ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
9650 Rockville Pike. Bethesda, Maryland 20814
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

26 October 2015

Comments to FDA, CDC and NLM on Promoting Semantic Interoperability of Laboratory Data
Submitted via Regulations.gov (Docket No. FDA-2015-N-2372)

The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostic industry. AMP appreciates the opportunity to comment on the important issue of semantic interoperability of laboratory data.

AMP agrees with the intent of the FDA, NLM and CDC to make interoperability of laboratory interfaces with Electronic Health Records (EHRs) easier to implement. However, neither LOINC nor SNOMED CT are currently capable of handling genomic data. We fully support the comments from the College of American Pathologists (CAP) presented at the FDA workshop on Semantic Interoperability on September 28, 2015. In support of and in addition to these comments, we remain concerned about the following unintended consequences of using LOINC or SNOMED-CT in their current formats:

- The specific molecular genetic test method is not described for many molecular LOINC codes, and this has the potential to cause tests performed by non-comparable methods to be mapped to the same code. This is a serious patient safety issue when two different test methods generate results with completely different reference ranges, levels of detection and results. For example, in the situation where two laboratories have both mapped a positive result for their quantitative viral load polymerase chain reaction (PCR) test to LOINC code 4996-5 (Cytomegalovirus DNA [Presence] in Blood by Probe and target amplification method). The two laboratories use different nucleic acid extraction methods and target amplification methods and therefore generate a different range of results which generate completely different results for the same specimen. A patient's sample was sent to the first laboratory a month ago, and the follow-up sample was sent to the second laboratory because of insurance changes that happened during the interim. If both of these results are mapped to the same row in an EHR laboratory screen based on having the same LOINC code, then a provider will not know that the results cannot be compared. If the second result is significantly higher, the provider may think that the patient is having a recurrence and give them unnecessary treatment. If the result is the same or lower, then the provider may not realize that the patient is having a recurrence of CMV and not institute necessary therapy. More information on this

particular issue can be found in the published medical literature (http://cid.oxfordjournals.org/content/early/2012/02/27/cid.cis212.full).

- Because it appears from some LOINC codes in the LOINC database that LOINC intends to code specific test results, then we agree with the CAP that the scalability of LOINC in its current format is of serious concern. Currently, LOINC only has 1 million available test codes. There are 19,000 currently estimated human protein coding genes, and in each of these genes are thousands to hundreds of thousands possible variants. In addition, the specimen origin of the variant has clinical implications for diagnosis, prognosis and therapy, particularly for acquired variants found in tumors. There are hundreds to thousands of possible tumor types and locations. Encoding molecular results therefore would require multiple millions of LOINC codes. Neither the current code architecture nor LOINC staff will be able to keep up with this demand.

Given the above information, AMP recommends the following:

- If LOINC is to be used for coding test orders, we recommend that LOINC add a prefix or suffix to the code to make it recognizable as an order code rather than a result code. Using the same code for an order as well as a result has the potential to cause confusion and to make data harder to mine for quality and surveillance purposes.

- LOINC should avoid coding specific results of a test and instead focus on appropriate coding of the test that was performed which must include the specific method that was used. This is the only way to prevent the problem of tests performed by different methods being mapped to the same laboratory result row in an EHR.

- LOINC should focus also on appropriate coding of molecular test orders using methodless or method-based codes where clinically appropriate for the questions that the provider is trying to answer.

Again, AMP appreciates the opportunity to comment on this important issue. If you have any questions, please contact either Robyn Temple-Smolkin, AMP Director of Scientific & Clinical affairs (rtemple@amp.org) or Tara Burke, AMP Policy Analyst (tburke@amp.org).