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March 12, 2010

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave., SW
Washington, D.C. 20201

Re: RIN 0991-AB58 – Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, Interim Final Rule

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Interim Final Rule (IFR). 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 pharmacists
- Adopted content exchange and vocabulary standards

The Role of Pharmacists

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

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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.

Within the IFR, there is no recognition of the important roles that pharmacists play. As the Office of the National Coordinator (ONC) finalizes the rule, the agency should ensure that the role of the pharmacist is accurately represented and included.

Adopted Content Exchange and Vocabulary Standards

Across all vocabulary standards mentioned in Table 2A, the provision of proof that content maintenance and structure follows good vocabulary practices should be required.¹ Comprehensiveness, concept permanence (i.e. stability of data values) and table-attribute structures are practices that are essential for achieving efficient and reliable coding that will result in intended patient care outcomes for the medication, problem, and allergy lists, etc. Local interface terms can be present in EHR for ease of documenting medication, problems, etc. The use of standards code sets is important for certain transmissions to achieve interoperability, however standard code sets do not replace interface terms.

Medication List: Designation of RxNORM's compilation of source terminologies in Stage I is a good interim solution while awaiting study and analysis by the National Library of Medicine of RxNORM, the source terminology (Stage 2). There are many important principles to be followed including concept permanence and status (e.g. active or retired) that require stable data structures, attributes and retirement/replacement identifier history information.

Medication Allergy List: ASHP recommends that the ONC adopt a standard to support meaningful use stage 1. The ONC and CMS should initiate pilot programs using preliminary standards before finalizing the standards for allergies. While the Unique Ingredient Identifier (UNII) is listed as the candidate standard to support meaningful use stage 2, the ONC and CMS should test the use of this standard before finalizing its use, and work with ASHP and others to formulate a comprehensive vocabulary standard for food and environmental allergies.

Designation of the UNII codes for Stage 2 is theoretically a more comprehensive list when compared to RxNORM source ingredients, drug ingredients, biologics, devices, and excipient ingredients since it is a molecular substance registration listing, yet it should be noted that allergy documentation is not the

¹ "Desiderata for controlled medical vocabularies in the twenty-first century," Cimino JJ. *Methods Inf Med.* 1998;37:394-403.

intended purpose of the UNII codes. The category of "Medication Allergy List" could, therefore, be changed to "Allergy List," which reflects this broader scope of UNII. However, if the intent is to focus only on the "medication allergy list," then the designate of RxNORM source terminology as the standard value set may be more relevant and usable (since it is being used for the medication list). ASHP recommends that the ONC design a comparison study on a real patient history data set. Since system translations of currently stored, allergy history content will need to occur across all systems, new cross-reference content will need to be made available through the Unified Medical Language System (UMLS) (similar to the availability of problem list SNOMED-CT to ICD9cm cross reference tables).

Additionally, ASHP believes that, even with a vocabulary standard for medication allergy information, the practice of documenting and over-alerting on non-allergy drug intolerance/idiosyncratic reaction history information will continue. There is a need to separate the clinical history information when possible, to accurately document the reaction manifestation details and interventions. These components are all essential for subsequent clinical decision support (CDS) allergy and intolerance alerts to be most relevant and not overridden.

ASHP recommends that the ONC, with other agencies, develop standard definitions and standards to support the concept of allergies, side effects, and reactions for use with allergy lists. This will allow for improved clinical decision support tools when allergy screening is implemented in electronic health records. Even something seemingly as straightforward as what is meant by drug-drug interaction, CDS is also somewhat vague since duplicate or overlapping therapies (e.g. opiate analgesics and other combination analgesics) or drugs with additive side effects (e.g. drug with additive anticholinergic effects or central nervous system effects, such as drowsiness) can be thought of as drug-drug interactions.² Intolerances and idiosyncratic reactions should be differentiated within these systems; however, current systems do not offer this level of customization.

No designation for allergen class concepts should be explicitly stated (i.e. the Veterans Affairs National Drug File Reference Terminology (NDF-RT) classes). ONC should support a collaboration to study the pros and cons of continuing to document "allergen class" e.g. penicillins, the terminology data set needed to support such a practice, and confusion regarding the reuse of various types therapeutic classification concepts that were not created for the purpose of allergy alerts.

Units of Measure: Stage 2 designates Unified Code for Units of Measure (UCUM). This designation, without some discussion relating to the type of entity information the units-of-measure are intended for, is out of context compared to the other vocabulary standards designations. Most individual vocabulary standards (e.g. RxNORM) will have their own relevant units of measure (e.g. dose form and strength units), which are maintained and created as part of the RxNORM solution with oversight by organizations such as the Institute for Safe Medication Practices (ISMP). UCUM is not a pool of the units of measure utilized within the RxNORM, LOINC, and SNOMED-CT terminologies. It is its own data set with a scope that includes engineering and business. Confusion will occur if UCUM is not more explicitly stated to be a value set for specific data elements or entities.

Drug Formulary Check: ASHP recommends that the ONC specifically note that the applicable Part D standard required by law (i.e. NCPDP Formulary & Benefits Standard 1.0) applies only in the outpatient and/or ambulatory setting, not the inpatient hospital setting.

Electronic Prescribing: Under adopted standard(s) to support meaningful use stage 1, the ONC identifies "any code set by an RxNORM drug data source provider that is identified by the United States National

² Issac T et al. Archive Intern Med. 2009;169:305-311.

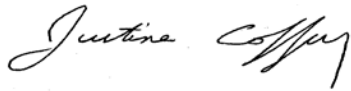
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Library of Medicine as being a complete data set integrated within RxNORM.” The ONC should clarify the definition of “complete” in this context.

Submission to Immunization Registries: HL7 Standard Code Set CVX is being designated in Stage 1. These codes are not currently included within the UMLS and therefore are not a source terminology within RxNORM. This data set should be included and can then be maintained and delivered via this standard mechanism.

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.

Sincerely,

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

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs