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

May 19, 2015

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
Member
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Sent via e-mail: Cures@house.mail.gov

Re: Regarding the 21st Century Cures Act third discussion draft

Dear Chairman Upton and Congresswoman DeGette,

The Association for Molecular Pathology (AMP) would like to congratulate you on the recent release of the next draft of the 21st Century Cures Act. Thank you for the tremendous effort put forth on this important piece of legislation. AMP has worked with the Committee for over a year in anticipation of this bill and would like to provide the feedback below on the most recent draft.

Local Coverage Determinations

AMP is pleased that the Committee understands that Medicare administrative contractors' (MAC) local coverage determination (LCD) process should be both uniform across MACs and transparent. However, we are very concerned that important text that was included in the earlier draft has been removed from this draft that would have required MACs to 1) extend comment periods to 60 days for LCDs that would limit or preclude coverage, 2) convene a meeting of its Carrier Advisory Committee (CAC) to secure its advice for LCDs that would limit or preclude coverage, 3) hold meetings with stakeholders upon request, and most importantly, 4) prohibit MACs from adopting another jurisdiction's LCDs only if they have conducted their own public comment period, provided responses to these comments, and held a stakeholder meeting. We have previously provided an explanation of why a transparent LCD process is so crucial for ensuring that patients have access to lifesaving diagnostics. Those comments can be found here.

Section 3081 should be changed to require the following:

- MACs should be required to provide a notice and comment period of no less than 45 days;
- MACs should hold open, public meetings at which draft LCDs are reviewed and the MACs receive comments;
- CMS should create a mechanism to appeal coverage determinations. This should be done by removing the new evidence requirement and including in LCD reconsideration requests, the option of making an appeal to an uninterested body such as a CMS regional office, or the CMS Administrator.
- MACs should be required to meet with specialty societies impacted by their draft LCDs, not just members within their jurisdictions;
- MACs should facilitate participation in their CAC and other public meetings by allowing remote participation;

- MACs should be required to hold webinars open to the public on these draft policies when LCDs would limit or preclude coverage;
- MACs should be required to develop and maintain a listserv or web-portal listing all draft LCDs so they can be easily found by interested parties;
- LCDs that restrict coverage should address only single services (covered under a single CPT), not broad non-coverage policies. Furthermore, MACs should be required to identify services by CPT code and diagnoses by ICD code and should not use or require locally-developed identifier codes;
- MACs may not duplicate the regulatory activities of CLIA such as evaluating analytical validity of diagnostic tests in making coverage or payment determinations;
- MAC may adopt another MAC's policy only after holding its own CAC meeting and public comment process

Travel Policy

In order to advance precision medicine, molecular pathologists must be able to exchange emerging scientific findings, discuss new theories with other thought-leaders in the field, and explore new technological approaches at premiere conferences both locally and abroad. While we appreciate that the Committee understands the importance of travel to medical and scientific conferences (Sections 1025 and 2282), AMP feels that Congress can accomplish a great deal more to reduce the regulatory burden on Federal employees regarding this issue while at the same time allowing scientists and health professionals to have access to the important data shared at these conferences. AMP respectfully requests that nonprofit scientific and medical associations' meetings for which education is the primary goal, be exempted from a cap or restriction on federal employee travel. We recommend the following language:

"Scientific, medical, and technical conferences are exempt from caps or restrictions on Federal employee travel. A scientific, medical, and technical conference is defined as a gathering, symposium, seminar, workshop or any other organized, formal conference where scientists; engineers of science, technology, engineering and mathematics (STEM) research and development fields; or physicians and other health professionals assemble to present, coordinate, exchange and disseminate information and research; to explore or clarify a defined subject, problem or area of knowledge in the STEM fields; or for continuing medical education."

We understand the Committee has jurisdiction over only select agencies, thus we recommend at the very least that scientific, medical, and technical conferences are exempt from caps or restriction on Department of Health and Human Services employee travel.

Precision Medicine

We thank the Committee for Section 2041 which would require FDA to issue, and periodically update, guidance documents intended to help advance the clinical development of genetically targeted treatments. However, we urge the Committee to edit the line "the development of companion diagnostics in the context of a drug development program" as a topic that FDA would have to address via guidance. AMP recommends that "companion diagnostics" be replaced with "targeted biomarkers". The single test, single drug paradigm as described by the term "companion diagnostic," is obsolete as new technologies allow for the testing of multiple analytes simultaneously with greatly reduced per-analyte costs. AMP strongly recommends that the term "companion diagnostic" not be included in any legislation or regulatory policy. Optimized patient care relies on testing that evolves with new discoveries and technologies. The concept that the only appropriate test is the one co-developed with the drug, or developed with studies using likely unobtainable specimens from patients being treated with that drug, would hinder the application of new technologies and improvements to current tests over the decades the drug is in use and result in suboptimal patient care. An ideal tool to help ensure accuracy and reliability as tests and technologies advance is standard reference materials. AMP strongly recommends that standard reference materials be created for targeted therapies, whether produced in a public-private

partnership such as Pharma-NIST or through Pharma-funded private mechanisms. Furthermore, AMP believes that drug labels should not specify the brand name of diagnostic tests.

We also strongly urge the Committee to require that the FDA withdrawal any draft guidance documents that have not been finalized within one year of the draft's release.

Considering that precision medicine will revolutionize our approach to health and disease, and that data sharing will be instrumental as research is done to realize our collective goals in the area, we strongly suggest the following changes:

- Section 1141 – Council for 21st Century Cures – Under Sec. 281C, replace "representatives of the medical device industry" with "representatives of the molecular diagnostics testing industry."

Continuing Medical Education

AMP is fully supportive of the inclusion of Section 3041 which would clarify those peer-reviewed journals, journal reprints, journal supplements, and medical textbooks are excluded from the reporting requirement under the Sunshine Act. However, the language should be altered to explicitly state that all travel expenses, not just tuition, need to be exempted.

Once again, AMP appreciates the opportunity to provide these comments in response to the 21st Century Cures Act discussion draft. Please do not hesitate to contact Mary Williams, AMP's Executive Director, at mwilliams@amp.org if we may be of assistance or provide additional information.

Sincerely,

Janina Longtine, MD
President, AMP