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# AMPlifications™

Vol. 21, No. 2, June 2015

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## ADVOCACY



**Next Generation Sequencing (NGS) Reimbursement:** AMP officially released the micro-cost and health economic models in March 2015. With **over 200 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, so this will be a major advocacy focus in 2015. The models and supporting materials are available here:

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

**Medicare Administrative Contractors:** In 2015, AMP has responded to numerous problematic draft LCDs from Palmetto and other Medicare Administrative Contractors. A flurry of draft LCDs were released in late May and AMP will continue to comment on various draft LCDs over the summer. Additionally, AMP continues to advocate regarding the Palmetto MBDX coverage and payment policies, which are influencing coverage policies in other Medicare jurisdictions as well as private payers.

The CMS will hold its annual **Clinical Lab Fee Schedule** meeting on July 16, 2015. AMP will have crosswalk recommendations.

**Proposals for Oversight of Laboratory-Developed Procedures (LDPS):** AMP submitted written comments to FDA on this proposed regulation, comments are available here:

<http://amp.org/advocacy/documents/FDAcommentsonLDTGuidance-FINAL.pdf>. AMP continues to monitor any activity and advocate for laboratory professionals on Capitol Hill regarding oversight of LDPS. To assist in lobbying efforts, AMP created a "**Principles for Oversight of Laboratory Developed Procedures**" which serves a checklist for any proposals or legislation that attempts to regulate LDPS. The checklist is available here: <http://amp.org/advocacy/documents/PrinciplesforOversightofLaboratoryDevelopedProcedures-FINAL.pdf>

In May, AMP provided comments to the House Energy & Commerce Committee on the third draft of the **21st Century Cures bill**. The bill did not include any proposed legislation on LDPS but AMP provided comments on the Medicare Local Coverage Determination process, federal travel, companion diagnostics, and continuing medical education. The comments are available here:

[http://amp.org/publications\\_resources/position\\_statements\\_letters/documents/AMPComments3rdraftof21Cures-FINAL.pdf](http://amp.org/publications_resources/position_statements_letters/documents/AMPComments3rdraftof21Cures-FINAL.pdf)

Keep an eye out for "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. in the July issue of *JMD*.

**March Hill Day Recap:** AMP met with the Senate Health, Education, Labor, and Pensions (HELP) Committee, the House Committee on Energy & Commerce (E&C), and four Congressional offices engaged in the issue regarding the regulation of diagnostics. The goals of the meetings were to either establish or strengthen relationships in anticipation of potential legislation on the oversight of laboratory developed testing services, to discuss AMP's position, and to evaluate the offices' response to proposed regulatory framework for all *in vitro* clinical tests.

AMP continues its work with in coalition with ACMG, CAP, AMA and others to address oversight of LDPS, and coverage and reimbursement issues.

## AMP AT WORK FOR YOU

**Thank you for your feedback!** We received great responses from AMP members who completed the 2015 Member Survey. Look for a special message from the Membership Affairs Committee (MAC) Chair, **Nirali Patel**, later this month.

The MAC will also be seeking volunteers to serve as committee members starting in November 2015. Look for a **call for volunteers** later this month.

The Publications and Communications Committee will be launching a **call for case reports** later this month. Look for the announcement on CHAMP.

## EDUCATION



**Welcome to the German Society of Pathology (DGP), AMP's newest International Affiliate!** <http://www.pathologie-dgp.de>

**Congratulations to the International Affairs Committee (IAC),** which transitioned from an AMP working group to an ad hoc committee in May.

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

- June: 2015 Korean Society of Genetic & Molecular Diagnostics Annual Meeting (Seoul South, Korea)
- August: The 2nd International Symposium on Personalized Medicine (Sao Paulo, Brazil)
- August: Cambridge Healthtech Institute's Next Generation Dx Summit (Washington, DC)
- September: Beaumont Annual Symposium on Molecular Pathology (Royal Oak, MI)
- Online Monthly: ASCO/CAP/AMP Molecular Oncology Tumor Board Case Study Series (free). 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 Chronic Lymphocytic Leukemia, ROS1 Rearrangement, and Colorectal Cancer.

For an up-to-date listing of AMP at associated meetings, visit:

<http://www.amp.org/meetings/associated/index.cfm>

Registration is now open for these summer webinars:

- June 18: Next-Generation Sequencing (NGS) Technologies for HIV Drug Resistance Testing, presented by Robert W. Shafer, MD.
- July 1: Development, Optimization and Implementation of Genomic Analysis Pipelines Using Next Generation Sequencing Technologies, presented by Raghu Metpally, PhD.
- August 11: Practical Applications of Next-Generation Sequencing in Clinical Microbiology, presented by Stephen J. Salipante, MD, PhD.

To register for an upcoming AMP Webinar, visit

[http://www.amp.org/Webinars/future\\_webinars.cfm](http://www.amp.org/Webinars/future_webinars.cfm).

## INNOVATION & IMPROVED PATIENT CARE

*The Journal of Molecular Diagnostics* has published **Do Circulating Tumor Cells, Exosomes, and Circulating Tumor Nucleic Acids Have Clinical Utility?**

a manuscript developed by the AMP Circulating Tumor Cells Working Group of the Clinical Practice Committee. The project was led by **Milena Cankovic** and manuscript authored by **Bert Gold, Larissa V. Furtado, Frederick Meier,** and

**Christopher D. Gocke.**

The **ASCO/CAP/AMP/ASCO Guideline for Molecular Markers for Evaluation of Colorectal Cancer Draft Recommendations** received over 3,300 individual responses during their open public comment period. Thank you to all who participated!

**Jennifer Crow** (Chair), **Annette Kim, Rachel Sargent,** and **Rebecca McClure** have been appointed to the **AMP Utility of Myeloid Mutations in Diagnosis and Prognosis of MDS, non-CML MPN, and MDS/MPN Working Group.**

**Larry Jennings** has been appointed Chair of the **AMP Development of Analytical Validation Standards for Next-generation Sequencing (NGS) Detection of Somatic Variants Working Group.**

**Madhuri Hegde** (Chair), **Elaine Lyon, Birgit Funke,** and **Sue Richards** have been appointed to the **AMP Copy Number Variation (CNV) Assessment for Large Next-generation Sequencing (NGS) Gene Panels Working Group.**

**Marilyn Li** was appointed as AMP's liaison to the **ACMG ClinGen Somatic Cancer Clinical Domain Workgroup.**

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](http://amp.org/committees/clinical_practice/members.cfm) or **Subdivision Leadership** <http://amp.org/subdivisions/index.cfm> representatives!

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