



Pharmacy e-Health Information Technology Collaborative

VIA Electronic Submission to <http://www.regulations.gov>

May 7, 2012

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0044-P
P.O. Box 8013
Baltimore MD 21244-8013

Re: CMS-0044-P Medicare and Medicaid Programs; Electronic Health Record
Incentive Program-Stage 2

Dear Administrator Tavenner:

On behalf of the membership of the Pharmacy e-Health Information Technology Collaborative (Collaborative), we are pleased respond to the Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2 Notice of Proposed Rulemaking published in the Federal Register on March 7, 2012.

The Collaborative recommends that CMS consider allowing pharmacists to become eligible professionals (EPs) in the Electronic Health Record (EHR) Incentive Program. The Collaborative is very supportive of the proposed measures and objectives for the EHR Incentive program; however, our concern is that the proposed measures and objectives will become unfunded mandates (these areas are noted throughout our comments below). Pharmacists are ineligible for EHR incentives, though they will need to exchange information with EHR systems to connect to and ensure needed bidirectional communication with EPs. Today, that exchange is not at an adequate level. Pharmacists have standards in place to meet these requirements.

As implementation of Stage 2 moves forward, it should not create additional or financial burdens on pharmacists, such as becoming an unfunded mandate. Also as our comments indicate, allowing pharmacists the opportunity to become EPs and receive EHR incentives may lead to adoption of these EHR standards at a level that may be significant.

Pharmacy e-Health Information Technology Collaborative

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The following are our comments concerning EHR Incentive Program – Stage 2 Notice of Proposed Rulemaking:

1) Proposed Measure: More than 60 percent of medication, laboratory, and radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE. (Pages 49-51)

Comment: Hospital pharmacists are in support of the 60 percent CPOE, and we agree with the 60 percent quality measure. We also agree that CPOE and the information that's being captured in an EHR, especially related to medications, laboratory, and radiology, are important in the in the exchange of clinical information with pharmacists.

2) Consolidated Objective: Implement drug-drug and drug-allergy interaction checks. (Page 53)

Comment: The best medical outcomes happen with an integrated team approach of health care providers. Pharmacists' unique experiences, expertise, and access to medication information that others may not have bring enormous value to physicians in their prescribing decisions, particularly, with regard to checking drug-drug and drug-allergy interactions. This is especially an important aspect in caring for patients after they are discharged from a hospital. Pharmacists also should be involved in helping to streamline drug-drug and drug-allergy interactions to prevent alert-fatigue.

To better incorporate the automated interaction checks process into the objective for "Clinical decision support to improve performance on high-priority health conditions", as is being proposed, we suggest that alerts be viewable by all users and capture the clinical justification for any prescriber override. Override justifications need to be documented and viewable by all users. Clinical justifications for overrides currently are not captured. Technology should support this evidence-based medicine environment. Additionally, we suggest that drug-drug and drug-allergy interaction checks be expanded to include drug-gene interactions. Genetic information needs to be part of CPOE and clinical support. Pharmacists may have experience in this area and information that EPs may not have.

At this stage, however, a barrier to ensuring a fully, integrated health care team approach within the EHR Incentive Program is that pharmacists are not eligible for the EHR incentives. We encourage CMS to evaluate the value that non-eligible pharmacists would bring to the EHR Incentive Program and afford them the opportunity to become eligible providers.

3) Proposed EP Objective: Generate and transmit permissible prescriptions electronically (eRx).
(Page 53)

Comment: We support the use of electronic prescriptions and agree that there are benefits to utilizing e-prescribing because of the potential to increase efficiencies, enhance patient safety, protect our drug supply, and provide pharmacists, prescribers and other members of the health care team with access to critical patient medical information as appropriate. Before moving forward with this objective into Stage 2, however, there are possible barriers to e-prescribing that may need to be overcome. These concern actual e-prescribing systems and current state laws. Implementing by 2014 may not be adequate time to address all potential hindrances. A few such concerns follow (these are not all inclusive, though many of the concerns had been raised in comments for Stage 1).

To enhance efficiencies, improve safety, security, and patient care, e-prescribing systems must reduce the time spent by pharmacists by clarifying prescription orders with prescribers; eliminate transcription errors; provide prescribers with information essential to assess contraindications such as drug allergies, drug interactions, and errors in drug selection, and prevent errors at the point of entry such as wrong dose or drug selection from drop-down menus.

E-prescribing also should include controlled substances; however, a hindrance to allowing this is current state laws. Although the DEA now permits controlled substance e-prescribing, not all of the states allow this. It may take longer than the biennial 2013-14 sessions for the several remaining states to allow controlled substance e-prescribing. For this to work efficiently, e-prescribing needs to be allowed in all 50 states and be done with uniform standards.

Concerning the exclusion of nonprescription medications (OTCs as they are referred in the NPRM) from the definition of a prescription drug in this objective, we recommend further research to determine how often prescribers write prescriptions for nonprescription medications. Nonprescription medications provide value to the patient and help to reduce health care costs, especially, when used properly. Concerns have been raised in recent years about contraindications with prescription medications being taken by those self-medicating with nonprescription medications. Some of these products that are subject to abuse have been removed from the shelves in pharmacies and other outlets and placed behind the counter, creating a third class of drug. The patient now must request these products. A prescriber working with a patient concerning the appropriate nonprescription medication therapy would be beneficial, and e-prescribing, though not required, would encourage appropriate selection and use of these medications.

Additionally, those making clinical decisions should include nonprescription medications in their drug-drug, drug-allergy interaction checks support systems. Active medication lists also should include nonprescription medications.

Lastly and importantly, as implementation of e-prescribing under Stage 2 moves forward, it should not create additional or financial burdens on pharmacists, such as becoming an unfunded mandate. As noted earlier, pharmacists are ineligible for EHR incentives. In 2009, the U.S. House of Representatives passed HR 3854, an act to amend the Small Business Act and the Small Business Investment Act, recognizing the importance of health information technology that supports meaningful EHR use by eligible professionals. Pharmacists were specifically included in the bill's definition of "eligible professional." We believe pharmacists should be considered EPs and be eligible for EHR incentives. EHR incentives would greatly help in connecting non-eligible pharmacists to EPs, especially in areas that have limited access to EPs and CAHs (e.g., rural areas).

Concerning instances where an EP may prescribe medications in a facility (such as a nursing home or ambulatory surgery center) where they are compelled to use the facility's ordering system, which may not be Certified EHR Technology, we agree that exclusionary criteria concerning this circumstance should not be proposed. We believe the focus should be getting information moving and exchanged regardless of the EHR platform being used. It should be taken into account that although facilities, such as nursing homes or ambulatory surgery centers, may be using different EHR platforms, pharmacists are in a similar circumstance and some of them may be using non-certified EHR technology as well.

4) Proposed EP Measure: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits. (Page 77)

Comment: We agree that although EPs provide paper summaries as the patient leaves the office, providing such clinical summaries electronically within 24 hours also would help more than just the patient. One aspect of encouraging better quality of care that appears not to be discussed in the description of a care plan for this proposed measure is that of transitioning care (though, it is discussed later in the proposed rules). In looking at transitioning patient care from the EP office or being discharged from a hospital to another health care provider, particularly pharmacists, 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. It is important to remember that pharmacists are involved in patients' medication action plans. Additionally, it is also important 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.

5) Proposed EP Objective: Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP. (Page 91)

Comment: We support this proposed objective, as it aligns with the role of pharmacist-

provided health care and the services pharmacists provide, and again, emphasize the importance of pharmacists being able to receive this information also from an EP or a patient. Because of the relationship and interaction that pharmacists have with their patients in providing care, especially on medication-related problems, pharmacists are not only likely to accept information from patients via electronic means, but with this information, pharmacists may be in a position to counsel patients, ensuring the information received is correct and address any medication problems at that time. Pharmacists are providing medication therapy management and conducting medication reconciliation and this gives reason for pharmacists to be meaningful users.

Currently, the Pharmacy e-HIT Collaborative is working on a project with NCPDP and HL7 on the consolidated CDA, in which the pharmacists' medication action plans would be available in electronic format for patients.

6) Proposed Objective: The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation. (Page 104)

COMMENT: We noted that for Stage 2 the electronic exchange of information is not a requirement for medication reconciliation. We believe that it should be a requirement. Transition of care involves more than EPs and eligible hospitals. Although pharmacists are not currently eligible for EHR incentives (we encourage CMS to allow pharmacists to become EPs), they will be involved in the transition of care and medication reconciliation. As noted in the pharmacy industry's *Improving Care Transitions: Optimizing Medication Reconciliation* (<http://www.pharmacist.com/mtm/reconciliation>),¹ the comprehensive goals of medication reconciliation are "to obtain and maintain accurate and complete medication information for a patient and use this information within and across the continuum of care to ensure safe and effective medication use," to electronically communicate accurate patient medication information, and then take appropriate actions to resolve any discrepancies. This bidirectional electronic communication concerning the movement of a patient is needed by pharmacists and may help alleviate a variety of medication-related problems that may lead to hospital readmission.

7) Proposed Objective: The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral. (Page 106)

Comment: We agree that transition of care is not only vitally important, but we believe the role of pharmacists needs to be recognized in this area, particularly, with regard to medication

¹ *Improving Care Transitions: Optimizing Medication Reconciliation*, the American Pharmacists Association and the American Society of Health-System Pharmacists, March 2012.

reconciliation at the transition of care. Pharmacists look at patients in a patient-centered way. That is pharmacists must follow their patients longitudinally through their care to increase medication-related patient safety. It is at these points of transition where pharmacists may see problems with the patients' medications that were prescribed.

In recent years, numerous studies have demonstrated the need to address medication-related problems and improve patient safety through medication reconciliation and medication therapy management. As noted in the pharmacy industry's *Improving Care Transitions: Optimizing Medication Reconciliation*, cited previously, evidence includes:

- Approximately 1.5 million preventable adverse drug events (ADEs) occur annually as a result of medication errors, at a cost of more than \$3 billion per year;
- Approximately half of all hospital-related medication errors and 20% of all ADEs have been attributed to poor communication at the transitions and interfaces of care;
- The average hospitalized patient is subject to at least one medication error per day;
- The occurrence of unintended medication discrepancies at the time of hospital admission ranges from 30% to 70%, as reported in two literature reviews.²

We want to ensure that those patients' medication issues are addressed at transition points in all practice settings. This also emphasizes the need for pharmacists to receive the clinical summaries provided by EPs to their patients.

8) Proposed Measures: EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:

The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals.

Proposed Second Measure: The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals. (Page 110)

COMMENT: Our comments concern the Proposed Second Measure. Although pharmacists are non-eligible providers, they are meaningful users of EHR and are in a position to exchange clinical information with other health care providers. Pharmacists already create a specialized transaction and an MTM consolidated CDA Release 2 for moving the documentation that is

² *Improving Care Transitions: Optimizing Medication Reconciliation*, the American Pharmacists Association and the American Society of Health-System Pharmacists, March 2012, page 2.

obtained for medication therapy management and can exchange that information in a structured way to another health care provider. Using an e-prescribing network or health information exchange can move this clinical information. Through their electronic connections, pharmacists can adopt their electronic health records to transport clinical information much more efficiently.

9) Proposed Objective: Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice. (page 121)

COMMENT: We support electronic data submission to immunizations registries and believe 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 175,000 pharmacists, including student pharmacists, trained to administer immunization.

10) Proposed Eligible Hospital/CAH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR) (pages 138).

COMMENT: We agree that hospitals should track medications from order to administration using an electronic medication administration record (eMAR). The eMAR is readily available and has been shown to improve patient safety and lower costs. Access to this medication information would be helpful to pharmacists providing transitional care to discharged hospital patients. As pharmacists we also support eMARs in other settings as well. Other settings are those where caregivers are administering medications to patients. Such settings may include long-term care facilities, assisted living, behavioral health, hospice, home care, etc. As pharmacists, we believe for patient safety of medications that eMARs need to be integrated with the electronic health records of these facilities. The eMAR should be electronically fed from the medication order and match what the dispensing operation is sending. This integration is an important element.

11) Proposed Eligible Hospital/CAH Objective: Generate and transmit permissible discharge prescriptions electronically (eRx). (Page 141)

COMMENT: We support the use of electronic prescriptions and agree that there are benefits to

utilizing e-prescribing when a patient is discharged to increase efficiencies, enhance patient safety, and provide in-network pharmacies with access to critical patient medical information as appropriate. We also support utilizing e-prescribing standards, (e.g., SCRIPT) and e-prescribing networks for hospitals to connect with pharmacies out of their networks. There may be circumstances in which a patient discharged from the hospital may not need a prescription at the time of discharge, and this may affect the refill or discontinuation of the prescription. This information needs to be shared with the pharmacist. This also may lead to a medication misadventure and hospital readmission. To provide necessary transitional care, pharmacists need to receive electronically all relevant discharge summary information. Our concern, however, is that this proposed objective is an unfunded mandate for pharmacists. As noted previously throughout our comments, pharmacists are not eligible for EHR incentives. Pharmacists are non-eligible providers, and we believe they should have the opportunity to become eligible providers.

12) Proposed Eligible Hospital/CAH Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology. (Page 142)

COMMENT: As the end-of-hospital-stay is an important part of medication reconciliation, pharmacists can help ensure that patients leaving the hospital are doing so with the appropriate medications that they were taking before entering the hospital and reconciling that with the patient's medication program formulary. Keeping the threshold at 10 percent appears to be a good number for testing this. Pharmacists have the capabilities to provide this drug formulary check and reconciliation and other aspects, such as medication adherence and discharge counseling, but providing these through unfunded mandates will be difficult to overcome and may not lead to adoption at a level that is significant.

13) Proposed Eligible Hospital/CAH Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission. (Page 144)

COMMENT: We support this proposed objective, and again, would like to emphasize the importance of pharmacists being able to receive this information. Because of the relationship and interaction that pharmacists have with their patients, especially on medication-related problems, pharmacists are not only likely to accept information from patients via electronic means, but with this information, pharmacists may be in a position to counsel patients, ensuring that the information received is correct and address any medication problems at that time.

14) Criteria for Selecting Clinical Quality Measures: We are soliciting comment on a wide ranging list of 125 potential measures for EPs and 49 potential measures for eligible hospitals and CAHs. We expect to finalize only a subset of these proposed measures. (page 168)

COMMENT: We support the clinical quality measures proposed for EPs and CAHs, and again, would like to emphasize the importance of pharmacists being able to receive this information. Pharmacists have a role in assisting EPs in meeting these criteria, as well as their important roles with patients, especially at the point of transition of care after patients are discharged from the hospital. Potential proposed measures of particular interest to pharmacists are the following NQFs: 0435, 0436, 0438, 0339, 0371, 0372, 0372, 0373, 0375, 0376, 0132, 0142, 0137, 0160, 0164, 0639, 0147, 0527, 0528, 0529, 0136, 0434, 0284, 0218, 0143, 0144, 1653, and 1659. These potential proposed measures involve the administration and use of prescription drugs and immunizations during the hospital stay and at the time of discharge from the hospital.

As noted previously, transition of care is not only vitally important, but we believe the role of pharmacists needs to be recognized in this area, particularly, with regard to medication reconciliation at the transition of care. Pharmacists look at patients in a patient-centered way. That is pharmacists must follow their patients longitudinally through their care to increase medication-related patient safety. It is at these points of transition where pharmacists may see problems with the patients' medications that were prescribed.

With regard to the six domains of which the proposed measures have been assessed, we believe they will adequately align with and support the breadth of CMS and HHS activities to improve the quality of care and health outcomes.

15) Consolidated Objective: Implement drug formulary checks (*incorporating into Proposed Objective: Generate and transmit permissible prescriptions electronically*). (page 84)

COMMENT: Implementing drug formulary checks are important to do at the initial prescribing stage by the EP. EPs must have the ability to conduct a drug formulary check prior to the prescription being transmitted and the drug being administered, as well as have the capacity for electronic bidirectional communication to alleviate the need for exchanging non-electronic information. If the formulary check is not done by the EP at initial prescribing stage and a drug prescribed is not on a formulary and is transmitted to a pharmacy, this puts the pharmacist in the tenuous position of having to conduct a drug formulary check for the EP. If there is no capacity for electronic bidirectional communication, the pharmacist then will need to phone the EP with the formulary information.

We believe the purpose of providing EPs electronic information on drug formularies prior to the prescribing process is to increase bidirectional communication to eliminate the exchange of non-electronic information.

Pharmacies that are connected for electronic prescribing need to have the means for bidirectional exchange of information so that when situations occur in which a physician isn't using the drug formulary check, the pharmacists would have the capability to electronically exchange that information with the EP.

Pharmacies are not receiving incentives for e-prescribing. If EPs or eligible hospitals that receive incentives for e-prescribing are not using a drug formulary check, this makes the drug formulary check and exchange of information an unfunded mandate for the pharmacist.

As implementation of e-prescribing under Stage 2 moves forward, it should not create additional or financial burdens on pharmacists, such as becoming an unfunded mandate. As noted earlier, pharmacists are ineligible for EHR incentives and should be afforded the opportunity to become eligible EPs.

16) Proposed Objective: Record patient family health history as structured data. (page 130)

COMMENT: Family health history is vitally important in clinical decision-making, especially with regard to preventive care and medications. We agree that the recording of family history as structured data should be a part of the EHR menu objective for Stage 2. Capturing and sharing this information among providers, including pharmacists, through EHR provides greater interoperability. As part of preventive and ongoing care, pharmacists need to have access to this information. As medication specialists, pharmacists are in a key position to interpret family history information related to medication and genetic information. Medications for certain conditions may prevent certain diseases indicated in the family history from occurring.

17) Proposed Measure: More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives. (Page 131)

COMMENT: Although the ONC does not plan to provide the exchange of information in this measure with other providers until Stage 3, collecting this information through family histories to match genetics for health care is vitally important, especially with regard to how a patient will respond to medications and preventive care. To provide patient care, pharmacists also need to have access and input into such structured data. Pharmacists also may be able to provide information on social history, such as smoking. We believe the definition for first degree relative as used by the National Human Genome Research Institute of the National Institutes of Health is adequate as a minimum definition.

18) Proposed EP Objectives: Capability to identify and report cancer or other specialized cases to a State cancer or specialized registry, except where prohibited, and in accordance with

applicable law and practice. (Page 132 & 134)

COMMENT: We support reporting to cancer and specialized registries and believe they can be effective tools to promote patient and population health. Pharmacists need access to such reports, as well as the ability to report. 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 and support the HL7 standard for this area. This would encourage EPs, hospitals, and CAHs to submit electronically and uniformly.

19) Proposed EP Measures: Successful ongoing submission of cancer and specific case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period. (Page 134 & 135)

COMMENT: We support ongoing submissions of cancer and specific case information and believe requiring the submission of data on an ongoing basis appropriate. Ongoing submissions and the sharing of this information with providers, including pharmacists, via the registry provides greater interoperability among integrated health care teams in providing patient care. As indicated previously, pharmacists need access to such reports, as well as the ability to report.

20) Proposed EP Objective: Use secure electronic messaging to communicate with patients on relevant health information. (page 135)

COMMENT: We support including this as a core objective. Protecting health care information exchanged, especially patient-protected information, through electronic messaging systems needs to have added safeguards. Electronic messaging should also maintain the ease of use for communications between patients and providers. Messaging is inexpensive and will foster better communication and coordination between providers and patients.

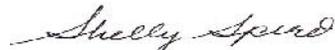
Information provided by providers electronically also should be presented to patients in a way that would allow them to understand the information. Education level, age, literacy, language barriers, visual and hearing impairments, etc., need to be taken into consideration. Pharmacists are trained in and have knowledge of effective tools to communicate with patients about medication-related information that take into account those factors thus making medication information more understandable.

Formed in the fall of 2010, the Collaborative's focus is to assure the meaningful use (MU) of standardized electronic health records (EHR) that supports safe, efficient, and effective medication use, continuity of care, and provide access to the patient-care services of pharmacists with other members of the interdisciplinary patient care team.

The Collaborative seeks to ensure pharmacist-provided patient care services are integrated into the National HIT interoperable framework. The 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 networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacists' services. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes six associate members from other pharmacy related organizations. For additional information, visit www.pharmacyhit.org

On behalf of the Pharmacy e-HIT Collaborative, thank you again for the opportunity to comment on the *Electronic Health Record Incentive Program-Stage 2* proposed rules. For more information, contact Shelly Spiro, Director, Pharmacy e-HIT Collaborative at shelly@pharmacyhit.org.

Respectfully submitted,



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