES



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

DEC - 1 2016

200 Independence Avenue SW Washington, DC 20201

To:

Daniel R. Levinson

Inspector General

From:

Andrew M. Slavitt

Acting Administrator Ohu

Centers for Medicare & Medicaid Services

Subject:

Office of Inspector General (OIG) Draft Report: Early Implementation Review:

CMS' Management of the Quality Payment Program, OEI-12-16-00400

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Department of Health and Human Services Office of Inspector General's (OIG) draft report on CMS' implementation and management of the Quality Payment Program. CMS appreciates the thorough review and documentation of CMS' progress towards implementing the Quality Payment Program and how lessons learned from launching other complex initiatives have been applied to the management of the Quality Payment Program.

CMS has been listening and learning from physicians and other clinicians to build Medicare into a system that delivers better care – where Medicare pays for what works, physicians and other clinicians are supported and patients remain at the center of their care. Part of the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Quality Payment Program aims to create a more modern, patient-centered Medicare program by promoting quality patient care while controlling escalating costs through the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (Advanced APMs).

After issuing a proposed rule for how to implement the new program, we held a listening tour across the country to hear clinicians' thoughts and concerns first-hand about the Quality Payment Program. As CMS engaged directly with clinicians, a common theme in the input received was the need for flexibility, simplicity, and support for small practices. We identified several priorities for the design of the program. First, CMS prioritized focusing on the patient. Clinicians want to focus on delivering the care that is best for their patients, not on reporting or paperwork. Next, CMS prioritized a flexible program where participants can start out gradually and increase involvement over time. CMS also prioritized creating more pathways to participate in Advanced APMs, which CMS has already begun work on. Additionally, CMS developed the program with consideration for small and rural practices, and will provide focused front line assistance to these practices, many of which may need additional tools and training. Lastly, CMS prioritized simplified reporting to the MIPS program by simplifying the reporting requirements for quality measures and improvement activities, and moving to align the advancing care information requirements with several of the improvement activities.

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The Quality Payment Program represents a multi-year journey in which CMS is particularly focused on allowing clinicians to transition at their own pace, continuing to get feedback from the field, providing meaningful support, and improving the program over time. Transforming something of this size is an undertaking CMS is approaching with great care and humility, knowing that it will take several years of listening, learning, and adjusting the Quality Payment Program to ensure it meets its goals.

In October, CMS released the Quality Payment Program final rule with comment period building on this principle of listening and learning from clinicians, which aims to protect small practices, reduce administrative burdens, and further the transformation of the health care system to support healthier people. CMS received more than 4,000 comments on the proposed rule, and over 100,000 people attended CMS' outreach sessions across the country. We recognize that practices are in differing degrees of readiness, and the new program in the final rule creates multiple pathways for participation. These include a variety of options for participating in the MIPS, enabling those clinicians who are just beginning to engage in quality reporting to test the program and avoid a payment reduction. In addition, CMS created an easier pathway for participating in Advanced APMs, which are locally formed physician led approaches like medical homes.

CMS recognizes the importance of small and rural practices and the challenges they may face in participating in quality programs. Small practices deliver the same high-quality care as larger ones, and CMS is committed to providing important support for those physicians and other clinicians, especially for practices in rural areas or areas with high disparities. CMS has taken steps to aid small practices, including: reducing the time and cost to participate, excluding more small practices from the requirement to participate, increasing the availability of Advanced APMs to small practices, allowing practices to begin participation at their own pace, and changing the financial risk qualification for an Advanced APM to be practice-based as an alternative to total Medicare expenditure-based so that more Advanced APMs can be created that are tailored to small practice participation. CMS is also focused on conducting significant technical support and outreach to small practices, both through activities well underway via the Transforming Clinical Practice Initiative and Quality Innovation Network-Quality Improvement Organizations, and through the MACRA-supported technical assistance for small practices that will begin soon.

In conjunction with the release of the Quality Payment Program final rule with comment period, CMS launched a new website, which explains the new program and helps clinicians easily identify the measures and activities most meaningful to their practice or specialty. CMS has adopted an agile IT development methodology to test components of the system during the development process rather than waiting to test until the system is fully built. This approach allows CMS to detect and mitigate issues earlier.

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In keeping with the principle of listening, CMS conducted extensive user testing in the design of the current website to make the information it shares understandable and experience of visiting it meaningful. For example, based on interviews with clinicians, CMS created the Explores Measures tool, which enables clinicians and practice managers to select measures that likely fit their practice, assemble them into a group, and print or save them for reference. We will continue using this approach as additional IT systems are developed to fully implement the Quality Payment Program.

Recently, CMS added a tool to the website to share electronic data that makes it easier for other organizations to retrieve and maintain the Quality Payment Program's measures and enables them to build applications for clinicians and their practices. This new release for the website is the first in a series that will be part of CMS's ongoing efforts to spur the creation of innovative, customizable tools to reduce burden for clinicians, while also supporting high-quality care for patients. There are also resources available where clinicians can get answers to questions about the Quality Payment Program by email and phone.

Overall, we are deeply appreciative to the OIG and other partners, from Congress to practicing clinicians, patient advocates, people with Medicare and their families, and technology companies, who provided input into the launch of the program. As CMS' mission requires us to take on ambitious projects of significant complexity, we continue to be committed to high levels of accountability, execution, and continuous improvement. Overcoming challenges and delivering results in this transparent manner will continue to make the Quality Payment Program better and stronger. CMS is committed to continuing to engage with and provide assistance to clinicians, and to optimize backend IT systems support, as it implements the Quality Payment Program with the overarching goal of advancing patient-centered, high-quality care for the millions of Medicare beneficiaries we serve every day.

Acknowledgments

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Endnotes

- ¹ Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act of 2015 (MACRA), P.L. No. 114-10 (April 16, 2015).
- ² CMS posted the final rule on its public website on October 14, 2016, and it was published in the Federal Register on November 4, 2016. See 81 Fed. Reg. 77008 (Nov. 4, 2016).
- ³ MACRA, P.L. No. 114-10 (April 16, 2015).
- ⁴ 81 Fed. Reg. 77008 (Nov. 4, 2016).
- ⁵ Omnibus Budget Reconciliation Act of 1989, P.L. No. 101-239, § 6102 codified at Social Security Act (SSA) § 1848. The Medicare physician fee schedule is derived using a resource-based relative value scale, which includes three resource components: (1) total physician work, (2) practice expenses, and (3) malpractice expenses. Each component is measured in terms of relative value units (RVUs). The Medicare physician fee schedule payment rates are based on RVUs, adjusted for geography, and multiplied by a national conversion factor to derive dollar amounts.
- ⁶ Section 1848(a)(1) of the Social Security Act established the Medicare physician fee schedule as the basis for Medicare reimbursement for all physician services beginning in January 1992.
- ⁷ SSA § 1848(f).
- ⁸ Annual spending targets were updated each year by applying a growth rate known as the sustainable growth rate (SGR). The SGR formula incorporated four factors: (1) inflation, (2) changes in enrollment in Medicare's fee-for-service program, (3) the estimated 10-year average annual growth rate of real gross domestic product per capita, and (4) the impact of changes in law or regulation. These factors were multiplied to yield an overall rate of growth. To determine the next year's spending target, the previous year's target was increased by the overall rate of growth estimated for the next year.
- ⁹ Congressional Budget Office (CBO), *The Sustainable Growth Rate Formula for Setting Medicare's Physician Payment Rates*, September 2006, p. 5. Accessed at https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/09-07-sgr-brief.pdf on October 13, 2016.
- ¹⁰ CBO, Medicare's Payments to Physicians: The Budgetary Impact of Alternative Policies Relative to CBO's March 2012 Baseline, July 2012. Accessed at https://www.cbo.gov/publication/41512?index=12240 on October 14, 2016.
- ¹¹ Tax Relief and Health Care Act of 2006, P.L. No. 109-432, § 101.
- ¹² Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275 § 131.
- ¹³ Patient Protection and Affordable Care Act, P.L. No. 111-148, § 3002 (March 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (March 30, 2010), collectively referred to as the Affordable Care Act (ACA).
- ¹⁴ ACA, § 3007.
- ¹⁵ American Recovery and Reinvestment Act of 2009, P.L. No. 111-5, § 4101-4103.
- ¹⁶ 42 CFR § 414.90(c) and (e).
- ¹⁷ 42 CFR § 414.1275.
- ¹⁸ 80 Fed. Reg. 62762 (Oct. 16, 2015).
- ¹⁹ MACRA, § 101.
- ²⁰ Clinicians included in the QPP include physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists. MACRA, § 101(c)(1)(C)).
- ²¹ MACRA, § 101(c), SSA § 1848(q)(2)(A).
- ²² MACRA, § 101(c), SSA 1848(q)(6)(F)(i)(I).
- ²³ MACRA, § 101(c), SSA § 1848(q)(6)(F)(iv)(I).
- ²⁴ CMS will use a "low-volume threshold determination period" to identify providers that meet the low-volume threshold and are thus excluded from MIPS reporting and payment adjustment. The low-volume determination period includes two 12-month segments; a provider who meets the threshold during either of the segments is excluded from MIPS. The initial segment spans from the last 4 months of a calendar year 2 years prior to the performance period through the first 8 months of the next calendar year. The second segment spans from the

last 4 months of a calendar year 1 year prior to the performance period through the first 8 months of the performance period in the next calendar year. 81 Fed. Reg. 77008, 77065 (Nov. 4, 2016).

- ²⁵ ACA, §§ 3021 and 3022.
- ²⁶ The Comprehensive End-Stage Renal Dialysis (ESRD) Care Model is designed to identify, test, and evaluate new ways to improve care for beneficiaries with ESRD. The Comprehensive Care for Joint Replacement Model aims to improve care and reduce payment for hip and knee replacements through episode-based payments. The Comprehensive Primary Care Plus program is being implemented in 14 regions where CMS, commercial insurance plans, State Medicaid agencies, and other selected payer partners will align on payment, data sharing, and quality metrics. More information about each APM is available at

https://innovation.cms.gov/initiatives/index.html#views=models.

- ²⁷ An APM entity is "an entity that participates in an APM or payment arrangement with a non-Medicare payer through a direct agreement or through Federal or State law or regulation." See 81 Fed. Reg. 77008 § 414.1305 (Nov. 4, 2016).
- ²⁸ MACRA, § 101(e)(2)).
- ²⁹ 81 Fed. Reg. 28161 (May 9, 2016). Comments on the proposed rule are available via https://www.regulations.gov/docket?D=CMS-2016-0060.
- ³⁰ OIG, *HealthCare.gov: CMS Management of the Federal Marketplace* (OEI-06-14-00350), February 2016. Available at https://oig.hhs.gov/oei/reports/oei-06-14-00350.pdf.
- ³¹ Approved entities include quality improvement organizations, regional extension centers, and regional health collaboratives.
- ³² 81 Fed. Reg. 77008 (Nov. 4, 2016).
- ³³ USDS, *Our Work*. Accessed at https://www.usds.gov/work on November 29, 2016.
- ³⁴ CMS. Agile Development for Merit-based Incentive System (MIPS), Solicitation HHSM-500-2016-RFP-0037, Statement of Objectives. Accessed at
- https://www.fbo.gov/index?s=opportunity&mode=form&id=a1784e8e8067c0b6b648074ccb8d8d31&tab=core&_cview=1 on October 12, 2016.
- ³⁵ A BPA is an ongoing agreement for recurring procurements that streamlines ordering procedures, reduces procurement lead time, and simplifies invoicing and other contractual processes. General Services Administration, *Blanket Purchase Agreements*. Accessed at http://www.gsa.gov/portal/content/199353 on October 3, 2016.
- ³⁶ OIG, Federal Marketplace: Inadequacies in Contract Planning and Procurement (OEI-03-14-00230), January 2015. Available at https://oig.hhs.gov/oei/reports/oei-03-14-00230.pdf.
- ³⁷ CMS, MACRA 101 and Quality Payment Program: Office of Management and Budget Briefing. May 2016.
- ³⁸ While it worked with USDS staff to create the Agile Development BPA for future procurement on other aspects of the QPP Portal, CMS used its existing IT contracts to develop the public-facing website. The QPP website is at https://app.cms.gov/.
- ³⁹ We define "solo or small practice" as a practice with less than ten clinicians.
- ⁴⁰ MACRA established the following criteria for QPP Advanced APMs: (1) require participants to use certified EHR technology; (2) provide payment for covered professional services based on quality measures comparable to those used in the quality performance category of MIPS; and (3) require APM Entities to bear more than a nominal amount of financial risk, or be a Medical Home Model expanded under section 1115A(c) of the Social Security Act. (See MACRA, §101(e)(2)).
- ⁴¹ CMS will publish a final list of the Advanced APM models for 2017 performance period by January 1, 2017. The list of currently available Advanced APMs included in this report was current as of October 28, 2016. In the final rule, CMS indicated that additional models may become available in 2017. CMS is exploring how to modify some APMs, including the Maryland All-Payer Model and the Comprehensive Care for Joint Replacement Model, to meet the criteria for Advanced APMs under the QPP. More information is available at https://gpp.cms.gov/learn/apms.
- ⁴² 42 CFR § 414.1430(a)(1), (3), (b)(1) and (3); 81 Fed. Reg. 77008 (Nov. 4, 2016).
- ⁴³ CMS, CMS-1L1-16-001 Grant Notice: Transforming Clinical Practice Initiative Support and Alignment Networks 2.0 (June 10, 2016). Accessed at http://www.grants.gov/view-opportunity.html?oppId=284529 on September 14, 2016.
- ⁴⁴ ACA, §§ 3021(c).

⁴⁵ The PTAC is composed of 11 appointees, and the HHS Assistant Secretary for Planning and Evaluation provides it with operational support. MACRA, § 101(e)(1), SSA § 1868(c).

⁴⁶ Patel, K.; Adler, L.; Darling, M.; Ginsburg, P.; Lieberman, S.M.; *How the Money Flows Under MACRA*. July 12, 2016. Accessed at https://www.brookings.edu/research/how-the-money-flows-under-macra/ on July 20, 2016. ⁴⁷ 81 Fed. Reg. 77008 (Nov. 4, 2016).