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May 29, 2015

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Office of the National Coordinator for
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**RE: 2015 Edition Health Information Technology (Health IT) Certification Criteria,
2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT
Certification Program Modifications**

Dear Dr. DeSalvo:

Established in 1943, the AAAAI is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We appreciate the opportunity to comment on policies outlined in the 2015 Edition Health Information Technology (Health IT) Certification Criteria proposed rule. Our comments focus on proposals related to medication allergy and pharmacogenomics data.

Medication Allergy

The information model for the allergy/intolerance list for an individual identifies that list as a compilation of conditions each of which represents a propensity of the individual to have an adverse reaction on future exposure to a specified substance. The list is often displayed as an index of those substances for this individual. Although the list most often includes those drugs, immunizations and biologicals that the individual has a history of adverse reactions to based on their unique sensitivity, when an individual has a prominent history of significant reactions to other substances, those are also documented in this list. Current EHR vendors routinely comingle various substances on the allergy/intolerance list. Some of these substances are of particular importance from a patient safety standpoint. These include latex or the materials in implantable devices, and others such as foods. The documentation of these conditions is critical because healthcare organizations typically provide nutrition to individuals in inpatient and residential facilities and because certain medications and immunizations contain potentially allergenic substances derived from food products. Restricting this list to medications represents a patient safety risk and deviates from an established norm of recording all allergy/intolerance sensitivities in the longitudinal record of an individual.

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Expecting that a new framework of clinical documentation should evolve as a quick solution to the challenge of encoding substances that an individual has demonstrated sensitivity to, is unreasonable.

Restricting the mechanism of reactions represented on the allergy/intolerance list to “immunologic reactions” is based on long outdated understanding of reactions and widely held misconceptions about the nature of many serious, sometimes life threatening reactions. Different individuals use the word “allergy” with different meaning; most clinicians and patients use the term to mean that an undesirable reaction happened on exposure to a specified substance and is expected to happen again if re-exposed. It is now understood that many reactions that have life threatening potential and have the appearance of an allergic reaction (based on IgE antibody) are in fact by non-immune mechanisms. Those reactions include life threatening reactions to aspirin and other NSAID drugs, ACE inhibitors, and most radio contrast media reactions. Perhaps more importantly, most documentation systems have provided only one list, the “Allergy List,” where significant reactions may be documented. The definition of the word has thus been generalized, even for those who may have a more in depth understanding of mechanisms.

Pharmacogenomics Data

Pharmacogenetic variants may predict significant variations in metabolism of one, or often more, drugs for an individual. The implications may be for toxic levels of a drug in that individual, toxic levels of drug metabolites, or even lack of efficacy because of rapid metabolism. These potential risks are not the equivalent of the unique sensitivity of an individual for a drug or group of related drugs based on that individuals’ history of a past reaction. A single pharmacogenetic variant may affect large numbers of drugs, which are unrelated in therapeutic indications or other grouping. Pharmacogenetic data should be recorded in laboratory value, since it is a laboratory determination, not a clinical observation, and not on an individual’s Allergy/Intolerance List. What is more, knowledge about the significance of different pharmacogenetic variants is evolving and current knowledge that may change should not be encoded in an individuals’ Allergy/Intolerance List. Such knowledge is properly located in the CDS service and only that data which is immutable, i.e. that an individuals’ particular genetic determinants, should be encoded in their record.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. We urge ONC to consider these concerns and address them appropriately in the final rule. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,



Robert F. Lemanske, Jr., MD FAAAAI
President