

Via Electronic Submission to: http://www.regulations.gov

June 27, 2016

Molly MacHarris, MIPS
James P. Sharp, APMs
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5517-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-5517-P: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Ms. MacHarris and Mr. Sharp:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments for the proposed rule CMS-5517-P: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models.

The Collaborative and its member organizations are supportive of continued certification criteria and standards for health IT and EHR. The Collaborative has been involved with the ONC and the Center for Medicaid and Medicare Services since the early development of these standards and criteria as they apply to the Meaningful Use EHR Incentive Program and their effect on non-eligible pharmacist health care providers.

Although pharmacists are ineligible for EHR incentives and MIPS at this time, pharmacists provide patient-centered care and services to Medicaid and Medicare, and they are part of many integrated health care teams comprising eligible professionals (EPs), eligible hospitals, critical access hospitals (CAHs), and what will now be the new eligible clinicians. The exchange of information through interoperable health IT and certified EHR is essential to pharmacists.

The following are our comments (page numbers correspond to the PDF version).

Expand the Definition of a MIPS Eligible Clinician to Include Pharmacists (page 48)

The Collaborative requests that pharmacists be made eligible clinicians for the MIPS program at the beginning of the third year of MIPS and that they be included in the proposed list of expanded eligible clinicians currently under consideration for this proposed rule. We note that the proposed rule and recent webinars conducted by the CMS state that providers such as dieticians, nutritionists, physical therapists, speech language pathologists, audiologists, and others are on the expanded list to be eligible clinicians starting in the third year of MIPS. The CMS also states in the proposed rule that it will be expanding the list of eligible clinicians, starting with the aforementioned groups in the third year.

The Collaborative and pharmacists have been requesting to be made eligible professionals (EPs) since the beginning of the Meaningful Use EHR Incentive program, including the Collaborative making this request in its most recent RFI comments regarding the implementation of MIPS submitted to the CMS on November 17, 2015, as well as comments submitted for the MACRA RFI on June 3, 2016. Pharmacists are still omitted from consideration for MIPS eligible clinicians.

Under section 1848(q)(1)(9)(C)(u) and (v) of MACRA, the CMS not only has the authority, but it now has the opportunity to correct this omission and add pharmacists as eligible clinicians for MIPS under this current rulemaking, and it does not need to wait for a future rulemaking to do this. We also ask that CMS respond to the following questions: What was the rationale for not including pharmacists on this initial list expanding the definition of MIPS eligible clinician? Are there criteria for determining who will be a MIPS eligible clinician? If yes, what are those criteria? Are pharmacists, who are clinicians, viewed differently?

As recognized patient-centered, health care providers and health IT users, pharmacists play an integral role in bringing value to the health care system by providing treatments, care, and services to patients, which improve quality outcomes, reduce or eliminate additional hospital stays through medication therapy management (MTM), comprehensive medication management, medication reconciliation, and help reduce overall health care costs. In some settings, pharmacists are first-line-of-care providers.

Pharmacists are the most readily accessible health care professionals, and they are in a unique position in the health care continuum to assist in improving quality in all EHR quality measure domains, as well as improving patient outcomes. Many of the quality measures currently required by the CMS, as well as the announced HHS goals for fee-for-services in Medicare, focus on medication use and are influenced by pharmacists. Some examples of the patient-centered services provided by pharmacists, as they relate to the CMS quality measures

and MIPS, include safe and appropriate medication use; medication adherence (i.e., avoiding high-risk drugs for the elderly); medication therapy management; comprehensive medication management; medication reconciliation; wellness and prevention; chronic disease management programs; and complex case management related to multiple medications with complex medication dosing regimens (i.e., comprehensive medication management as referred to in the ongoing Centers form Medicare and Medicaid Innovation (CMMI) Center's Comprehensive Primary Care (CPC) and CPC plus Alternative Payment Models).

The literature is replete with research studies demonstrating the value of pharmacist patient care services. In this regard, a randomized study published in June 21, 2016, *Journal of the American College of Cardiology* found that after three months, patients at high risk for future heart disease who received intensive medication services from community pharmacists had a 21 percent lower risk of future heart events when compared with those who received usual care. The benefit was attributed to better control of elevated blood pressure and cholesterol, as well as greater smoking cessation.

Surveillance and Oversight of Certified Health IT (pages 38-40; prevention of information blocking, pages 719, 766-768)

The Collaborative supports surveillance and oversight of certified health IT as proposed, including ONC and ONC-ACBs being granted access to observe the performance of production systems of EPs, eligible clinicians, eligible hospitals, and CAHs and revising the definition of meaningful EHR user at §495.4 to require EPs, eligible hospitals, and CAHs to attest the cooperation with certain authorized health IT surveillance and direct review activities.

The Collaborative also supports requiring an eligible clinician, EP, eligible hospital, and CAH to demonstrate and attest that it did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of the certified EHR technology via a three-part attestation.

With regard to information blocking specifically, the Collaborative supports Health IT Now's recommendation that information error blocking reporting should be built into the certification requirement to automatically report if the system is unable to generate a report to another system or process a request from another system. Building this into the certification requirement will help address concerns about information blocking and indicate where it may be occurring and by whom.

Pharmacists are frequently blocked from the multi-directional exchange of relevant clinical information, which is critical to maximize the benefit of coordinated team-based care. Enabling pharmacists access to relevant patient information through interoperable health IT, particularly bidirectional communication, and certified EHRs is essential for improving patient care and helping practitioners deliver effective care. Implementing the proposed rule without

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Resource Category: Evidence of Value of Pharmacists' Patient Care Services, Joint Commission of Pharmacy Practitioners, accessed June 22, 2016, http://jcpp.net/resourcecat/evidence-of-value/

addressing pharmacists' need for and reporting of information limits the integration of pharmacists into health care teams, fails to utilize pharmacists' expertise and experience, and would be inconsistent with the principles of value-based coordinated care models that underpin the proposed rule.

What appears to be missing; however, are requirements for health IT vendors in this area. We note that there are no vendor/developer requirements discussed in the proposed rulemaking, including those pertaining to information blocking. The Collaborative suggests that the CMS review these areas to ensure that those developing these systems demonstrate they are not limiting or restricting compatibility or interoperability of certified EHR technology.

Telehealth (pages 55)

The Collaborative supports the proposed inclusion of telehealth services in the definition of patient-facing encounters.

Proposed Data Submission and Use of CEHRT (pages 82-87)

The Collaborative is concerned that the CMS is not specifically requiring the use of CEHRT for data submission in all areas of MIPS but rather is proposing to "encourage MIPS eligible clinicians to report on applicable measures...through the use of CEHRT and QCDRs." CMS further states, "We have multiple policies to encourage the usage of QCDRs and CEHRT...and are promoting the use of CEHRT by awarding bonus points in the quality scoring section for measures...." This section also appears to be inconsistent with other proposed requirements that specifically state required use of CEHRT (e.g., Advancing care information performance category).

The Collaborative believes that the use of CEHRT should be required in all areas of the MIPS program and should be consistent with the definition of Meaningful EHR User for MIPS (page 699), which requires the use of CEHRT. This definition states that a meaningful user is "a MIPS eligible clinician who possesses CEHRT and uses the functionality of CEHRT...."

After the many years of developing and advancing the stages of the Meaningful Use EHR Incentive programs, the use of CEHRT is required to participate in these programs. This should be carried over to MIPS and the merging of the three programs. Requiring the use of CEHRT is also an important component for ensuring successful interoperability for those systems used to exchange information and for those systems to use information that has been exchanged. Interoperability is vitally important to pharmacists who may be submitting data concerning patients of MIPS eligible clinicians for whom pharmacists provide patient-centered services, even though pharmacists are not currently eligible clinicians under MIPS. This is also a very valid reason for making pharmacists eligible clinicians for the MIPS program.

Advancing Care Information Performance Category (pages 82-95, 187-192, and 719)

The Collaborative supports the components in the advancing care information performance category, particularly those

- focusing on three measures: patient electronic access, coordination of care through patient engagement, and health information exchange;
- aligning the performance period for one full calendar year;
- removing the separate 90-day performance period;
- requiring the use of technology certified to the 2015 Edition to meet the objectives and measures, beginning in 2018; and
- supporting health information exchange and the prevention of information blocking by requiring MIPS eligible clinicians to attest they did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of CEHRT.

The Collaborative also supports the proposed objectives and measures for this performance category, which includes:

- Protect patient health information; Measure: Security Risk Analysis;
- Electronic prescribing;
- Use of clinical decision support (CDS);
- Use of computer provider order entry (CPOE);
- Patient electronic access;
- Coordination of care through patient engagement;
- Health information exchange; and
- Public health and clinical data registry reporting.

MACRA Changes (page 188)

The Collaborative supports the inclusion of the meaningful use of certified EHR technology as a performance category under MIPS and maintaining the current structure of the Medicare EHR Incentive program.

Patient Safety (page 122)

The Collaborative supports measures that reflect the safe delivery of clinical services in all health care settings, especially those designed to reduce risk in the delivery of health (e.g., adverse events; complications from medication use).

Person and Caregiver-Centered Experience and Outcomes (page 122)

The Collaborative supports measures that reflect the potential to improve patient-centered care and quality of care delivered to patients. As noted previously, pharmacists provide patient-centered care and services. Under Medicare, for example, pharmacists are explicitly listed as a practitioner that may provide medication reconciliation post-discharge.

However, by not being included in the definition of MIPS eligible clinician, the proposed rule essentially limits the pharmacist's potential contribution to the care team, failing to utilize the pharmacist's expertise and skillset.

Communication and Care Coordination (page 123)

The Collaborative supports measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve patient and care team communication. For pharmacists, ensuring interoperability and bidirectional communication in this area are extremely critical.

Effective Clinical Care (page 123)

The Collaborative supports measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines or measures of patient-centered outcomes of disease states. As noted previously, pharmacists provide patient-centered care and services; included among those services is medication-related disease state management. Moreover, pharmacists will likely be key contributors to educating physicians about MACRA, MIPS, and how collaboration can achieve optimal patient outcomes, and thus their payment for performance.

Community/Population Health (page 123)

The Collaborative supports measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. As noted previously, pharmacists provide patient-centered care and services and are on the front line of preventive health care. In the community setting, many pharmacists offer and promote health screenings, such as immunization management, blood glucose and blood pressure evaluations to assess a patient's diabetes and hypertension risks; cholesterol tests; as well as smoking cessation programs, to name a few. These pharmacists' patient-centered services bring value, including helping to offset some aspects of limited access to preventive services in certain regions (e.g., rural areas) and certain populations.

Efficiency and Cost Reduction (page 123)

The Collaborative supports measures that reflect efforts to lower costs and significantly improve medication-related outcomes and reduce errors.

MACRA Changes (pages 188-192)

The Collaborative supports developing requirements for the advancing care information performance category based on the objectives of the HITECH Act and

maintaining all of the objectives and measures finalized in the 2015 EHR Incentive programs final rule.

Advancing the Goals of HITECH Act in MIPS (pages 192-195)

The Collaborative supports improving the use of EHR and health care quality by advancing the goals of the HITECH Act as proposed by the objectives and measures in the advancing care information performance category, particularly three specific objectives: patient electronic access, coordination of care through patient engagement, and health information exchange which are essential for leveraging certified EHR technology and health IT to improve care and the overall health of patients. We also recommend advancing the goals of the HITECH Act in MIPS by considering options that would make additional funds available to improve care coordination, consistent with the intent the CMS discussed in State Medicaid Directive 16-003 when the agency expanded the 90 percent HITECH funding match to eligible Medicaid providers, which often includes pharmacists.

The Collaborative supports the adoption and use of certified EHR technology by incorporating this technology into the other MIPS performance categories. Again, the Collaborative believes the use of certified EHR technology should be a requirement for MIPS participation rather than encouraging participants to use this technology.

With regard to the proposed concept of a "holistic approach" to health IT, similar to the concept of outcomes measures in the quality performance category, the Collaborative would support such an approach that may allow the CMS to directly link health IT adoption and use to patient outcomes into a more patient-focused health IT program, understanding that the technology and measurement for this type of program is not available at this time. Although the CMS is asking for comments on what this type of measurement would look like, we believe the best approach at this stage would be for the CMS to provide more details as to its vision for how it perceives this type of measurement. We believe that would provide others with a better and clearer understanding of the CMS's thinking so as to respond with more definitive comments and proposals

Certified Health IT (page 199-201)

The Collaborative supports the proposed use of technology certified to the 2015 Edition to meet the objectives and measures specified for the advancing care information performance category, which correlate to Stage 3, beginning in 2018.

MIPS Objectives and Measures Specifications (page 218-233)

The Collaborative supports the proposed objectives and measures for the advancing care information performance category of MIPS as outlined, and specifically the following: protect health information, electronic prescribing, clinical decision

support (CDS), CDS intervention, drug interaction and drug-allergy checks, computerized provider order entry (CPOE), medication orders, secure messaging, health information exchange, patient care record exchange, public health registry reporting, medication reconciliation, and immunization registry.

Impact on Other Health Care Programs and Providers (page 680)

The Collaborative agrees that there are other affected provider entities; pharmacists being among them. Although the CMS states that it does not "believe that MIPS would have significant effects on substantial numbers of providers," the Collaborative does not fully agree with that assessment. As we have indicated throughout our comments, pharmacists are not considered eligible clinicians for MIPS, though this program will affect them. According to the Bureau of Labor Statistics, there are over 295,000 practicing pharmacists in the U.S. (May 2015 figure). That is a significant number that may be affected by MIPS.

Certified Electronic Health Record Technology (CEHRT) Meaning (page 693)

The Collaborative supports the meaning of CEHRT as proposed.

Table E: 2017 Proposed MIPS Specialty Measure Sets (page 836)

The Collaborative supports the 2017 proposed specialty measures; especially those relating to allergy and immunology, medication management, diabetes, and preventive care.

The Pharmacy HIT Collaborative's vision and mission are to assure the nation's health care system is supported by meaningful use of health IT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of health IT and the inclusion of pharmacists within a technology-enabled integrated health care system. The Collaborative was formed in the fall of 2010 by nine pharmacy professional associations, representing 250,000 members, and also includes associate members from other pharmacy-related organizations. The Pharmacy HIT Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's Associate Members represent e-prescribing and health information networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacists' services. For additional information, visit www.pharmacyhit.org.

On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on CMS-5517-P: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models.

For more information, contact Shelly Spiro, Executive Director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,

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