THE CHAMPION

AMP update on U.S. policy issues affecting molecular diagnostics.

Vol. 3, No. 1, November 2016

PAMA Updates

The Centers for Medicare and Medicaid Services (CMS) released the long overdue Protecting Access to Medicare Act (PAMA) final rule in June of 2016. In the final rule, CMS delayed the effective date for the implementation of PAMA price setting for lab tests by one year, until January 1, 2018. Under PAMA, laboratories are required to report HCPCS laboratory codes, associated private payer rates, and volume data if they have more than $12,500 in Medicare revenues from laboratory services on the Clinical Laboratory Fee Schedule (CLFS) and receive more than 50% of their Medicare revenues from laboratory and physician services during a collection period. The first round of data reporting will begin in 2017 with initial reports due to CMS by March 31, 2017.

Details on registration and reporting procedures have begun to emerge from CMS. CMS recently released more information on data collection and reporting including a sub-regulatory guidance to laboratories for data collection and reporting and a clinical lab fee schedule reporting template. Additionally, CMS continues to update a document containing frequently asked questions to assist laboratories in navigating this process. All of this information is available at CMS's PAMA Regulations page: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html

If you are unfamiliar with the changes to the Medicare payment system required by PAMA, check out AMP's archived webinar titled "The Who, What, and When of the PAMA Final Rule" available here by clicking on "download archived webinars," located on the upper left side menu: http://amp.org/Webinars/2016.cfm

Mark Your Calendars:

On Wednesday, November 2, 2016 from 2:30pm to 3:30pm ET, CMS will hold a conference call on data reporting required by the new Clinical Diagnostic Laboratory Payment System final rule. To register, click here: https://blh.ier.intercall.com/details/0a732f5f0d834dd0965f79d7ce5d4d2d

The Economic Affairs Committee will host a session at this year's annual meeting on **Friday, November 11, 2016 from 7:00am-8:00am ET titled "PAMA is here: What Your Lab Should be Doing Today!"** and will include an overview of PAMA, PAMA data collection and reporting requirements, and information on operationalizing PAMA data collection and reporting at your institution. There is still time to register for the Annual Meeting. Click here for more information: http://www.amp.org/meetings/2016/registration.cfm

Advocacy News

On September 20, 2016, AMP participated in two events designed to help educate lawmakers and congressional staff about LDPs and the vital role they play in precision medicine and patient care. AMP co-hosted a briefing with the American College of Medical Genetics and Genomics (ACMG) and Infectious Diseases Society of America (IDSA). At the briefing, **Dr. Janina Longtine** represented AMP, presenting examples of how LDPs are vital in oncology clinical practice. **Drs. Sherri Bale and Angela Caliendo** also gave impactful presentations on the value of LDPs. **Dr. Karen Kaul** was a witness at the U.S. Senate Committee on Health, Education, Labor & Pensions (HELP) Hearing titled "Laboratory Testing in the Era of Precision Medicine," where she testified to the HELP committee about how LDPs are currently designed, validated, regulated, and used in a variety of clinical settings, specifically explaining the potential harms and benefits of additional LDP regulation that could be enormously disruptive to health care and likely have profound adverse consequences for patients across the country. To watch a recording of the hearing or to read the testimony of the witnesses, click here.

Throughout 2016, the Economic Affairs Committee (EAC) undertook a significant initiative to bring together molecular pathology experts and payers to discuss how traditional routes for establishing coverage apply to molecular procedures. An EAC subcommittee, led by **Dr. Sam Caughron**, planned and participated in an in-person meeting, held on May 11, 2016 in Chicago, IL, which aimed to identify opportunities for working together to ensure patient access to appropriate procedures. The one day gathering focused on discussion topics such as ideas for improvement of the current coding structure to better assist laboratories and payers, establishment of proper processes to ensure coverage policy that allows patients to receive appropriate testing, and determination of payment rates for molecular procedures and ways the laboratory community can assist. The EAC found tremendous value in the meeting and has hosted three subsequent virtual meetings with both private and Medicare payers. The conversations are an important opportunity for dialogue on critical issues and an ability for payers to provide input and feedback to AMP's efforts at improving the economic landscape for molecular testing. The EAC plans to build upon this engagement with payers in 2017.

On October 14, 2016, in light of the recent concerns regarding test performance characteristics of the Trioplex rRT-PCR (Trioplex) assay for the testing of Zika, dengue, and chikungunya, AMP worked with the American Society for Microbiology (ASM) and Pan-American Society for Clinical Virology (PASCV) in writing a letter to CDC regarding molecular testing for Zika virus. The letter urged CDC to increase transparency and communication about the Trioplex Assay and release data evaluating the test performance characteristics. AMP, ASM, and PASCV also asked that CDC release details of the DHHS investigation and EUA approval of the Trioplex assay. The letter went further, asking CDC to consider evaluating the Singleplex Zika assay for EUA approval and provide verification and implementation support to laboratories that adopt the Singleplex assay. Read the letter here

Recent Comment Letters

AMP Works with ASM, APHL, IDSA, and PASCV to Provide Joint Comments to FDA on Draft Guidance for Infectious Disease NGS-Based Diagnostic Devices

In June, FDA released a draft guidance for infectious disease NGS-based diagnostic devices. AMP collaborated with the American Society for Microbiology (ASM), Association of Public Health Laboratories (APHL), Infectious Disease Society of America (IDSA), and the Pan-American Society for Clinical Virology (PASCV) to develop comprehensive comments to FDA on this issue. The societies asked FDA to focus the guidance on agnostic testing, as it is particularly vital to infectious disease detection. The comments urged FDA to be flexible with regards to the review of ID NGS-based tests, expressed concern over the proposed requirement to use the FDA-ARGOS database, and stated the critical role of the laboratory and health care professional to ensuring proper test performance, and clear and timely communication of results. The societies submitted the comments in September. Read the comments here: http://amp.org/publications_resources/position_statements_letters/documents/ASM-AMP-APHL-IDSA-PASCV-IDNGSGuidancecomments-FDA-2016-D-0971-FINAL.pdf

AMP Submits Comments to FDA on Two Draft Guidances Related to NGS-based Tests for Hereditary Diseases

In July, to support the President's Precision Medicine Initiative, FDA released two draft guidances on NGS. The first draft guidance provides recommendations for designing, developing and validating NGS-based tests for rare hereditary diseases, and addresses the potential for using FDA-recognized standards to demonstrate analytical validity, which is how well a test predicts the presence or absence of a particular genomic change. The second draft guidance describes an approach wherein developers of tests for germline conditions may rely on clinical evidence from FDA-recognized public genome databases to support clinical claims for their tests and provide assurance of accurate clinical interpretation of genomic test results – an easier path for marketing clearance or approval. Subsequently, in September, FDA held a workshop to discuss both drafts. AMP provided both written and oral comments on these drafts, with **Dr. Madhuri Hegde** presenting AMP's oral comments. In the comments, AMP addressed specific questions asked by FDA and stressed that FDA focus its attention on helping to ensure the performance characteristics of NGS instruments, reagents, and related software. AMP emphasized that new regulatory initiatives must utilize an approach that is sufficiently flexible to readily accommodate the continual technological developments and exponentially increasing body of medical and scientific knowledge that characterizes NGS-based diagnostic tests in a timely manner. AMP submitted the comments in October. The comments are available here: http://amp.org/publications_resources/position_statements_letters/documents/AMPComments-Databases-NGS-FDA-2016-D-1233-FINAL.pdf and http://amp.org/publications_resources/position_statements_letters/documents/AMPComments-Standards-NGS-FDA-2016-D-1270.pdf

To view all of AMP's 2016 position statements and letters, visit:
http://amp.org/publications_resources/position_statements_letters/AMP2016PositionStatements.cfm

Meet AMP Advocates

Victoria Pratt, PhD

If you don't already know Dr. Victoria (Vicky) Pratt, you will likely see her in Charlotte as she is this year's Annual Meeting Program Committee Chair. Her AMP service does not end there! She has been intimately involved in AMP advocacy for many years and is currently a member of the Professional Relations Committee. Additionally, she serves as the AMP representative to the National Academies of Science, Health and Medicine Division, Roundtable on Genomics and Precision Health (aka The Academies), where she assists the Roundtable in dissecting critical scientific and policy issues to enable the translation of genomics into health care applications. Dr. Pratt advances molecular pathology economic affairs by serving on AMA's Molecular Pathology CPT Advisory committee and is the AMP nominee to CMS's Advisory Panel on Clinical Diagnostic Laboratory Tests. If you just thought "THAT's A LOT!"….That's because it is!

As one of the most active AMP advocacy volunteers, what would you say is the greatest accomplishment of AMP's advocacy committees in the last few years?

It is hard to pick just one AMP Advocacy accomplishment. AMP and its members are considered the go-to molecular pathology thought leaders on Capitol Hill and work hard to act rapidly to pressing issues. For example, last December, AMP responded quickly with a detailed rebuttal to FDA's report on 20 LDT case studies FDA claims may have caused harm to patients.

You obviously spend a lot of time volunteering for AMP and sharing with our community your knowledge and experience, what do you derive from these volunteer activities?

I think that decisions are made at high levels without completely understanding patients and what we as molecular professionals do for them each day. I hope that what I do gives a voice to our patients.

Do you have advice for those who are new to AMP and want to get involved?

Look on ChAMP for calls from PRC and EAC seeking assistance on current projects. The EAC especially is always looking for subject matter experts in specific areas to assist in responding to coverage policies. Feel free to reach out to committee members or staff to let them know you are interested in helping.

Coverage News

Effective October 13, 2016, the Medicare Administrative Contractor, Palmetto, updated the MolDx ***Genetic Testing for Lynch Syndrome*** *(LS)* local coverage determination (LCD) by removing age restrictions contained in the policy. Palmetto updated its policy to align with guidelines from the American Gastroenterologcial Association, National Comprehensive Care Network and others. AMP urged Palmetto to revise the policy to lift the age restriction to better align with standard of care. The previous Palmetto policy limited Lynch Syndrome genetic testing to a stepped approach to all patients diagnosed at ≤70 years of age, and those > 70 years who meet the revised Bethesda LS guidelines. The updated policy covers Lynch syndrome genetic testing for **ALL** patients with CRC, regardless of age.

The policy change will impact 25 states in the Palmetto, Noridian, CGS, and WPS Jurisdictions. To view the updated policy, click here.

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