



March 12, 2010

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-0033-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: CMS-0033-P, Medicare and Medicaid Programs; Electronic Health Record Incentive Program Proposed Rule**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Electronic Health Record Incentive Program Proposed Rule (proposed rule). For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

ASHP will provide comments on the following issues:

- The role of the pharmacist
- Clinical decision support
- Active medication list
- Recommendations by the Office of the National Coordinator's Health Information Technology (HIT) Policy Committee on generic usage and problem lists
- Reporting clinical quality measures

**The Role of the Pharmacist**

Within the proposed rule, there is no recognition of the important roles that pharmacists play in meeting meaningful use objectives. As CMS finalizes the rule, the agency should ensure that the role of the pharmacist is accurately represented and included.

The Society is concerned that the proposed rule does not accurately reflect the role pharmacists play in medication management and medication reconciliation.

Pharmacists meet patient care needs by providing medication management and, in states where it is authorized, collaborative drug therapy management. Collaborative drug therapy management is a multidisciplinary process for selecting appropriate drug therapies, educating patients, monitoring patients, and continually assessing outcomes of therapy. Pharmacists participate in collaborative drug therapy management for a patient who has a confirmed diagnosis by an authorized prescriber. The activities of a pharmacist in collaborative drug therapy management may include, but are not limited to, initiating, modifying, and monitoring a patient's drug therapy, ordering and performing laboratory and related tests, assessing patient response to therapy, counseling and educating a patient on medications, and administering medications.

Additionally, the Medicare Modernization Act of 2003 and its implementing regulations recognize pharmacists' participation in medication therapy management. Part D prescription drug plan sponsors are required to establish a medication therapy management program, provided by a pharmacist or other qualified provider, designed to optimize therapeutic outcomes for targeted beneficiaries by improving medication use and reducing adverse events.

Pharmacists should play a significant role in medication reconciliation. They are frequently responsible for coordination of interdisciplinary efforts to develop, implement, maintain, and monitor the effectiveness of the medication reconciliation process. Furthermore, pharmacists have a responsibility to educate patients and caregivers on their responsibility to retain an up-to-date and readily accessible list of medications the patient is taking. Pharmacists also assist patients and caregivers by assuring the provision of a personal medication list as part of patient education and counseling efforts.

In February, 2007, the pharmacy profession developed a shared workgroup vision about medication reconciliation as a responsibility of pharmacists caring for patients who transition from one sector of health care to another. The shared medication reconciliation definition that resulted from this workgroup follows<sup>1</sup>:

***Medication reconciliation is the comprehensive evaluation of a patient's medication regimen any time there is a change in therapy in an effort to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions, as well as to observe compliance and adherence patterns. This process should include a comparison of the existing and previous medication regimens and should occur at every transition of care<sup>2</sup> in which new medications are ordered, existing orders are rewritten or adjusted, or if the patient has added non-prescription medications to their self-care.***

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<sup>1</sup> ASHP-APhA Medication Reconciliation Initiative Workgroup Meeting, February 12, 2007, Summary and Recommendations. Accessed March 4, 2010:

[http://www.ashp.org/s\\_ashp/docs/files/MedRec\\_ASHP\\_APhA\\_Wkgrp\\_MtgSummary.pdf](http://www.ashp.org/s_ashp/docs/files/MedRec_ASHP_APhA_Wkgrp_MtgSummary.pdf)

<sup>2</sup> *The Joint Commission Home Care Standards Manual Glossary*; Definition of transfer: The formal shifting of responsibility for the care of an individual (1) from one care unit to another, (2) from one

***Medication reconciliation should be a patient-centered process, taking into account the patient's level of health literacy, cognitive and physical ability, and willingness to engage in his or /her personal health care. The goal of medication reconciliation is improvement in patient well-being through education, empowerment, and active involvement in the accurate transfer of medication information throughout transitions along the healthcare continuum. By promoting communication among patients and healthcare providers, medication reconciliation can resolve discrepancies in medication regimens and improve patient safety.***

***Medication reconciliation should be standardized across the continuum with a common set of data elements; such as prescriber, drug name, regimen, and allergies; that facilitate the efficient transfer of information among providers and patients. This data set should be established by an interdisciplinary group of practitioners, with the pharmacist serving as a key contributor in implementing medication reconciliation in the healthcare system.***

***Aspects of this definition were inspired by definitions published by The Joint Commission and the Agency for Healthcare Research and Quality.***

### **Clinical Decision Support**

Furthermore, CMS should consider broadening the proposed rule to include clinical decision support (CDS) that focuses not only on the prescribing and ordering of medications, but also on the administration and monitoring of medications as part of the electronic health record. Including these aspects ensures that medications are taken as prescribed and monitored to ensure effectiveness and prevent toxicity. These are key elements to maximizing the intent of using EHR to improve patient outcomes. Pharmacy information technology systems have a long history of CDS functionality that spans many implementation format types, including knowledgebase queries (e.g. for drug - pregnancy alerts) and rule engines. ASHP encourages CMS to consult with health-system pharmacists as it further develops CDS requirements. The Society believes that the requirements should consist of evidence-based application of CDS and universal requirements for core features such as medication allergy checking, dose checking, checking for contraindicated drug combinations, and the use of more advanced rules known to improve patient outcomes (e.g., order sets that adhere to evidence-based guidelines).

CDS relating to quality measures and demonstrating improved outcomes is potentially achievable across the entire medication use continuum. The format of CDS implementation (i.e. "implement five clinical decision support rules") relevant to specialty or high clinical priority areas should not be expressly stated as limited to "rules-based." There are many passive and active forms of clinical decision support that can be

incorporated into Computerized Prescriber Order Entry (CPOE) systems. We recommend that five applications of clinical decision support be demonstrated. For example, order sets are a form of CDS that are not rules-based, but when implemented in the CPOE system, evidence-based order sets have demonstrated improved quality and patient care outcomes.

### **Active Medication List**

#### ***Stage 1 Criteria for Meaningful Use, Health IT Functionality Measures, Eligible Professionals (EP)/Eligible Hospital Objective: Maintain Active Medication List***

In order for hospitals to meet this objective, CMS should define the term “active medication list.” ASHP suggests the following definition: An active inpatient medication list should contain the medications that have been prescribed by a provider for dispensing and administration in the care of the patient in a facility where patients routinely stay overnight. The medication list in most other environments of care consists of the home medication list. These two lists may differ based, for example, on reasons for admission to a facility or the facility’s formulary preferences. For an eligible provider, the “active medication list” is a listing of patient medications known by the provider to be prescribed (prescription medications), recommended (over-the-counter medications and/or herbal supplements), or attested to be used by the patient/caregiver/peer via an interview or clinical information exchange. This is conceptually different from the list of medications that have been electronically prescribed. Furthermore, until the United States Drug Enforcement Administration promulgates rules allowing electronic prescribing of controlled substances for ambulatory patients, there cannot be an active and complete medication list that is truly electronic in nature.

### **Recommendations by the Office of the National Coordinator’s HIT Policy Committee on Generic Usage and Problem Lists<sup>3</sup>**

The HIT Policy Committee recommends inclusion of an efficiency measure dealing with the use of generic medications. The recommendation states that all EPs should report to CMS the percentage of all medications, entered into the EHR as a generic formulation, when generic options exist in the relevant drug class. While ASHP agrees that reporting related to the use of generic medications should be included as an efficiency measure, the Society believes that the measure used should be the number of generic medications administered to patients, rather than the number of orders for generic medications. In a hospital that typically provides generic medications under the direct guidance of the Pharmacy and Therapeutics Committee, whether the brand or generic drug is ordered by the provider, the generic drug is provided to the patient per the hospital’s policy. So a measure that looks at the medication the patient actually receives, rather than what was ordered, is a more accurate measurement of the use of generic formulations.

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<sup>3</sup> HIT Policy Committee Recommendations, February 17, 2010, draft letter to David Blumenthal, MD, MPP, National Coordinator for Health Information Technology.

The HIT Policy Committee also recommends that EPs and hospitals should report the percentage of patients with up-to-date problem lists, medication lists, and medication allergy lists. In order to support quality of care and care coordination, key summary information must be maintained in the electronic health record. ASHP believes that managed and up-to-date medication lists and allergy lists are reasonable measures to show meaningful use of an EHR in Phase 1. These are critical elements for safe patient care and can be managed by multidisciplinary caregivers including pharmacists, physicians and nurses. However, up-to-date problem lists are not a well-accepted practice, even at hospitals that have well-utilized EHRs, and should not be included as part of the reporting requirement. Furthermore, there is no uniform standard for what should be contained in a problem list. We agree with the importance of an up-to-date and managed problem list, but demonstrating that the problem list is accurate will place an unnecessary and difficult requirement on hospitals. We believe this requirement should be moved to 2013 requirements or CMS should retain the metric at 80% with codified problem list documentation in 2011 and proceed with the “managed and accurate problem list” in 2013.

CMS should clarify that the problem list to be maintained, for example, during a hospitalization, may have local user interface terms and functionality that help identify patients for quality measures and reporting. This active problem list does not have to be natively coded with standards terminology, but is to be coded with standards at points of transmitting, e.g. sending a Continuity of Care Document (CCD) or quality measure reports, where the problem list needs to be coded using ICD9cm/10cm or SNOMED-CT for interoperability purposes.

### **Reporting Clinical Quality Measures**

#### ***Reporting on Clinical Quality Measures Using EHRs by EPs and Eligible Hospitals; Requirements for Submission of Clinical Quality Measures by EPs and Eligible Hospitals***

ASHP supports delaying full implementation of electronic reporting of quality measures until 2012, when the infrastructure to support this use will be available. ASHP encourages CMS to complete interim assessments of this reporting capacity to ensure completion by the target reporting date, and make these assessments available to the public.

#### ***Statutory Requirements and Other Considerations for the Proposed Selection of Clinical Quality Measures Proposed for Electronic Submission by EPs or Eligible Hospitals***

ASHP is pleased that CMS proposes to give preference to clinical quality measures endorsed by the National Quality Forum (NQF), as required under the Social Security Act, when selecting the clinical quality measures eligible hospitals and eligible

professionals must report in order to demonstrate meaningful use of certified EHR technology. However, ASHP is concerned that CMS will consider, and has proposed, measures that are not currently NQF endorsed in an effort to include a broader set of clinical quality measures. As a member of NQF, ASHP strongly recommends that CMS include only those measures that have been endorsed through the rigorous consensus-building process of NQF. ASHP disagrees with the Agency that measures that are not currently NQF endorsed should be included. Clinical quality measures developed by CMS, professional societies, or other stakeholders, even with a period of public comment, do not reflect or incorporate the robust and comprehensive process used to establish NQF endorsement.

***Proposed Clinical Quality Measures for Electronic submission by Eligible Hospitals***

CMS proposes to begin clinical quality reporting through attestation in the 2011 payment year, and then require clinical quality reporting electronically in 2012. ASHP recommends that, for 2011, CMS provide a standard for reporting measure information. ASHP further recommends that CMS identify a small group of five or six core measures already used for the Department of Health and Human Services' Hospital Compare, and include additional optional measures selected from the pool of available measures included in the proposed rule. Compensation could then be based on meeting the core measures, with additional compensation for hospitals that also meet additional optional measures.

***Proposed Reporting Method for Clinical Quality Measures for 2011 and 2012 Payment Year***

For 2011, CMS proposes to require that Medicare EPs and hospitals attest to the use of a certified EHR system to capture the data elements and calculate the results for the applicable clinical quality measures. For 2012, an EP or eligible hospital must submit summary information on the clinical quality measures selected by the Secretary using certified EHR technology in order to demonstrate their meaningful use of certified EHR technology. Additionally, CMS is proposing that EPs and eligible hospitals be required to electronically submit the summary information for a selected clinical quality measure using certified EHR technology. Regarding CMS's three proposed clinical quality measures data submission methodologies, currently, quality measures are identified and reported through hospital billing systems with ICD-9 codes assigned by medical records coders after the patient has left the hospital and the chart is closed. The current approach to quality measure reporting is retrospective versus a prospective approach that occurs after the patient is discharged. Transitioning this approach would be burdensome and may require additional time to implement. Billing systems may be separate from electronic health record systems, and medical records coders may not be able to code directly from the problem list that physicians are required to maintain.

ASHP is concerned about whether the data to identify patients for quality measure reporting will come from the billing system (which relies on diagnosis codes) or the EHR (which would be driven by the problem list). Data that comes from the EHR is more accurate, but the challenge of maintaining a complete and managed problem list may lead to identifying fewer patients than appropriate for a particular quality measure set. Reporting based on an active problem list that must be maintained is a challenge. For example, a patient may be admitted for a differential diagnosis of heart failure and COPD. Both diseases might be listed on the problem list, but the care record may indicate only treatment for heart failure. In this instance, which disease would drive the selection of quality measures for reporting? Additionally, it may be difficult to remove an item from a problem list.

ASHP recommends that CMS start with five measures sets if problem lists are used rather than using post discharge ICD- 9-CM coded charts. In the alternative, CMS could continue to use ICD-9-CM coded charges and transition to physician-managed problem lists once evidence exists that these problem lists are being actively populated and managed.

CMS should consider developing specific definitions and standards around the timing of the data that is to be collected in relation to the time intervals of orders and procedures. Important issues are, for example, the timing of the order for a prophylaxis in relation to the timing of the diagnosis, and the administration of a medication in relation to the confirmed or suspected diagnosis. Additionally, since there is no uniform format or standard for recording drug therapy (e.g., frequency, duration of dosing), CMS should consider developing standards around this type of recording.

The Society appreciates this opportunity to provide comments. Please feel free to contact me if you have any questions. I can be reached by telephone at 301-664-8702, or by e-mail at [jcoffey@ashp.org](mailto:jcoffey@ashp.org).

Sincerely,



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