Collaboration of the Health Information Technology Policy and Standards Committees

Final Summary of the December 6, 2016, Virtual Joint Meeting

KEY TOPICS

Call to Order

Michelle Consolazio, U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), welcomed participants to the Health Information Technology Policy Committee (HITPC) and Health Information Technology Standards Committee (HITSC) joint meeting. She reminded the group that it was a Federal Advisory Committee Act (FACA) meeting being conducted with an opportunity for public comment (limited to 3 minutes per person) and that a transcript will be posted on the ONC website. She called the roll and told members to identify themselves for the transcript before speaking.

Remarks

P. Jon White, ONC, reminded the members that ONC exists under statute. Career employees will ensure a smooth transition to the incoming administration. He referred to pending legislation—the 21st Century Cures Act, which when enacted and signed will require a transition to a new advisory committee structure. White assured the members that he values the work of the Health IT FACAs and that the expected transition will be transparent. He thanked the members for their work.

Review of Agenda

HITPC Co-chairperson Kathleen Blake noted the importance of both of the reports on the agenda. The agenda was distributed in advance of the meeting. She asked for a motion to approve the summary of the October 5, 2016, meeting as circulated with the meeting materials. A motion was made and seconded. The summary was approved unanimously by voice vote.

> **Action item #1: The summary of the October 5, 2016, joint meeting was approved unanimously by voice vote.**

Quality Payment Program Review

HITPC Co-chairperson Paul Tang thanked the ONC staff, in particular Consolazio, for their excellent work. Kate Goodrich, Centers for Medicare and Medicaid Services (CMS), described the Merit-based Incentive Payment System (MIPS) and the Advanced Alternate Payment Models (APMs), explaining the rationale for the changes from the proposed rule version. MIPS moves Medicare Part B clinicians to a performance-based payment system and:

- Provides clinicians with flexibility to choose the activities and measures that are most meaningful to their practice
- Reporting standards align with Advanced APMs wherever possible

Medicare Part B clinicians billing more than $30,000 a year and providing care for more than 100 Medicare patients a year are eligible. Non-patient facing clinicians are eligible to participate in MIPS as long as they exceed the low-volume threshold, are not newly enrolled, and are not a Qualifying APM Participant (QP) or Partial QP that elects not to report data to MIPS. The non-patient facing MIPS-eligible clinician threshold for individual MIPS-eligible clinicians is fewer than 100 patient facing encounters in a

designated period. A group is non-patient facing if fewer than 75% of National Provider Identifiers (NPIs) billing under the group's Tax ID Number (TIN) during a performance period are labeled as non-patient facing. There are more flexible reporting requirements for non-patient facing clinicians. Not participating in the Quality Payment Program (QPP) for the transition year will result in a negative 4% payment adjustment. Goodrich's slides showed that some practices may choose to participate in an Advanced APM in 2017, and there are specific requirements for those who choose a test pace, partial year, or a full year. She went on to describe the minimum data required to qualify for each. Since MIPS payment adjustment is based on data submitted, clinicians should pick what is best for their practice. Full year participation is the best way to get the maximum adjustment, provides the most measures to choose from, and prepares eligibles for the future of the program. An individual may participate under an NPI number and TIN where they reassign benefits. Group participation is available if two or more NPIs have reassigned their billing rights to a single TIN or as a MIPS APM entity. MIPS payments are weighted by measures of quality, cost, improvement activities, and advancing care information, and these vary by transition year, test pace, full, or partial year. Goodrich went through the details of each as shown on the slides.

Goodrich continued. Section 106(b)(2) of the Medicare Access and CHIP Reauthorization Act (MACRA) requires eligible providers to demonstrate that they have not knowingly and willfully limited or restricted the interoperability of certified EHR technology. The Centers for Medicare & Medicaid Services (CMS) finalized a required attestation for health care providers using certified EHR technology in the EHR incentive programs and MIPS to support the prevention of information blocking. To prevent information blocking, a provider is required to attest that it:

- Did not knowingly and willfully take action to limit or restrict the interoperability of certified EHR technology
- Responded to requests to retrieve or exchange information—including requests from patients and other health care providers regardless of the requestor's affiliation or technology
- Implemented appropriate standards and processes to ensure that its certified EHR technology was connected in accordance with applicable law and standards, allowed patients timely access to their electronic health information; and supported exchange of electronic health information with other health care providers.

ONC has required surveillance of certified health IT since 2011 and has recently expanded these programs through the Enhanced Oversight and Authority (EOA) Final Rule to include a stronger focus on ensuring that health IT products and capabilities continue to perform as expected when they are implemented and used. ONC direct review and ONC-Authorized Certification Body (ONC-ACB) surveillance of health IT provides confidence that technology meets federal standards and possesses the capabilities that health care providers need to improve patient care and meet program requirements. As it relates to ONC direct review, the attestation is required. As it relates to ONC-ACB surveillance, the attestation is optional. Goodrich moved on to slides describing how APMs can apply to a specific condition, care episode or population, and may offer significant opportunities for eligible clinicians who are not ready to participate in Advanced APMs.

For the 2017 performance year, the models are: the comprehensive end stage renal disease care model, comprehensive primary care plus, shared savings program tracks 2 and 3, next generation accountable care organization model, and oncology care model. The list of Advanced APMs is posted at QPP.CMS.GOV and will be updated with new announcements on an ad hoc basis. Benefits of participating in an Advanced APM as a QPP are exclusion from MIPS, a 5% lump sum bonus, and a higher physician fee schedule update starting in 2026.

In order to assist small practices to participate in the QPP, CMS is:

- Reducing the time and cost to participate
- Providing an on-ramp to participating through Pick Your Pace
- Increasing the opportunities to participate in Advanced APMs
- Including a practice-based option for participation in Advanced APMs as an alternative to total cost-based
- Conducting technical support and outreach to small practices through the forthcoming QPP Small, Rural and Underserved Support (QPP-SURS) as well as through the Transforming Clinical Practice Initiative

In addition, small, rural and Health Professional Shortage Areas exceptions were established that:

- Set a low-volume threshold of less than or equal to $30,000 in Medicare Part B allowed charges or less than or equal to 100 Medicare patients.
- Reduced requirements for improvement activities performance category to one high-weighted activity or two medium-weighted activities.
- Increased ability for clinicians practicing at Critical Access Hospitals, Rural Health Clinics, and Federally Qualified Health Centers to qualify as a QP.

CMS has several organizations on the ground to help clinicians who are eligible for the QPP:

- Transforming Clinical Practice Initiative (TCPI): Designed to support more than 140,000 clinician practices over the next 4 years in sharing, adapting, and further developing their comprehensive quality improvement strategies.
- Quality Innovation Network (QIN)-Quality Improvement Organizations (QIOs): Includes 14 QIN-QIOs and promotes data-driven initiatives that increase patient safety, make communities healthier, better coordinate post-hospital care, and improve clinical quality.
- The Innovation Center's Learning Systems provides specialized information on successful Advanced APM participation.

Goodrich concluded her 51 slides by reminding the members to submit comments referring to file code CMS-5517-FC by December 19, 2016. The final rule with comment includes changes not reviewed in this presentation. Presentation feedback is not considered formal comments on the rule.

Q&A

Kevin Johnson asked whether any consideration has been given to aligning the MIPS improvement activities with Medical Specialty Board Maintenance of Certification activities (Performance in Practice). Goodrich said that CMS is working with specialty boards and registries on abstraction and reporting of EHR data and is open to feedback from members for doing this in future years.

Saying that he represents practicing physicians, Eric Rose wondered what CMS is doing regarding the burden of reporting and data entry during encounters, which creates risks for clinician distraction and patient dissatisfaction. Goodrich acknowledged the validity of the burden and distraction issue, which, she indicated, goes beyond QPP. CMS reduced the requirements for advancing care for the first year. CMS staff are thinking about measures that are important to clinicians and patients. CMS announced an effort to reduce documentation, which is just getting underway. Rose concluded that CMS has no real

plan to assess and mitigate the burden. According to Goodrich, CMS staff are open to advice from the committees.

Leslie Kelly Hall acknowledged her confusion with having both a requirement and a bonus for using certified technology. Goodrich explained that for the advancing care category, a provider must use certified technology. Under the improvement category, there are 18 optional activities for points that cross over to advancing care. When the providers can attest, they will get a bonus. Advanced APM requires certified technology. MACRA does not change the previous requirements for the use of certified technology.

Rich Elmore asked about the role of patient safety organizations (PSO). Goodrich indicated that reports to PSOs are not currently included in improving care activities. CMS issues an annual call for suggestions for safety activities, and the public is invited to make suggestions.

Kelly Hall asked about the incorporation of cost information. Goodrich responded that an organization is working to make information about the price of drugs available to the patient at the point of care. CMS would like to find a way to incentivize the use of this information.

Blake inquired about the extent of progress with the Core Quality Measures Collaborative, which seeks to harmonize federal and private payer requirements, thereby reducing the burden of reporting. Goodrich said that the collaborative works to obtain consensus about measures. Most of the agreed-upon measures have been incorporated into the regulations. About 80% of payers agree on the core measures. Clinicians can select core measure sets. MACRA calls out the goal of coordination with private payers.

Enhanced Oversight and Accountability Review Final Rule

Elise Anthony, ONC, said that the Enhanced Oversight and Accountability Program:

- Establishes a regulatory framework for ONC to directly review already certified health IT products
- Increases ONC oversight of health IT testing bodies
- Increases transparency and accountability by making identifiable surveillance results of certified health IT publicly available

The program does not create new certification criteria requirements for health IT developers not under direct review or new certification health IT requirements for providers; establish a means for ONC to directly test and certify health IT (ONC-Authorized Certification Bodies (ACB) will continue to test and certify); or establish regular or routine auditing of certified health IT by ONC.

The ONC direct review will be independent of (and may be in addition to) ONC-ACB' surveillance and other functions under the program, and will focus on capabilities and aspects of health IT that are certified under the program (i.e., "certified capabilities"), taking into consideration other relevant functionalities or products to the extent necessary to determine whether certified health IT is functioning in a manner consistent with requirements. The focus will be on circumstances involving potential risks to public health or safety or practical challenges that may prevent ONC-ACBs from carrying out their surveillance responsibilities. ONC may initiate direct review if it has a reasonable belief that certified health IT may not conform to requirements because the certified health IT may be causing or contributing to conditions that present a serious risk to public health or safety. In that case, ONC staff will consider:

- The potential nature, severity, and extent of the suspected conditions
- The need for an immediate or coordinated government response

- If applicable, information that calls into question the validity of the health IT's certification or maintenance thereof under the program

ONC may initiate direct review if it has a reasonable belief that certified health IT may not conform to program requirements and the suspected non-conformity presents issues that may:

- Require access to confidential or other information that is unavailable to an ONC-ACB
- Require concurrent or overlapping reviews by multiple ONC-ACBs
- Exceed an ONC-ACB's resources or expertise

Mike Lipinski, ONC, explained the process of reviews. ONC may issue a Notice of Potential Non-Conformity to which the developer must respond to ONC and/or a third-party acting on behalf of ONC by (1) cooperating, (2) providing access to the certified health IT under review, and (3) providing a written explanation, within 30 days, unless adjusted by ONC, addressing the potential non-conformity.

If there is an actual non-conformity with the certified health IT, ONC will issue a Notice of Non-Conformity to which the developer must respond in the same fashion as for a Notice of Potential Non-Conformity and must submit a proposed corrective action plan (CAP). The CAP is intended to allow ONC to work with developers to address issues that arise. CAPs require health IT developers to:

- Notify all potentially affected customers of the non-conformity and plan for resolution.
- Attest and provide documentation that the non-conformity and all issues were resolved in the specified timeframe.
- Explain, and agree to execute, the steps that will prevent the non-conformity from re-occurring.

The direct review process includes opportunities for developers to respond to ONC concerns and to appeal suspension and termination determinations made by ONC. Developers are required to notify all potentially affected customers of the non-conformity and the plan for a resolution as part of CAPs that may result from direct reviews. Developers must notify customers when the certification of their health IT is suspended or terminated. ONC will also post the information on the ONC Certified Health IT Products List.

ONC will coordinate with other HHS programs, such as the Advancing Care Information/Medicare and Medicaid Electronic Health Record Incentive Programs, to identify and make available appropriate remedies to users of terminated certified health IT. Suspension of certified health IT is limited to when ONC has a reasonable belief that the certified health IT may present a serious risk to public health or safety. ONC would consider the nature, extent, and severity of the risk and the conditions giving rise to it, in light of the information available to ONC at the time. Separately, ONC could conclude that certified health IT poses a serious risk to public health or safety were it aware of information calling into question the validity of the certification. Then, ONC would declare "proposed termination," which calls on ONC to propose to terminate a certification issued to a Complete EHR or Health IT Module before an actual termination can occur. This additional step gives developers opportunities to correct non-conformities and work with and engage with ONC during direct review. There is a two-step process for a developer to file a statement of intent to appeal and then filing the appeal and supporting documentation:

- Statement of intent to appeal must be filed within 10 days of receipt of the notice of suspension or notice of termination
- Appeal, including all supporting documentation, must be filed within 30 days of the filing of the intent to appeal

Any ONC written statement must be provided to the health IT developer within 15 days of the health IT developer's filing of an intent to appeal. A certification ban would prohibit the certification of health IT,

unless it serves to correct the non-conformity. This may incentivize a health IT developer to correct non-conformities and remedy the situation for affected customers.

There is a process for developers to meet the requirements for lifting a certification ban. ONC makes the determinations regarding the lifting of a certification ban in all circumstances. Health IT developers must demonstrate to ONC's satisfaction that all non-conformities have been addressed, and the correction must be made available for all affected customers with appropriate remediation. Appropriate remediation can be achieved through various means (e.g., making a replacement version available, obtaining a customer release, or obtaining an alternative health IT developer's certified product).

Moving to ONC-Authorized Testing Laboratories (ATL), Lipinski explained that the program also establishes regulatory processes for ONC to have more direct oversight of testing labs under the program. These processes are similar to the ONC-ACB processes. One provision enables ONC to oversee and address testing and certification performance issues throughout the entire continuum of the program by authorizing testing labs as ONC-ATLs. However, it does not require labs applying for ONC-ATL status to obtain additional accreditation beyond National Voluntary Laboratory Accreditation Program accreditation for health IT testing. Requirements for retaining ONC-ATL status and the means for ONC to suspend and revoke ONC-ATL status are specified under the program. ONC-ACBs are required to make identifiable surveillance results publicly available on the web-based Certified Health IT Product List (CHPL) on a quarterly basis. The information will include:

- Names of health IT developers
- Names of products and versions
- Certification criteria and program requirements surveilled
- Identification of the type of surveillance (i.e., reactive and randomized)
- Dates of surveillance was initiated and completed
- Number of sites that were used in randomized surveillance
- Results of surveillance

Results will first be posted no later than early April 2017.

Q&A

In response to questions from Tang, Lipinski said that in a situation determined to present a serious risk to public health and safety, ONC could issue an immediate suspension, which the developer can appeal. This process could move quickly. If suspension is upheld, it would remain until ONC determines otherwise. A developer can appeal suspension and termination only, not the notices. The rule is not related to any recommended or future health IT safety center that may be put in place. Complaints can be submitted in various ways. Developers often self-report. Developers are expected to maintain a log of complaint received.

Josh Mandel asked about the sharing of results pertaining to standards conformance problems. Lipinski said that such issues would be described in the CAP. Lipinski said that he was uncertain as to the level of detail in the CAP. Mandel emphasized that this information is essential to standards development. Lipinski offered to seek additional information. HITSC Co-chairperson Arien Malec observed that Mandel's comment pertained to improving interoperability. But the review and accountability process is probably the wrong process to apply to the problem. Anthony said that the focus is not on de-certification, rather the goal is improvement of technology by working with the developer. Mandel suggested that, nevertheless, by-products of the process may be useful in standards development.

Gayle Harrell inquired about the impact on the purchaser of a certified product if it is later terminated. Anthony said that ONC will work with CMS on how to address a de-certified product. CMS could issue a waiver to the impacted providers. The final rule was reviewed by CMS and other HHS agencies. Harrell wondered whether, in the case of suspensions or terminations, ONC would investigate the extent to which the certifying body was performing as expected. What is the process for looking back at the certification bodies when there is a question about the validity of the original certification? Lipinski said that the rule includes processes and mechanisms, including termination, for addressing any malfeasance. However, in the 6 years of the certification program, no such concerns have been identified, and none are expected.

Kelly Hall inquired about the process for a patient to participate in reporting safety issues and challenging certification. Anthony said that there is a web interface for submitting reports on problems with technology. (Health IT-related concerns or complaints can be shared through the ONC-established complaint process at: healthit.gov/healthitcomplaints.) To distinguish the technology from problems with implementation, ONC has set up a case-by-case procedure; prior to initiating a review, staff will investigate to differentiate whether the problem is due to implementation by the provider. Lipinski added that if there is a problem of implementation beyond the developer's control, it falls outside of the rule. The scope of the rule is limited to certification.

Public Comment

Anthony announced that ONC is convening the Public Health Task Force. Its first assignment will be to advise on standards related to capturing pregnancy status in EHRs, as well as related lab orders and reports. This is a concern that came to light in designing a response to Zika and the all-hazards approach to surveillance. Anthony reminded the members that Zika-related efforts were reported on at the October meeting. Members who are interested in volunteering for the task force can email Consolazio. Members of the public who wish to volunteer for the task force may do so via the FACA website.

Next Meeting: An in-person meeting is scheduled for January 10, 2017.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the October 5, 2016, joint meeting was approved unanimously by voice vote.

Meeting Materials

- Agenda
- Summary of the October 5, 2016, joint meeting
- Presentations and reports slides