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April 4, 2007

Office of the National Coordinator for Health Information Technology
Attention: Medication Management Use Case
Mary Switzer Building
330 C Street, S.W., Suite 4090
Washington, DC 20201

Re: Medication Management Prototype Use Case

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Office of the National Coordinator for Health Information Technology's (ONC) request for feedback for the Medication Management Prototype Use Case (Prototype Use Case). ASHP represents pharmacists who practice in hospitals and health-systems. The Society's more than 30,000 members include pharmacists and pharmacy technicians who practice in a variety of health system settings, including inpatient, outpatient, home care, and long-term-care settings.

ASHP is pleased that the ONC is developing this use case, and providing an opportunity for review and feedback by interested stakeholders within both the public and private sectors. However, the Society is concerned that the Prototype Use Case does not accurately reflect the role pharmacists play in medication management and medication reconciliation. Our comments, which contain input from members of ASHP's Section of Pharmacy Informatics and Technology, are intended, in part, to assist in developing a Prototype Use Case that more accurately reflects the pharmacist's role in meeting the needs of patients.

Pharmacists meet the primary care needs of patients 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 also play a 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.

The comments that follow are intended to provide suggested language that can be incorporated into the Prototype Use Case to more accurately reflect the role pharmacists play in medication management, collaborative drug therapy management, and medication reconciliation. ASHP has also addressed other issues throughout the Prototype Use Case, including suggested language where appropriate.

2.0 Use Case Stakeholders

Clinicians - The working definition of "clinicians" should be modified to include pharmacists. Many pharmacists are health care providers with patient care responsibilities. They are credentialed personnel, privileged by the institution that employs them. Pharmacists that fulfill the Prototype Use Case working definition of clinician should therefore be included as clinicians, and the working definition of clinicians should be amended to read as follows: "Health care providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, pharmacists, and other credentialed practitioners with clinical privileges involved in treating patients."

Pharmacists - The working definition of pharmacists should be modified to recognize that pharmacists manage patient medication therapy, and are recognized as patient care providers. The working definition of pharmacists should be amended as follows: "Health professionals who are licensed to prepare and dispense medications in response to licensed clinician orders, as well as those who manage patients' medication therapy and provide related patient care and public health services. Pharmacists are recognized as patient care providers and sought out by patients to help them achieve the most benefit from their therapy."

Pharmacy Systems – The working definition of pharmacy systems should be modified as follows to include contraindication algorithms: "Electronic systems that support

pharmacists with their role in dispensing medication. For medication management, this includes systems that may be able to provide useful information on consumers' past medication history, and systems that contain contraindication algorithms, for example, drug-drug interactions.”

3.0 Issues and Obstacles

Medication Management Interoperability – The last paragraph of this section, page 8, should be modified as follows to include drug intolerances: “*Standardized terminology for allergies to medications, drug intolerances, and other allergies (e.g. foods).* Agreement is needed on the specific vocabulary(s), as well as exact data types within each vocabulary (e.g. Semantic Brand Name for RxNORM) to be used to document allergies and on the elements for accompanying information (e.g. nature of reaction, severity of reaction, and source of information).”

Clinical Decision and Support – This section should be modified to include indications: “One goal for managing medication information in EHRs is to enable an additional layer of patient safety by using clinical decision support tools that can support medication ordering by screening orders for contraindications such as drug-drug interactions, indications, and potential errors in dosing. Effective contraindication screening will be facilitated by tools that are supported by standardized vocabularies for describing medication, allergies, and indications. These barriers need to be overcome to realize the full potential of the use case for improving patient safety.”

4.0 Use Case Perspectives

Clinician – Many pharmacists are health care providers with patient care responsibilities. They are credentialed personnel, privileged by the institution that employs them. Pharmacists that fulfill the Prototype Use Case working definition of clinician should therefore be included in the clinician perspective.

This section should be modified as follows: “The clinician perspective includes health care providers with patient care responsibilities including physicians (and other credentialed practitioners such as physician assistants and pharmacists) who order medication and nurses (and others, including pharmacists) who play a role in medication reconciliation. Clinicians can also be referred to as “prescribers” when an activity is focused on the writing of orders or prescriptions.”

Pharmacist – Pharmacists should not be referred to as “dispensers.” The pharmacist perspective should be modified as follows to recognize that pharmacists manage patient medication therapy, and are recognized as patient care providers: “The pharmacist perspective includes health professionals who are licensed to prepare and dispense medications in response to licensed clinician orders, as well as those who manage

patients' medication therapy and provide related patient care and public health services. This perspective includes hospital pharmacists and pharmacists in institutional and community pharmacies. Pharmacists are recognized as patient care providers and sought out by patients to help them achieve the most benefit from their therapy."

5.1 Scenario 1: Inpatient Medication Reconciliation – The first bullet point should be amended as follows to include medication intolerances: "Gathering and documenting information on current medications, allergies, and medication intolerances."

Chart - Scenario 1: Inpatient Medication Reconciliation - The chart on page 13 should be amended to accurately reflect the flow of information from inpatient pharmacist back to clinician. An arrow should be drawn from 6.2.1 receive medication order back to 6.1.5 consider contraindication information, to more accurately reflect the flow of information from the inpatient pharmacist back to the clinician.

6.1.3 Perform medication reconciliation at admission - This section should be modified to include the following statement: "Patients with implanted medication infusion devices (eg. insulin, baclofen, opiates for pain) should be required to report these devices to their provider during the interview to ensure the patient does not suffer complications when admitted to the hospital."

6.1.5 Consider contraindication information – To contribute to medication safety, in addition to providers, pharmacists should have access to clinical decision support tools. The second sentence in this section should be amended as follows: "The hospital EHR can contribute to medication safety by providing clinical decision support tools that providers and pharmacists can use to reduce adverse drug events."

6.1.8 Write new discharge prescriptions – This section should include a process to inform the patient about which medications should be discontinued on discharge. Otherwise, a patient may continue taking old medications while also taking newly prescribed medications.

6.1.9 Provide information to the patient and next provider of care - New allergies identified during hospitalization must be communicated. The first sentence of the *Data Exchange* section should be amended as follows: "Discharge information, including the medication list, allergy information, new allergies identified during hospitalization, instructions and new prescriptions, is communicated to the patient, family members, patient advocate, and/or next provider of care."

6.2.1 Receive medication order – The section on *Data Exchange* should include more information regarding pharmacist review and actions taken. This section should be revised as follows: "An inpatient pharmacist receives medication orders, and reviews for contraindications. At this time, the pharmacist will take action to resolve any

contraindications or to clarify any problem with the medication order. The format and standards for this information flow could vary depending on the degree of integration between medication order entry and pharmacy systems.”

6.3.1 Self-report medication and allergy information – The last sentence of the second paragraph in this section should be revised to include intolerances: “Ideally, this information includes allergen, intolerances, type of reaction, and severity of reaction.”

The *Data Exchange* section should be revised to include medications that were previously unsuccessful in treating the patient. This section should be revised as follows: “Patient can self-report information on allergies and any medication use including prescriptions, over-the-counter medication, herbal and other supplements, and any medications that were previously unsuccessful in treating the patient.”

6.3.2 View medication and allergy information - The *Data Exchange* section should be amended as follows to include self-reported discontinued allergies: “Consumer can view information on allergies and medication. This includes previously self-reported items, as well as discontinued allergies, prescribed medication and allergy information that may come from information sources such as EHRs, PNIs, PBMs, and other systems.”

Chart – Scenario 2: Access to Current Medication and Allergy Information in an Ambulatory Care Setting – This chart should be amended to include “Section 7.3 Pharmacist” under Perspectives/Roles.

7.1.4 Review dispensing status of current medication – This section should provide the clinician with the ability to electronically access multiple formularies, so the clinician can know all available drugs in the same class that are covered under an insurance company’s formulary, and can write a prescription for the lowest priced drug. In the *Data Exchange* section, the following sentence should be added as the last sentence: “The clinician is also able to review multiple drug formularies when prescribing.”

A new section, **7.3 Pharmacist Perspective**, should be added.

Pharmacists have a role in meeting the primary care needs of patients by providing patient education, advice to prescribers, medication therapy management and, in states where it is authorized, through their expanded responsibilities in 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. When making decisions about patient care, pharmacists benefit from a complete view of the patient's current medication and allergies. It is therefore essential that the pharmacist perspective be included under Access to Current Medication and Allergy Information in an Ambulatory Care Setting.

8.13 Consider contraindication information – Clinicians may know that a patient has taken a drug previously, and that the patient is not allergic to it. Or the clinician may have specific reasoning for prescribing a non-traditional combination of medications, or non-formulary medication. The clinician should be provided with a place to comment on these situations in the drug profile.

8.2.1 Receive Prescription – This section should include a requirement that overrides related to clinical decision support are being sent to the pharmacist with the electronic prescription. This requirement will alleviate calls made back to the prescriber from the pharmacist tasked with filling the prescription. Standardization of the prescription's SIG also needs to be accomplished to further minimize errors.

8.3.1 Request Refills – This section should also include a statement that refill requests can be sent to the patient's provider from the patient's pharmacy. Often, patients do not realize they require a renewal or additional refills until they attempt to obtain the medication from their pharmacy.

Appendix A: Glossary

Page A-1 The definition of “clinician” should include pharmacists: “Health care providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, pharmacists, and other credentialed practitioners with clinical privileges involved in treating patients.”

Page A-2 Delete the term “dispensers” from the glossary.

Page A-2 The definition of dietary supplement should be added to the glossary: “A dietary supplement is a product taken by mouth that contains a ‘dietary ingredient’ intended to supplement the diet. The “dietary ingredients” in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders.”

Page A-3 - The definition of “pharmacist” should be modified as follows: “Health professionals who are licensed to prepare and dispense medications in response to licensed clinician orders, as well as those who manage patients’ medication therapy and provide related patient care and public health services. Pharmacists are recognized as

Office of the National Coordinator for Health Information Technology

Medication Management Use Case

April 4, 2007

Page 7

patient care providers and sought out by patients to help them achieve the most benefit from their therapy.”

ASHP appreciates this opportunity to respond to ONC’s request for feedback for the Prototype Use Case. Please feel free to contact me if you have any questions regarding these comments. I can be reached by telephone at 301-664-8702, or by email at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey

Director, Federal Regulatory Affairs