Pharmacy Health Information Technology Collaborative

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

May 29, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3310-P
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-3310-P – Medicare and Medicaid Program; Electronic Health Record Incentive Program – Stage 3

Dear Sir/Madam:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments in response to your Request for Comment for *Medicare and Medicaid Program; Electronic Health Record Incentive Program – Stage 3.*

The Collaborative is supportive of the proposed measures and objectives for Stage 3. Although pharmacists are ineligible for electronic health record (EHR) incentives, they will need to exchange information with EHR systems to connect to and ensure needed bidirectional communication with EPs. As indicated throughout our comments, that exchange is not at an adequate level today. Pharmacists provide patient-centered care and services, and as part of the integrated health care team, they are directly involved with patients in various practice settings, particularly with a patient's medication action plan. Pharmacists have standards in place to meet Stage 3 requirements.

The following are our comments regarding CMS-3310-P: *Electronic Health Record Incentive Program – Stage 3.*

Objective 1: Protect Patient Health Information
Proposed Objective: Protect electronic protected health information (ePHI) created or maintained by the certified EHR technology (CEHRT) through the implementation of appropriate technical, administrative, and physical safeguards.

The Collaborative supports the proposed measure requirement that security risk analysis should be conducted or reviewed at least annually to assess the risks and vulnerabilities to ePHI created or maintained by the CEHRT, implement security updates as necessary, and correct and identify security deficiencies as part of the provider's risk management process.

Objective 2: Electronic Prescribing

Proposed Objective: EPs must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

The Collaborative supports maintaining the objective and measure finalized in the Stage 2 final rule for electronic prescribing for EPs and extending it to eligible hospitals and CAHs to transmit permissible discharge prescriptions electronically. The Collaborative also supports the threshold increase from 50 percent to 80 percent for the Stage 3 proposed EP measure.

Pharmacists play an integral role at points of transition of care in assuring orders created by EPs, eligible hospitals, or CAHs' inpatient or emergency departments are correct in all practice settings.

As we indicated in our January 14, 2013 comments regarding Stage 3 Definition of Meaningful Use of Electronic Health Records, which included a discussion on electronic prescriptions, recent studies on medication errors show that transitions from one care setting to other settings are a time of high risk for adverse drug events (ADEs). Evidence shows that the discharge from a hospital is particularly dangerous for potential medication errors. The Institute of Medicine estimates that there are at least 1.5 million preventable ADEs in the United States each year and that the risk of medication errors is higher upon discharge from a hospital because discrepancies in medication errors are more common.[1] Certified EHRs should allow pharmacists to review medication orders before electronic prescriptions are transmitted.

Objective 3: Clinical Support

Proposed Objective: Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

The Collaborative supports maintaining the Stage 2 objective for the use of CDS to improve performance on high-priority health conditions and associated measures. The Collaborative also supports proposed Measure 2 for EPs, eligible hospitals, and CAHs implementing the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Although pharmacists are ineligible for EHR incentives, they have access to a high level of drug-drug interaction lists and other medication-related clinical decision supports. As health care providers, pharmacists are required by state Pharmacy Practice

[1] *Preventing Medication Errors*, the Institute of Medicine, 2006.

Acts and various federal and state programs to review drug-drug interactions, clinically relevant medication orders, cost-effectiveness, and assure medications are appropriately ordered. Additionally, they have access to and use information provided from various registries, Internet queries, etc., that provide pharmacists with pertinent clinical decision support related to medication use for patients with high-priority health conditions including multiple chronic conditions.

Pharmacists provide team-based, patient-centered care that improves the medication management of many disease states (e.g., diabetes, hypertension, asthma) for patients in various practice settings. As part of the integrated health team, pharmacists are directly involved with patients.

As we indicated in our January 14, 2013 comments regarding Stage 3 Definition of Meaningful Use of Electronic Health Records, the Collaborative strongly recommends the inclusion of bidirectional exchange to share information and data among pharmacists in all practice settings, EPs, eligible hospitals, and CAHs as a required element for this objective. Bidirectional exchange appears to be lacking in this objective. Including bidirectional exchange would align this objective more clearly with the 2015 health IT certification criteria.

Objective 4: Computerized Provider Order Entry

Proposed Objective: Use computerized provider order entry (CPOE) for medication, laboratory, and diagnostic imaging orders directly entered by any licensed health care professional, credentialed medical assistant, or a medical staff member credentialed to and performing the equivalent duties of a credentialed medical assistant; who can enter orders into the medical record per state, local, and professional guidelines.

The Collaborative supports continuation of the policy from the Stage 2 final rule that medication and laboratory orders are to be included in this objective. We also support the proposed measures for medication orders (more than 80 percent) and laboratory orders (more than 60 percent) to be recorded by EPs, eligible hospitals, or CAHs' inpatient or emergency departments during the EHR reporting period using CPOE.

CPOE pharmacist electronic health records comply with MU Stage 3. Pharmacists have access to a high level of drug-drug interaction lists and other medication-related clinical decision support. As health care providers, pharmacists are required by state Pharmacy Practice Acts and various federal and state programs to review drug-drug interactions, clinically relevant medication orders, cost-effectiveness, and assure medications are appropriately ordered.

Objective 5: Patient Electronic Access to Health Information

Proposed Objective: The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit or retrieve their health information through an API within 24 hours of its availability.

The Collaborative supports this new proposed Stage 3 objective, as it aligns with the role of pharmacists-provided health care and the services pharmacists provide. However, we

would ask for a clarification on the timeframe since the initial publication of the Stage 3 proposed rules. The initial proposal indicated that information should be made available within 24 hours if generated during the course of a visit; lab or other types of information not generated within the course of a visit are to be made available to patients within four business days of the information becoming available to EPs. There appears to be a change in the timeframe for providing information regardless of when the information was generated.

In our January 14, 2013 comments for Stage 3, we mentioned that although EPs provide paper summaries as the patient leaves the office, providing clinical summaries electronically within 24 hours, as well as the ability to view online, download, and transmit their health information in four business days, also would help more than just the patient. It is critical that pharmacists either receive these clinical summaries from EPs, as they will have an impact on dispensing or changing of medications, or that pharmacists be able to query this information, as needed, via health information exchanges. Pharmacists need bidirectional exchange of this information, which should also be a requirement for this objective.

It is important to remember that pharmacists are involved in patients' medication action plans, including the provisions of Medicare Part D, in which pharmacists are required to provide Comprehensive Medication Review (CMR) structured documents. Pharmacists are in a position to capture medication-related progress notes, as well as results from patient information concerning diabetes, anticoagulation therapy, geriatrics, and share these with providers.

It is also important to note that long-term care and nursing facilities, as well as home infusion settings, have clinical summaries, particularly lab results/values. These settings also involve pharmacists.

We also support the increase of the threshold for Measure 1 from the Stage 1 and Stage 2 threshold of 50 percent to 80 percent for Stage 3 and for Measure 2 from 10 percent to 35 percent.

Objective 6: Coordination of Care through Patient Engagement

Proposed Objective: Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

The Collaborative supports incorporating the policy goals of Stage 2 objectives related to secure messaging, patient reminders, and the threshold increase of the proposed measures of patient engagement requiring patients (or their authorized representatives) to view, download, and transmit their health information using the functionality of the certified EHR technology into this objective. The Collaborative also supports expanding the options through which providers may engage with patients under the EHR Incentive Program, including the use of APIs, though such other electronic communications methods or applications should be certified to ensure they are secure.

As mentioned previously, pharmacists are part of the integrated health care team, although they are not eligible for EHR incentives. In order to meet true interoperability of this objective and the proposed measures, there needs to be assurance that pharmacists can exchange information electronically with EPs, eligible hospitals, and CAHs. The Collaborative strongly recommends that the bidirectional exchange of information be included as a

requirement for this objective. As indicated on pages 110-11, pharmacists would appear to be included in the new proposed definition for non-clinical setting for Measure 3 as drafted, though pharmacists are not specifically mentioned in examples provided. The proposal states that a "non-clinical setting shall be defined as a setting with any provider who is not an EP, eligible hospital, or CAH as defined for the Medicare and Medicaid EHR Incentive Programs."

Proposed Measure 3: Patient-generated health data or data from a non-clinical setting is incorporated into the certified EHR technology for more than 15 percent of all unique patients seen by the EP or discharged by the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.

Questions Posed by CMS for Proposed Measure 3

- *How information could be captured, standardized, and incorporated into an EHR?*

Various options for capturing patient-generated health data or data from non-clinical settings and incorporating into an EHR are available. Manual inputting of data is one method. Medical devices, medical applications, or other APIs collecting data could and should be integrated with the EHRs.

Standardization of data/information, especially with regard to vocabularies (clinical or others), is absolutely essential for data exchange and to the success of integrating data/information into the EHR.

- *Should the data require verification by an authorized provider?*

Data provided should require verification by an authorized provider. We take provider to mean the patient or patient's authorized representative, the EP, the eligible hospital, the CAH, or the authorized provider in the non-clinical setting.

- *Should the incorporation of the data be automated?*

Automated incorporation of the data would be the ideal. Automated incorporation of the data would be more efficient and would lead to improved workflow, accuracy, timeliness, and productivity in non-clinical settings. Automated incorporation of patient-generated data/information captured from medical devices, medical applications, mobile devices, and mobile medical applications also would be beneficial. To advance the automated incorporation of data, the Collaborative recommends that CMS look at the Food and Drug Administration's (FDA) involvement in connected health. Connected health uses electronic technology to delivery health care remotely. FDA's role in connected health continues to evolve along with medical device technology. The FDA's Center for Devices and Radiological Health (CDRH) plays an important role in enabling a connected health environment while assuring that patients stay safe, and the new technologies work as intended. Currently, CDRH is focusing its efforts in several areas, including:

- The convergence of wireless technologies with medical devices in partnership with the Federal Communications Commission (FCC);
- Medical devices used in a home environment;
- Mobile medical apps;
- Medical device data systems, and
- The role of software in medical devices.

On August 6, 2013, the FDA issued a federal register notice *Modifications to the List of Recognized Standards, Recognition List Number: 032* that recognizes voluntary consensus standards to help support and strengthen the interoperability and cyber security of networked and connected medical devices.[2]

- *Should there be structured data elements available for this data as fields in an EHR?*

Structured data elements must be used and should be data fields in an EHR for this to be successful. The use of standard and structured data organization enhances the ability of these systems to operate in a meaningful way and for EHR data to be used.

- *Should the provenance of the data be recorded in all cases and for all types of data?*

Because accurate and reliable data are integral to patient care, the provenance of the data should be recorded in all cases and for all types of data. It is important that data are managed and validated for accuracy in reporting. Having the data set's history, origin, and any modifications since its creation could be beneficial to patients and providers. We also would recommend that the time stamp of when a file was created be incorporated along with one indicating when the last update was done. This would also help with audit trails. An example of how a time stamp would help pharmacists or other EPs is the drug formulary or preferred drug list. A time stamp would let the pharmacist or EP know how recently the formulary or preferred drug list was updated.

On February 11, 2002, the FDA published its Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures; Time Stamps.[3]

The use of a time stamp is under consideration by the Office of the National Coordinator's (ONC) proposed 2015 Edition Health Information Technology (Health IT) Certification Criteria, currently in the public comment stage.

Objective 7: Health Information Exchange

Proposed Objective: The EP, eligible hospital, or CAH provides a summary of care record when transitioning or referring their patient to another setting of care, retrieves a summary of care record upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their EHR using functions of certified EHR technology.

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[2] Connected health - FDA (accessed April 17, 2015).

[3] FDA Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures; Time Stamps, http://www.fda.gov/OHRMS/DOCKETS/98fr/00d-1542_gdl0001.pdf (accessed May 21, 2015).

The Collaborative supports revising this objective for Stage 3 to allow the inclusion of transitions of care and referrals in which the recipient provider may already have access to the medical record maintained in the referring provider's CEHRT. We also support the proposed measures; particularly Measure 3, which requires the EP, eligible hospital, or CAH to perform clinical information reconciliation for medication, medication allergy, and current problem list. We agree with the proposed requirement for Measure 3 that all summary of care documents must be populated with the current problem list, a current medication list, and a current medication allergy list using the common clinical data set (CCDS) certification standards for those fields. All summary of care documents maintained should contain the most recent and up-to-date information on all elements.

The Collaborative, however, asks CMS to reconsider its position on summary of care documents at transitions of care regarding pertinent and relevant items to the patient's care. As we understand, CMS is only proposing to encourage providers to send a list of these items rather than a list of all problems. For coordination of care to be successful, especially during the transition, we believe these items should be a requirement for inclusion on summary of care documents, rather than being left to the discretion of the provider. What may be considered not relevant or not pertinent to the provider initiating the summary of care document may in fact be considered relevant and pertinent to the provider at the point of the transition of care. This is particularly critical for issues involving medications.

As we mentioned in Objective 2, recent studies on medication errors show that transitions from one care setting to other settings are a time of high risk for adverse drug events (ADEs). Evidence shows that the discharge from a hospital is particularly dangerous for potential medication errors. This risk is also true for other aspects of a patient's care during transition from one care setting to another. In its review of transitions of care at hospital discharge, the *Journal of Hospital Medicine* states, "The period following discharge from the hospital is a vulnerable time for patients. About half of adults experience a medical error after hospital discharge, and 19%-23% suffer an adverse event, most commonly an adverse drug event."[4] The review also states that a key challenge is ineffective physician-patient communication, which further adds support for requiring that all relevant and pertinent information be included, rather than leaving this to the discretion of a provider.

Transition of care involves more than EPs, eligible hospitals, and CAHs. Pharmacists will be involved in the transition of care and medication reconciliation. Pharmacists also are able to collect social history as it relates to the patient's medical history (e.g., alcohol use, smoking). The Collaborative supports the reconciliation of contraindications for medications, medication allergies, and medication problems. Although pharmacists are capturing this information, they need electronic bidirectional exchange with EPs, eligible hospitals, CAHs, and other providers to share and receive problems related to patients' medications, especially at the transition of care level. Pharmacists support the bidirectional exchange as the focal point of transition of care in all practice settings, especially with regard to problem lists and more current updated problem lists that providers may not have access to. We strongly encourage

[4] "Promoting Effective Transitions of Care at Hospital Discharge: A Review of Key Issues for Hospitals," *Journal of Hospital Medicine*, 2007.

CMS to make bidirectional exchange or communication a requirement for this objective.

Pharmacists also provide a summary of care record through CMR using consolidated clinical document architecture (C-CDA). It is vitally important that pharmacists have access to current problem lists at transition of care, particularly with regard to long-term care, to match medications for patients to use. This is particularly important for medication therapy management services pharmacists provide under Medicare Part D. Again, bidirectional exchange of summary of care documents will help meet this objective.

We also believe that providers who are receiving a summary of care record using CEHRT for the purposes of Measure 2 should have a similar requirement for the transport of summary of care documents requested from a transitioning provider. Additionally, the Collaborative supports the proposed measure of clinical information reconciliation, which incorporates the Stage 2 objective for medication reconciliation and expands the options to allow for the reconciliation of other clinical information such as medication allergies.

Objective 8: Public Health and Clinical Data Registry Reporting

Proposed Objective: The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.

The Collaborative supports this objective, especially the proposal to create a centralized repository of national, state, and local PHA and CDR readiness. Of particular interest and importance to pharmacists are proposed Measure 1 – Immunization Registry Reporting and Measure 2 – Syndromic Surveillance Reporting. Although the ONC is proposing to adopt a bidirectional exchange standard for reporting to immunization registries/IIS, which the Collaborative supported in its comments to the ONC, we would strongly encourage CMS to adopt and require bidirectional exchange for this objective as well. Pharmacists need access to such reports.

There also needs to be a uniform standard of reporting. The Collaborative encourages and supports the harmonization of HL7 and NCPDP (SCRIPT and Telecommunications) standards for this area. We believe this would encourage EPs, eligible hospitals, and CAHs to submit data electronically and uniformly.

Pharmacists are readily accessible providers of immunizations throughout the United States. As such, pharmacists document vaccine contraindications and the reasons for vaccine refusals. Because of their frequent access to patients, pharmacists are in the position to capture immunization, cancer, hypertension, and diabetes information and submit to public health agencies and other registries in accordance with applicable laws. The Collaborative is working with structured documents, using C-CDA to electronically exchange immunization information with EHRs, which includes contraindications and substance refusals.

The Collaborative supports electronic data submission to immunizations registries and believes they can be effective tools to promote patient and population health; however, because such registries are maintained at the state and local levels through public health agencies, there needs to be a uniform standard for reporting. We would encourage the support and harmonization of standards, such as the HL7 and NCPDP (SCRIPT and Telecom) standards for this area. This would not only encourage EPs, hospitals, and CAHs to submit

electronically and uniformly, but it would also afford uniform reporting opportunities for non-EPs, especially pharmacists, who are administering immunizations. The American Pharmacists Association reports that there are 260,000 pharmacists, including student pharmacists, trained to administer immunizations.

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The Pharmacy HIT Collaborative's vision and mission are to assure the nation's health care system is supported by meaningful use of HIT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of HIT 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 eight 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

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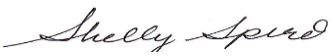
On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the Request for Comment for *Medicare and Medicaid Program; Electronic Health Record Incentive Program – Stage 3*

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

Respectfully submitted,



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