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AMPlifications

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Reminder - the advance registration deadline for the following AMP events is Tuesday, October 20! AMP 2015 Annual Meeting

Molecular Pathology Outreach Course

International Showcase (free event - registration required) Science Educator Workshop (free event - registration required)

ADVOCACY



Advisory Panel on Clinical Diagnostic Tests: Established by the Protecting cess to Medicare Act (PAMA), the panel is to advise on various issues under PAMA including payment rates for various new tests, including whether to use

crosswalking or gapfilling processes; application of market rates for established tests; and evaluation and designation of tests as "advanced laboratory diagnostic tests" as defined by the Act. Several AMP members were selected for the panel. CMS convened the first meeting of the advisory panel on August

26, 2105. The purpose of the meeting was for the panel to make recommendations on new test codes for the 2016 CLFS. Aaron Bossler, representing both AMP and CAP, presented a detailed explanation of the rationale for crosswalk recommendations for the 2016 CLFS molecular pathology procedures and the new 2016 genomic sequencing procedures. The presentation is available here: http://amp.org/publications_resources/position_statements_letters/documents /2015CLFSMeeting-AMPpresentation-FINAL_000.pdf

The long overdue Protecting Access to Medicare Act (PAMA) proposed rule was released on September 25, 2015. AMP is currently reviewing the rule and will provide comments to CMS. The proposed rule is available here: https://s3.amazonaws.com/public-inspection.federalregister.gov /2015-24770.pdf

CMS released the Calendar Year 2016 Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations and the Final Gapfill Payment Determinations for Calendar Year 2015. New 2016 Molecular Pathology Procedure CPT codes were crosswalked to existing codes, while CMS proposed that new 2016 Genomic Sequencing Procedures undergo the gapfill process. For the 2015 gapfill final determinations, a handful of codes were priced, including a few genomic sequencing procedures codes. However many of the codes remain unpriced. Comments are due to CMS on October 26, 2015 and AMP will be providing comments. Members are encouraged to do so as well. The preliminary determinations are available here: https://www.cms.gov/Medicare /Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2016-Preliminary-Payment-Determinations.pdf

The gapfill payment determinations are downloadable here: https://www.cms.gov/Medicare /Medicare-Fee-for-Service-Payment/clinicallabfeesched/gapfill-pricing-inquiries.html

AMP continues to advocate with CMS regarding actions taken by Medicare Administrative Contractors (MACs). It is important that all AMP members be aware of draft LCDs, articles, and other policies in their jurisdictions that could restrict patient access to testing. Tara Burke, AMP's Policy Analyst, distributes on CHAMP new draft LCDs regarding molecular tests. Be alert also for notices directly from your MAC. Communicate your concerns directly to your MAC Medical Director, contact information may be found at: https://www.cms.gov/medicare-coverage-database /indexes/contacts-part-b-medicare-administrative-contractor-index.aspx?bc=AgAAAAAAAAAAAA

Next Generation Sequencing (NGS) Reimbursement: AMP officially released the micro-cost and health economic models in March 2015 with over 400 downloads thus far. We hope members are utilizing these models to accurately calculate the cost of their NGS services and, therefore, effectively communicate value and cost to payers. AMP is currently conducting a survey It is important that all who download the models complete this survey so we can determine use of the models and outcomes. The models and supporting materials are available here: http://amp.org /committees/economics/NGSPricingProject.cfm

Proposals for Oversight of Laboratory-Developed Procedures (LDPs): On August 4, AMP met with Senate HELP Committee staffers and presented AMP's Proposal for Modernization of CLIA Regulations for Laboratory Developed Testing Procedures (LDPs). AMP's proposal keeps authority of oversight of all LDPs under the CLIA regulations. AMP continues to provide expertise to assist Hill staff as they tackle this complex issue and continues to meet with the larger community of stakeholders to discuss the proposal. Roger Klein has been conducting numerous press interviews on AMP's proposal. Download the proposal and read recent press articles here: http://amp.org/advocacy/CLIAModernization.cfm

AMP co-organized the plenary keynote session at the Next Generation Dx Summit in Washington, DC on August 19, 2015. The session titled "In the Best Interest of the Patie Balancing Innovation and Regulation" discussed how innovative diagnostics can thrive with both appropriate regulation and quality results. The session was moderated by Elaine Lyon with panelists Jamie McDonald, Jordan Laser and Stephen Day. The video recording of this session is available here: https://www.youtube.com/watch?v=TNUbB2hayxk

ADDITIONAL OPPORTUNITIES AT AMP 2015



Will you be in Austin for AMP 2015? If you plan to attend and you're either new to AMP or new to the meeting, please join the specialty luncheon hosted by the Membership Affairs Committee on Thursday, November 5.

If you plan to be at AMP 2015 and are early in your career and/or interested in being of service at AMP, join the AMP Membership Affairs Committe and Chairs

EDUCATION



Registration is now open for our fall Webinars: October 22: Informatics 101 - Leveraging the Electronic Health Record to Implement Genomic Medicine presented by Marc S. Williams, MD. To register go to: https://attendee.gotowebinar.com/register /1579437826824315649

Help guide the T&E Committee in planning future educational projects by taking the 2015 Educational Needs Survey at https://www.surveymonkey.com /r/AMP2015EducationSurvey. Results will be discussed at a special luncheon on Thursday, November 5

Registration is now open for the Training & Education Committee's two special educational events both being held on Wednesday, November 4th in Austin, Texas:

 <u>The Molecular Pathology Outreach Course</u> targeting pathologists, residents, laboratory directors and technologists who have little experience with or those who want a refresher on the fundamentals of molecular diagnostic testing.

New! <u>Science Educator Workshop</u> targeting high school and college science teachers who live and/or work in the vicinity of Austin, Texas.

Selected case studies involving international collaborations will be presented at the new International Showcase Event hosted by the AMP International Affairs Committee, to held on Wednesday, November 4th. Registration for the event is now open.

The T&E Committee is hosting three specialty luncheons at the Annual Meeting: • Identifying the Educational Needs of AMP on Thursday, November 5

 Molecular and Medical Laboratory Technologists Luncheon on Friday, November 6 Annual Trainee Luncheon on Friday, November 6. Textbook donations are being solicited for this event! Contact ampeducation@amp.org

AMP's educational collaborations continue with other organizations such as: •CAP'15 (October 4-7)

Two short courses will be presented by AMP speakers: Beyond Single Gene Analysis: Paving the Way to Comprehensive Tumor Genomic Profiling, presented by Neal Lindeman & Lynette Sholl and

, Sequence Gazing: Variant Calling and Interpretation for Next-Generation Sequencing, presented by Eric Duncavage & Ian Hagemann

2015 ASCP (October 28-30)

AMP T&E Committee members Nilesh Dharajia and Cecilia Yeung will present a Molecular Diagnostic Primer for Technologists

•Online Monthly (free): ASCO/CAP/AMP Molecular Oncology Tumor Board Case Study Series. Go to http://university.asco.org/motb to review the case study of the month and post your comments on the discussion board. Previous months' topics included Ovarian cancer, Prostate cancer and Acute Myeloid Leukemia.

For an up-to-date listing of AMP at associated meetings, visit: http://www.amp.org/meetings /associated/index.cfm

INNOVATION & IMPROVED PATIENT CARE



MP is pleased to again host the annual Reference Material Forum on Tuesday November 3 in Austin, Texas, This event is an open forum organized by Lisa Kalman prior to the AMP 2015 Annual Meeting, but attendance space is limited. To register & attend, please send an email to Lisa Kalman. Further details and agenda are available at http://www.amp.org/meetings /2015/ReferenceMaterialForum.cfm

John Pfeifer has been appointed to the AMP Development of Analytical Validation Standards for Next-Generation Sequencing (NGS) Detection of Somatic Variants Working Group. "Next Generation Sequencing for Infectious Disease Diagnosis and Management: A Report of

AMP" was released online ahead of publication in The Journal of Molecular Diagnostics. Congratulations to authors Martina Lefterova, Carlos Suarez, Niaz Banaei and Benjamin Pinsky! This project was jointly supported by AMP's Clinical Practice Committee and Infectious Diseases Subdivision Leadership.

The Clinical Practice Committee of AMP will be hosting two Specialty Lunch sessions and two workshops at the AMP 2015 Annual Meeting. Please mark your calendars to attend the sessions that interest you. We look forward to seeing you in Austin!

AMP launched the Variant Interpretation Test Across Labs (VITAL) project building on the publication of the "Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of ACMG and AMP" manuscript to evaluate incorporation of the recommendations into clinical practice. Elaine Lyon, Carolyn Sue Richards, Madhuri Hegde, Julie Gastier-Foster and Sherri Bale were appointed to the project workgroup. This AMP project is funded by an unrestricted educational grant by QIAGEN, Inc. Details describing how you can volunteer to participate in the study will be coming soon!

The AMP Annual Meeting is a great opportunity to reach out to your AMP leadership! Please visit

of other AMP Committees for the Early Career - Pathway to AMP Service Luncheon on Saturday, November 7.

AMP's <u>Clinical Practice Committee</u> or <u>Subdivision Leadership</u> webpages to identify these leaders and for more information on AMP initiatives.

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