Pharmacy e-Health Information Technology Collaborative

VIA Electronic Submission to http://www.healthit.gov/buzz-blog/from-the-onc-desk/hit-strat-plan/

May 6, 2011

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
Hubert Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Federal Health HIT Strategic Plan

Dear Dr. Mostashari:

Overview of the Pharmacy e-Health Information Technology Collaborative and Comments in Response to the Strategic Plan

On behalf of the membership of the Pharmacy e-Health Information Technology Collaborative (Collaborative), we are pleased to submit comments regarding the pharmacist's role in the Federal Health IT Strategic Plan (Strategic Plan) released on March 25, 2011 by the Office of the National Coordinator for Health Information Technology (ONC). Formed in the fall of 2010, the Collaborative's focus is to assure the meaningful use (MU) of standardized electronic health records (EHRs) that supports safe, efficient, and effective medication use, continuity of care, and provides access to the patient-care services provided by pharmacists with other members of the interdisciplinary patient-care team. The Collaborative's goal is to assure that the pharmacist's role of providing patient-care services is integrated into the National HIT interoperable framework. The group is pursuing EHR standards that effectively support the delivery, documentation of, and billing for pharmacist-provided patient care services across all care settings.

The Collaborative seeks to ensure that pharmacist-provided patient care services in all practice settings are represented in the MU of EHRs. 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, and a transaction processing network. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes three associate members from

other pharmacy related organizations. For additional information, visit www.pharmacye-hit.org.

As the comments below describe, pharmacists as meaningful users of EHRs will help collect data and provide clinical services in the five goal areas established by ONC to achieve the federal HIT agenda, including the targeted areas under goals I, IV, and V. Our comments focus on pharmacists' role in collecting data and providing clinical services to patients, with specific examples of pharmacists' successes in prevention of heart attacks, a key health care outcome identified by ONC in the Strategic Plan (but also other services identified as beneficial to many other disease states as well).[1] Specifically, the Collaborative requests that ONC use the Strategic Plan and other initiatives associated with the adoption of EHRs to:

- Foster and support current and new exchanges as per Goal I of the Strategic Plan. The Collaborative supports the inclusion of pharmacists as a component of the EHR information exchange, a component currently lacking. As described in our comments, use of pharmacists' clinical services help to reduce the incidence of heart attacks and stroke as a means to support Goal II of the Strategic Plan, i.e., information sharing and care coordination.

- Ensure that the Pharmacist/Pharmacy Provider EHR (PP-EHR) functional profile, as described below, be integrated with other certified healthcare EHRs, and to help achieve Objective I.B.3, ensure that health information exchange takes place across individual exchange models. The PP-EHR is a means to ensure medication related information provided by pharmacists is interoperable across different organizations. The Collaborative will assist the healthcare industry's adoption of the PP-EHR to ensure that policies and costs related to implementation are addressed.

- Incorporate pharmacist-specific quality metrics adopted by the Pharmacy Quality Alliance (PQA), including smoking cessation, blood pressure monitoring, and appropriate use of medications for the prevention of heart attacks, all of which support ONC's overall objective to reduce and prevent heart attacks. This can be augmented by information sharing that goes beyond medication information for purposes of electronic prescribing. Inclusion of pharmacists as meaningful users helps to achieve Strategy I.A.8, work with private sector payers and provider groups to encourage providers to achieve meaningful use, and Objective I.B of the Strategic Plan.

- Adopt the definition of medication reconciliation that includes pharmacists as supported by the Collaborative, the Joint Commission, and the Agency for Healthcare Research and Quality (AHRQ).

- Support new and innovative payment methodologies that reward pharmacists for

[1] Chislom-Burns, MA, Kim Lee, J, Spivey C *et al*. US pharmacists' effect as team members on patient care: systematic review and meta-analysis. MedCare 2010; 48(10): 923-33.

positive health outcomes associated with clinical interventions as described by Goal II, Objective C, demonstrate HIT-enabled reform of payment structures, clinical practices, and population health management. Pharmacists have already demonstrated success in implementing clinical programs in a variety of health care settings. These successes should be leveraged and expanded with the development of new programs.

- Ensure that pharmacists are identified as a key health care provider to provide patient medication information through EHRs consistent with Goal V of the Strategic Plan to achieve a learning health system that reduces heart attacks and unnecessary hospitalizations.

- Ensure the privacy and security of health information consistent with current standards, laws, and regulations.

Include Pharmacists as Meaningful Users of EHRs Consistent with Goal I to Foster and Support New and Current Exchanges

The Collaborative believes that the inclusion of pharmacists' clinical services is critical to achieving the new focus areas identified by the plan, including Goal I of the Strategic Plan that is to foster and support current and new exchanges.[2] The current federal HIT infrastructure limits pharmacists' exchange of information to electronic prescribing. Data elements exchanged through electronic prescribing systems are generally limited to minimal patient and provider information in addition to the information on the medications prescribed. Much more extensive clinical information is necessary for pharmacists to implement patient-care recommendations, however. To fully achieve the desired health outcomes of the federal Strategic Plan, ONC must consider the inclusion of pharmacists as a component of the EHR information exchange, which currently is not the case.

Pharmacists providing patient care services need a standard EHR to document and electronically exchange health information with other healthcare providers. For pharmacists to be meaningful users of the EHR, the Collaborative members worked with standard development organizations to develop the Pharmacist/Pharmacy Provider EHR (PP-EHR) functional profile. The PP-EHR was developed by a joint Health Level Seven (HL7) and National Council for Prescription Drug Programs (NCPDP) work group and it has been approved through the balloting process of both organizations.

The Collaborative will be working with the national EHR certification organizations and pharmacy system vendors to assure that the PP-EHR functionality is adopted, including the development of certification criteria to meet the MU of EHR concepts related to pharmacists using the PP-EHR in a meaningful way. As a means to meet objective I.B.3 and the goals of the

[2] ONC Federal Health IT Strategic Plan: 2011-2015. p. 9 (March 25, 2011). Available at http://www.healthit.gov/buzz-blog/from-the-onc-desk/hit-strat-plan/. Accessed April 10, 2011

standardization and interoperability framework,[3] the Collaborative recommends that the PP-EHR, once certification criteria are defined and the PP-EHR is certified by the nationally recognized EHR certification organizations, be integrated with other certified healthcare EHRs. The PP-EHR will support the exchange of clinical information (e.g., CCD), will leverage existing interoperability specifications (e.g., HITSP C83, ISO7 and ISO9), utilize existing standards (e.g. HL7 and NCPDP), and will support data flow that can be tested.

The Collaborative is prepared to assist in the healthcare industry's adoption of the PP-EHR to ensure policies and costs are addressed. The Collaborative is in the process of working with ONC and CMS to address policy, regulatory and legislative issues. For example, in March 2011, the Collaborative recommended that data requirements for medication therapy management services (MTMS) electronic transactions under Medicare Part D be incorporated into the "Standardized Format for the Comprehensive Medication Review Action Plan and Summary". This will assure that completion of the forms for the patient is driven off existing electronic data elements so that rekeying will not be necessary.

This recommendation is supported through American National Standards Institute (ANSI) Standard Development Organizations, including NCPDP, Accredited Standards Committee (ASC X12), and HL7 processes, to assure MTMS electronic standard transactions are developed. The Collaborative supports and works with these organizations to make certain data elements such as those in the proposed forms are populated from the "Pharmacist EHR" and/or other types of interoperable electronic systems. The Collaborative will assist in the facilitation of studies to demonstrate the cost savings attributed to the adoption of the PP-EHR by pharmacists in all practice settings.

Pharmacist-Focused Quality Metrics Are Aligned with ONC MU-related Quality Measures

As to ONC's overall health outcome goal of the reduction and prevention of heart attacks through the application of clinical and functional measures, a well documented body of clinical evidence shows that pharmacists' clinical services improve outcomes and reduce morbidity and mortality and, therefore, lends support to the need for pharmacists to be meaningful users of EHRs through the PP-EHR. Pharmacists often provide the services identified as measures to achieve clinical quality under the meaningful use objectives for heart attack, including smoking cessation programs and blood pressure monitoring.

PQA is an organization committed to improving health care quality and patient safety through a collaborative process aimed at defining pharmacy performance measures to improve medication use and medication-related services across the health care system. PQA has approved several pharmacy-specific quality metrics related to the prevention of heart attack among at risk patients and management of medication regimens in patients who have had a heart attack. Measurements include the proportion of days that patients 18 years or older who actually possess and receive certain medications for heart attack prevention for at least 80

[3] *Ibid*.

percent of the time in a given year and measuring gaps in therapy for the following medications: beta-blockers, angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARB), calcium channel blockers, and statins. (The use of statin medications for patients with coronary artery disease is currently being tested as a new potential measure.[4]) These measures are integrated into electronic systems to provide outcomes data. Integration of these measures into an EHR will help to improve outcomes and allow pharmacists to better collaborate with other members of the health care system to achieve that end.

The Collaborative supports the inclusion of information exchange that allows pharmacists to provide patient care and to exchange medication information beyond that available for purposes of electronic prescribing. While the Collaborative understands that funding is not currently available to provide pharmacists with incentive payments, this should be considered as an option for the future as ONC seeks to add other providers to the list of meaningful users consistent with Strategy I.A.8 and Objective I.B[5] of the Strategic Plan.[6]

Adopt the Definition of Medication Reconciliation Supported by the Collaborative, the Joint Commission, and AHRQ

The Strategic Plan identifies medication reconciliation through EHRs could significantly reduce the number of hospitalizations associated with adverse drug events and enhance data collection to help interpretation and identification of trends as a means to achieve heart attack reductions.[7]

Several members of the Collaborative have previously submitted recommendations regarding comprehensive medication reconciliation in response to the Centers for Medicare & Medicaid Services *Medicare and Medicaid Programs; Electronic Health Records Incentive Program*; *Proposed Rule* (42 CFR 412 *et al*) and the Department of Health and Human Services *Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule* (45 CFR Part 170) in March 2010. The Collaborative continues to support these recommendations, which also include components defined by the Joint Commission national patient safety objective goal #8 in 2005[8] and AHRQ. The definition proposed by several pharmacy organizations and supported by the Collaborative is:

> 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

[4] Pharmacy Quality Alliance available at http://www.pqaalliance.org/. Accessed April 10, 2011.
[5] *Ibid* at 2 p 14.
[6] *Ibid* at 2 p 13.
[7] *Ibid* at 2 p 9.
[8] Joint Commission website. Available at http://www.jointcommission.org/. Accessed April 11, 2011.

regimens and should occur at every transition of care 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.

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.

Pharmacist-Led Clinical Interventions Help to Improve Information Sharing and Care Coordination to Prevent Unnecessary Hospitalizations

Inclusion of pharmacists as meaningful users of EHRs will also help achieve ONC's Goal II of sharing information and care coordination to prevent unnecessary hospitalizations.[9] A key study demonstrating the positive benefit of pharmacists in preventing heart attacks is shown in the results from *ProjectImPACT: Hyperlipidemia* (Improve Persistence and Compliance with Therapy) sponsored by the American Pharmacists Association Foundation. This study demonstrates the positive outcomes associated with pharmacists' clinical interventions working in collaboration with physicians to achieve the goals of the National Cholesterol Education Program (NCEP) in 397 patients in 12 states with hyperlipidemia over the period of 1996-1999.[10]

Hyperlipidemia is a major cause of coronary artery disease (CAD) that leads to premature heart attack. Patients with elevated plasma levels of LDL are at increased risk for heart attack and 12 times more likely to die from heart attack or stroke than CAD patients with normal levels.[11] Patients enrolled in the study who received pharmacists' intervention showed a level of persistence and compliance with

[9] *Ibid* at 2 p 22.
[10] Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical Care Svcs and Results in ProjectImPACT: Hyperlipidemia. J Am Pharm Assoc 2000; 40:157-65.
[11] *Ibid*.

medication therapy of approximately 90% and by the end of the 24.6 month observation period, 62.5% of patients reached and maintained the NCEP lipid goals. Overall, patients experienced reduced LDL levels of 22.1% and HDL levels improved by 14%, resulting in a potential reduction in CAD of nearly 30-40% and thus an overall reduction in the potential for a heart attack requiring hospitalization.[12]

ProjectIMPACT and other studies demonstrate that the use of pharmacists' clinical interventions may help prevent unnecessary hospitalization for heart attack. Pharmacists' clinical services have also been shown to be effective for other chronic conditions and disease states. However, as suggested above, without incorporation as meaningful users of EHRs, the ability of pharmacists to make a true impact is greatly limited. Further, incorporation of PQA-generated measures as described above may help to achieve Goal II, Objective B to better manage care, efficiency, and population health through EHR reporting measures and reduced health disparities.[13]

The Collaborative also supports new and innovative payment methodologies that reward pharmacists for the positive health outcomes patients experience as a result of clinical interventions as described by Goal II, Objective C. For example, pharmacist-led programs (supported by physicians and nurses) have been developed to manage hyperlipidemia and other conditions, patient's medication regimens, and formulary compliance, thereby reducing drug costs and the number of hospital admissions. Often these programs are affiliated directly or indirectly with physician offices with the goal of helping physicians to better manage patient outcomes through pharmacists' interventions.[14] As the health care system moves to a system of rewarding value, the number of pharmacist-managed programs will likely grow because of their ability to manage costs and improve health care outcomes. Delaying the recognition of pharmacists as meaningful users of PP-EHRs could forestall the adoption of this important component of health care by years. Therefore, pharmacists should be recognized immediately as meaningful users of EHRs despite the lack of incentives available to them.

Today, pharmacists in a variety of practice settings obtain and document information related to medication persistence and adherence, blood pressure monitoring, blood glucose testing, and pulse monitoring which then must be distributed to patients and health care providers for purposes of tracking, follow-up, and regular monitoring through EHRs. Pharmacists currently do not have the ability to enter this information into an EHR, nor is it necessarily available to other health care providers if created and provided by pharmacists. Pharmacists often provide patient monitoring services for the purposes of creating a personal health record (PHR) maintained by patients. Collaborative members support the development

[12] *Ibid*.
[13] *Ibid at* 2 (Strategic Plan) p 23.
[14] Smith M, Guliano MR, Starowski MP. In Connecticut: improving patient medication management in primary care. *See also* Health Aff. 2011; 30:646-654 Snella KA, Sachdev GP. A primer for developing pharmacist-managed clinics. Pharmacotherapy 2003; 23(9).

of standard formats for the transfer of data from the PP-EHR to another EHR and/or PHR. This will promote reduced redundancy of information from multiple sources.

Pharmacists are easily accessible by individuals in all communities, including those that may not otherwise have access to other health care providers, which can mean reduced health care disparities. Pharmacists as meaningful users of EHRs would be able to provide more timely and accurate medication related information and suggest appropriate, cost-effective medication therapies. The transfer of data from the PP-EHR to another standard EHR or a PHR also facilitates medication reconciliation, particularly in transitions of care, by ensuring that medication lists are updated, accurate and comprehensive. Accurate, comprehensive medication lists will also help pharmacists and other health care professionals provide appropriate education and information related to patient-self management of treatment.

Pharmacists Should Provide Patient Medication Information Through EHRs and ONC's Proposed Health Learning System

Goal V of the Strategic Plan suggests that information about medication-related problems leading to heart attacks should be collected and reported to federal agencies for purposes of the creation of a learning system that helps to identify individual patients who are at greater risk for a heart attack because of a medication. Pharmacists often obtain up-to-date and comprehensive lists of active prescription and over-the-counter medications, herbal supplements, and vitamin products and possess the professional expertise needed to evaluate medication-related problems, including drug interactions. For these reasons, it is important that pharmacists actively engage in the exchange of information in EHRs to provide the most comprehensive and accurate assessment of patient medications.

Minimal standards for metadata associated tagged data elements are recommended for all EHRs used by pharmacists including the PP-EHR. The facilitation of mapping existing semantic taxonomies (e.g. ICD10) into tagged data elements and supporting the incorporation of the National Library of Medicine (NLM) codes including RxNORM into the EHR. Member organizations of the Collaborative are working with the NLM to establish standard clinical terms used to document pharmacist provided patient care services. These terms will be added to the NLM's Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) codes by developing a Medication Therapy Management (MTM) Value Set to supplement the MTM Current Procedural Terminology (CPT) codes. Pharmacists providing patient care services in all practice settings will use the MTM Value Set to facilitate tagging data elements to measure the MU of the PP-EHR.

The Collaborative:

1. Is aligned with standards development organizations' (HL7 and NCPDP) defined EHR functionalities used by pharmacists providing patient care services for exchanging clinical information with other healthcare providers and to patients using an electronic personal health record (PHR);
2. Supports the implementation specifications outlined by ONC for the adoption of the PP-

EHR by pharmacists providing patient care services in all practice settings;

3. Follows the certification criteria defined for the MU of the EHR for certifying the PP-EHR or other EHRs used by pharmacists providing patient care services including, but not limited to, MTM and immunization administration for patients in all practice settings.

Pharmacists are the appropriate providers to distribute educational materials to patients regarding medication problems. Federal law mandates that pharmacists distribute patient medication information materials, including Medication Guides and patient package inserts. Recently, the Food and Drug Administration has suggested that it will revise the system for distributing patient medication information, including by electronic means, and pharmacists are expected to continue to play a key role in the distribution of this information. If educational materials are distributed through an EHR and pharmacists do not have access to the EHR or the information related to educational materials received, patients may be inundated with multiple, duplicative educational materials that may result in confusion rather than beneficial understanding.

The Collaborative Supports Laws, Regulations and Initiatives to Ensure Privacy and Security of Patient Health Information without Restrictions to Pharmacists' Access

Finally, the Collaborative reiterates its support of all technological developments and policy actions related to the privacy and security of health data provided that pharmacists are recognized as providers of patient care services and are not limited by any provision exclusion, such as minimum necessary requirements.

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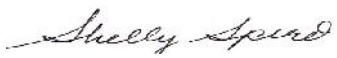
On behalf of the Pharmacy e-HIT Collaborative, thank you again for the opportunity to comment on the Strategic Plan and the work of ONC to establish the nationwide HIT infrastructure. As the process moves forward, the Collaborative urges you to consider the important role pharmacists play in achieving the clinical and functional objectives to meet meaningful use that results in improvement in patient care and outcomes. For more information, please contact Shelly Spiro, Director, Pharmacy e-HIT Collaborative at shelly@pharmacye-hit.org.

Respectfully submitted,



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