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, 2017. Under PAMA, laboratories are required to report HCPCS codes and corresponding charges. CMS has set the lab fee, at $12,000 in Medicare revenues from laboratory on the Clinical Laboratory Fee Schedule (CLFS) and review more than 52% of their charges from laboratory to physician services during a certain 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 released new information on data collection and reporting including a sub-regulatory guidance to laboratories for data collection and reporting and released an FAQ on the CLFS 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 can be found on the PAMA Regulations page: https://www.cms.gov/Medicare/Provider- Payment-Compliance/FFS chỉnh/Patient-Access-to-Medicare-ACT-Rule-FAQs.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, Where, When and How of PAMA Final Rule” available here by clicking “Download archived webinar.” located on the left upper side menu. www.AMP.com/Webscasts/2016.png

Mark Your Calendars:

The Economic Affairs Committee will host a seminar at this year’s annual meeting on Friday, November 11, 2016 from 7:30am-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 on how to register for the Annual Meeting: http://www.amps.org/meetings/2016/registration.html

Advocacy News

On September 20, 2016, AAMP participated in two events designed to help educate lawmakers about issues affecting our lab personnel. On Capitol Hill, Senator Cory Booker (NJ) held a roundtable discussion on the importance of science education. The Senator was joined by members of the lab community in the fight against H.I.V. AMP had the opportunity to testify on behalf of clinical laboratory science (CLS) professionals on the importance of investing in our labs. Members of the lab community have been preparing for world-class cancer care on Capitol Hill, for the past several years. AAMP, the American Society of Microbiology (ASM), the American Society for Clinical Laboratory Science (ASCLS), the American Society for Clinical Pathology (ASCP), and the American Society for Lymphoma (ASL) advocated for increased federal funding for cancer research. AAMP is pleased to announce that the funding bill passed both the Senate and House of Representatives.

Recent Comment Letters

AMP Works with AAM, APSM, AHDA, 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 Diseases Society of America (IDSA), and the Public Health Laboratory Society (PHLS) to develop comprehensive comments to FDA on this issue. The societies asked FDA to focus the guidance on clinical testing, as it is particularly vital to infection disease detection. The comments urged FDA to be consistent with the revised exposure of clinical testing.

AMP Submits Comments to FDA on Two Draft Guidance Documents 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 NGS tests to provide actionable information for patients and providers. 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 written and oral comments on these deliberations. AMP also 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 allow an approach that is sufficiently flexible to readily accommodate emerging technologies and new innovations that characterize NGS-based diagnostic tests in a timely manner. AMP submitted the comments in October. The comments are available here: http://www.amps.org/publications_resources/positionStatements/documents/AMP-AMPM-NGS-PASCV-GNMS/document-submissions-FDA-2016-D0715_FINAL.pdf and http://www.amps.org/publications_resources/positionStatements/documents/AMP/AMPM-NGS-PASCV/GNMS/document-submissions-FDA-2016-D0807_FINAL.pdf

Coverage News

Effective October 13, 2016, the Medicare Administration Adaptable Contractor, Palmetto, updated the Modified Genetic Testing for Leukemia Cytogenetic (MGLC) fee schedule for Genetic Testing for Leukemia Cytogenetic (GLC) by removing age restrictions on coverage, thereby permitting further expansion of the service to beneficiaries aged 65 and older. Palmetto updated its policy to align with guidance from the National Coalition for Leukemia Gene Testing (NCLGT) which supports removing age restrictions. Palmetto, one of the nation’s largest independent laboratory medicine suppliers, is a sister company to Palmetto. The new policy is in line with current genetic testing for leukemia cytogenetic to its patients diagnosis of 200 years of age, and those 70 years who meet the Medicare benefit policy’s standard for having genetic testing for a stepaddwed to its patients diagnosis of 200 years of age. The new age restriction eliminates unnecessary limited reviews to assess in answering to coverage policies. Feel free to reach out to members of AMP or AMP to let us know you are interested in helping