



AMPlifications™

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ADVOCACY



Palmetto: AMP responded to a new policy by Palmetto entitled "[Analytical Performance Specifications for Comprehensive Genomic Profiling](#)". AMP expressed numerous serious concerns including circumvention of the local coverage determination (LCD) process, strict testing limitations, and a prohibition against PhD scientists, which is in direct violation of the Social Security Act and CMS' regulations in both CLIA and the PFS. AMP's letter to Palmetto is available here: [http://amp.org/publications_resources/position_statements_letters/documents/AMPResponsetoM00118-](http://amp.org/publications_resources/position_statements_letters/documents/AMPResponsetoM00118-V1_FINAL.pdf)

[V1_FINAL.pdf](http://amp.org/publications_resources/position_statements_letters/documents/AMPResponsetoM00118-V1_FINAL.pdf)

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. **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=AgAAAAAAAAAA&>

In collaboration with CAP, AMP recently responded to numerous draft LCDs issued by various MACs. To view our recent responses please visit:

http://amp.org/publications_resources/position_statements_letters/AMP2015PositionStatements.cfm

Clinical Lab Fee Schedule (CLFS) Meeting: **Aaron Bossler** represented AMP at the annual CLFS meeting at CMS on July 16, 2015. He presented crosswalk recommendations for the 2016 CLFS molecular pathology procedures, 2015 molecular pathology and genomic sequencing procedure reconsiderations, and the new 2016 genomic sequencing procedures. AMP's recommendations were very well received and endorsed by other organizations such as AACC and CAP. AMP's CLFS crosswalk recommendations are available here:

http://amp.org/publications_resources/position_statements_letters/documents/AMPCommentsonCLFS-CY2016-FINAL.pdf

Preliminary Gapfill Determinations: AMP provided comments to CMS on the preliminary gapfill determinations of several molecular pathology and genomic sequencing procedures. AMP's comments are available here:

http://amp.org/publications_resources/position_statements_letters/documents/AMPCommentsonPreliminaryGapfill2015-FINAL.pdf

Next Generation Sequencing (NGS) Reimbursement: AMP officially released the micro-cost and health economic models in March 2015. With **almost 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. Hampering the success of pricing efforts is emerging non-coverage decisions for multi-gene sequencing assays, this continues to be a major advocacy focus in 2015. AMP is currently conducting a survey on downloaders to gather information on how laboratories are using these models. The models and supporting materials are available here:

<http://amp.org/committees/economics/NGSPricingProject.cfm>

Jill Hagenkord submitted **CPT code change proposals** to AMA for cardiac channelopathies and inherited cardiomyopathy on behalf of AMP on July 8, 2015.

Proposals for Oversight of Laboratory-Developed Procedures (LDPs): To assist in discussion efforts about the various proposals circulating in Congress, AMP created a "**Principles for Oversight of Laboratory Developed Procedures**" which serves a checklist for any proposals or legislation that address regulation of LDPs. The checklist is available here:

<http://amp.org/advocacy/documents/PrinciplesforOversightofLaboratoryDevelopedProcedures-FINAL.pdf>

In June, **AMP provided comments to the House Energy & Commerce Committee on Draft Legislation on the Regulation of In Vitro Clinical Tests.** AMP does not support this legislation and the comments summarize our concerns. AMP maintains that Laboratory Developed Procedures (LDPs) are professional services and thus are very distinct from distributed tests. Additional concerns include inappropriate risk classification, inadequate updates to CLIA regulations, and increased regulatory burden on and product liability to laboratories and medical professionals. AMP's comments are

EDUCATION



Registration is now open for these summer webinars:

August 19: Informatics 101: Data Viewing IGV (Integrative Genomics Viewer - Broad Institute), presented by Ahment Zehir, PhD

September 9: Informatics 101: Applications for Clinicians and Research Models, presented by Eric W. Klee, PhD

September 10: NGS 101: An Integrated Approach to Assay Selection and Validation, presented by Avni B. Santani, PhD

To register for an AMP Webinar, visit http://www.amp.org/Webinars/future_webinars.cfm.

Abstract notifications for the AMP 2015 Annual Meeting were sent to corresponding authors on July 16th. Find poster information at <http://www.amp.org/meetings/2015/posters.cfm> or contact ampeducation@amp.org.

The Training & Education Committee is presenting **two special educational events**, both being held on November 4th in Austin, Texas:

- The [Molecular Pathology Outreach Course](#) 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.
- A new [Science Educator Workshop](#) 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 **Annual Trainee Luncheon** will be held on Friday, November 6th. Textbook donations are being solicited for this event! Contact ampeducation@amp.org

AMP's educational collaborations continue with organizations across the world, such as:

- August: **The 2nd International Symposium on Personalized Medicine** (Sao Paulo, Brazil)
- August: **Cambridge Healthtech Institute's Next Generation Dx Summit** (Washington, DC)
- September: **2015 Korean Society of Genetic & Molecular Diagnosis Meeting** (Seoul, South Korea)
- September: **Beaumont Annual Symposium on Molecular Pathology** (Troy, Michigan)
- October: **CAP '15 The Pathologists' Meeting** (Nashville, TN)
- October: **2015 American Society for Clinical Pathology** (Long Beach, CA)
- 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 Colorectal cancer, Ovarian cancer and Prostate cancer.

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

available here:

http://www.amp.org/publications_resources/position_statements_letters/documents/AMPcommentsonECDiagnosticDraftBill-FINAL.pdf

On June 22, AMP met with Senate Health, Education, Labor, and Pensions (HELP) Committee staffers comprised of the LDT working group to discuss the oversight of diagnostics. The working group formed in order to begin the process of drafting legislation focused on regulating LDPs. Drs. **Janina Longtine, Roger Klein, Eric Konnick, and Cindy Vnancak-Jones** participated in the meeting. AMP members answered questions and helped educate staffers on many aspects of laboratory practice such as where labs get their samples, how testing procedures are developed, and how many testing procedures are performed each year.

AMP continues to provide expertise to assist Hill staff as they tackle this complex issue. 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). The proposal is a product of the CLIA Modernization Workgroup of the Professional Relations Committee (PRC). In developing this proposal, AMP reached out to other professional associations and received very useful comments, and were able to incorporate most of them. AMP continues to dialogue with the larger community of policymakers and stakeholders. The proposal is available here: <http://amp.org/advocacy/documents/AMPCLIAmodernizationproposalFINAL.pdf>.

Genetic Information Nondiscrimination Act (GINA): AMP joined over 60 other organizations in a letter to the Equal Employment Opportunity Commission (EEOC) on the EEOC Proposed Rule expressing concern that the Proposed Rule regarding the Americans with Disabilities Act (ADA) would erode long-standing and important protections afforded to employees under the ADA and would pave the way for weakening the GINA. The letter is available here: http://amp.org/publications_resources/position_statements_letters/documents/AdvocateSign-onletterreEEOCNPRMonwellnessprogramsandtheADA.pdf

“The evolving role of the laboratory professional in the age of genome sequencing: A vision of the Association for Molecular Pathology” by **Iris Schrijver** et al. was published in the July issue of JMD. The AMP paper describes the current and future roles of the laboratory professional as genomic sequencing analysis becomes an ever more increasingly important tool in diagnostic medicine. The paper is available here: <http://jmd.amipathol.org/article/S1525-1578%2815%2900071-9/abstract>

OPPORTUNITIES FOR YOU



The deadline to apply to serve on the AMP Membership Affairs Committee is August 31. Trainees and members with an interest in infectious disease and informatics are encouraged to apply. Visit http://www.amp.org/Get_Involved/volunteer_at AMP.cfm for details and to apply today.

The deadline to submit a case report for possible publication in CAP TODAY is August 31. Take advantage of this opportunity to display your expertise, be of service to AMP and gain visibility among thousands of your colleagues! Visit http://www.amp.org/publications_resources/documents/CallforCaseReviewsV4.pdf for details.

INNOVATION & IMPROVED PATIENT CARE



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The Journal of Molecular Diagnostics has published *The Evolving Role of the Laboratory Professional in the Age of Genome Sequencing: A Vision of the Association for Molecular Pathology*, a manuscript developed by the AMP Whole Genome Analysis Working Group of the Clinical Practice Committee and the 2013-2014 Executive Committee. The project was led by **Iris Schrijver**; additional manuscript authors are **Daniel Farkas, Jane Gibson and Elaine**

AMP is hosting a Reference Material Forum, organized by Lisa Kalman, on Tuesday November 3 in Austin, Texas. There is no registration fee for this open forum meeting prior to the AMP 2015 Annual Meeting, but space is limited. To register, please send an email to [Lisa Kalman](mailto:Lisa.Kalman@amp.org). If you are interested in presenting at the Reference Materials Forum, please send an email with a brief description for consideration to Lisa Kalman. Submission deadline is August 21, 2015. A final agenda will be posted by November at <http://www.amp.org/meetings/2015/ReferenceMaterialForum.cfm>

Maria Arcila, Christopher Corless, Suzanne Kamel-Reid and Ira Lubin have been appointed to the **AMP Development of Analytical Validation Standards for Next-Generation Sequencing (NGS) Detection of Somatic Variants Working Group**. AMP members serving as CAP liaisons to the project are Mark Routbort and Karl Voelkerding.

The Interpretation of Sequence Variants in Somatic Conditions Work Group welcomes liaison members **Neal Lindeman** and Michael Datto (CAP), Lia Tsimberidou and Anas Younes (ASCO), Shashikant Kulkarni and Dayna Wolff (ACMG). **Neal Lindeman, Michael Datto, Shashikant Kulkarni and Dayna Wolff** are AMP members.

Have a great idea for a future AMP project? Please contact any of AMP's Clinical Practice Committee http://amp.org/committees/clinical_practice/members.cfm or Subdivision Leadership <http://amp.org/subdivisions/index.cfm> representatives!

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