

ADVOCACY



Reimbursement for molecular pathology tests is AMP's primary advocacy issue, and the Economic Affairs Committee has been addressing problems with the gap filling process, denial of coverage and the Palmetto Molecular Diagnostic Services (MoIDX) Program

On October 30, AMP contacted the **National CMS Administrator**, Marilyn Tavenner, with a request to discuss AMP's concerns and recommendations for changes to the Molecular Diagnostic Services Program ("the MoIDX program"), Medicare's policy for coverage of molecular diagnostic tests, and the assignment of payment rates to those tests via the "gap filling" process. The request letter was co-signed by CAP, ACMG, ASCP, ASHI and ASCLS. AMP is concerned that the issues of payment and by extension coverage have been inappropriately commingled and believes the **MoIDX Program fails to follow CMS rules** and creates serious concerns about Medicare beneficiaries' access to medically necessary testing used for diagnosis, prognosis and therapeutic decision-making.

The letter (drafted by Jewell) contains nearly 100 pages documenting the problems and requesting specific changes. Other recipients of the letter included other officials from CMS, the Regional Office Directors who oversee the Medicare Administrative Contractors (MAC), the MAC Medical Directors, contacts in Congress, the White House, and the media. It is imperative that these issues be rectified and that the MACs follow the instructions for determination of coverage as set by CMS and the statutory requirements. **The letter and its attachments are available for distribution which we invite you to share widely and can be found at:** http://www.amp.org/publications_resources/position_statements_letters/2013AMPPositionStatements.cfm

Several AMP members have been working on the **AMA Molecular Pathology Advisory Group** and code specific subworkgroups to define code descriptors and submit code change proposals (by the November deadline) for specific genomic sequencing panels based on the AMP proposal provided to the AMA. In anticipation that a CPT code system will be established and will require pricing, **AMP is requesting and reviewing proposals for cost analysis from consultants.**

Jan Nowak attended the **Pathology Coding Caucus (PCC)** meeting on September 20, 2013. Prior to the meeting, AMP reviewed and submitted recommendations regarding Pathology and Laboratory Code Change Proposals.

The Economic Affairs Committee **thanks Dr. Paul Rasiavicus** for his years of service and wisdom regarding all things CPT. We will certainly miss his insight and wish him all the best in his well-deserved retirement.

The LDT Working Group white paper that addressed the **complexities involved with oversight of LDTs** was accepted for publication in *JMD* and will be published in the January 2014 issue. The LDT Working Group included: **Andrea Ferreira-Gonzalez, Rajyasree Emmadi, Stephen Day, Robert Klees, Elaine Lyon, Jan Nowak, Victoria Pratt, Mary Williams, Jennifer Leib, and Roger Klein.**

The PRC, EAC, and CPC will join forces to draft two white papers. The first will seek to provide a framework of evidence necessary to **demonstrate clinical utility**. The concept of "clinical utility" is complex, and includes factors and has impact beyond reimbursement. The second paper will **explore the negative impact to patient care** of current, proposed, and anticipated regulations, including new coverage and pricing policies and changes to oversight of LDTs.

AMP will submit comments in response to CMS draft regulations issued under the "**Test Act**," which addresses sanctioning of laboratories for inadvertent PT referral, and in response to an NHGRI request for **comments on genomic data sharing.**

AMP continues to participate in a **variety of policy discussions** with other professional societies, laboratory groups, as well as coalition groups such as the Personalized Medicine Coalition, the Coalition to Strengthen the Future of Molecular Diagnostics, as well as AdvMedDx.

A new **Industry Member Advisory Group** has been formed to assist the Professional Relations Committee to respond to FDA draft guidances to industry and other issues of importance to AMP industry members. Members are **Kenneth Bloom, Perry Sai Chan, Manohar Furtado, Dan Jones, Jill Hagenkord, Michael Langley, Amin (Chris) Riley-Portuges, Mats Sanden, John Sninsky, and Patrik Vitazka.**

AMP AT WORK FOR YOU



AMP has adopted a **new dues structure for 2014** where dues rates for many members will actually decrease! Associate members (students, trainees, and residents) now have the option to forgo a print copy of JMD and pay only \$35 per year for AMP membership. In addition, individuals in countries outside of the US may pay lower dues in 2014. All other dues rates remain the same for 2014. Look for a renewal notice via email sometime this week. For details on the 2014 dues rates, visit: <http://www.amp.org/membership/MembershipDuesRates.cfm>

The **enhanced systems** being implemented at AMP headquarters are nearly in full swing! By now, you should have received your new user name and password. This will allow you to login and renew your membership for 2014. Through early 2014, you'll need to retain your "old" login and password in order to access JMD online and CHAMP. We regret the temporary inconvenience and thank you for your patience. For more information, visit <http://www.amp.org/AMPLoginPassthru.cfm>. If you have not received your **new user name and password**, please email AMP at amp@amp.org.

EDUCATION



Recruitment for a **volunteer junior member to serve on the T&E Committee** for two years (2014-2015) is underway. Go to http://www.amp.org/Get_Involved/volunteer_at_AMP.cfm to apply.

The T&E Committee will host a webinar, "**Applications of Next Generation Sequencing Technology in the Clinical Microbiology Laboratory**", on December 13 at 1:00pm (ET). Presented by Noah Hoffman, MD, PhD (University of Washington) and hosted by T&E member, **Rangaraj Selvarangan**, BVSc, PhD, D(ABMM). To register, go to <https://www2.gotomeeting.com/register/169483898>

A **thank you to Ted Schutzbank** for leading the T&E Committee these past two years and a welcome to Laura Tafe, who will be chairing the committee for the coming two years.

The AMP 2013 **Molecular Pathology Outreach Course, AMPlicons: A Practical Molecular Toolkit and Case Studies**, will be offered on Wednesday November 13 in Phoenix. Pathologists, residents, laboratory directors and technologists who have little experience with molecular diagnostic testing are encouraged to attend. The course will provide an overview of techniques and instrumentation used in molecular testing from the framework from the "Molecular Pathology/Molecular Diagnostic Toolkit." Limited space is still available for on-site registrations. Visit: <http://www.2013amp.org/mpoc/>.

AMP Annual Meeting - Selected Highlights (Visit www.amp.org/2013 for details)

A specialty lunch on **what education can AMP offer** you will be held on Thursday, November 14. Let your voice be heard in this lunch session facilitated by AMP Training & Education Committee members **Laura Tafe, Chris Curtis, and Devon Chabot-Richards**. A summary of the recent Annual Education Needs Survey will be presented for group discussion. Help shape what AMP can provide you in terms of quality, high-impact education, whether it be webinars, live or online courses.

The **AMP Trainee Luncheon** is scheduled for Friday November 15. Designed especially for students, residents, fellows and recent graduates, this is a great opportunity to learn more about the T&E Committee, and to exchange ideas on how to improve your education in Molecular Genetic Pathology (MGP). This year, **Iris Schrijver**, MD (Stanford University Medical Center) and **Dan Farkas**, PhD, HCLD (Sequenom Laboratories) will share their experiences in the field and will offer trainees their perspectives on the present and future paths of Molecular Genetic Pathology. Thanks to the generosity of many members of our AMP community, the Trainee Luncheon will once again have its annual drawing for donated textbooks.

New to AMP or a first-timer to the Annual Meeting? Attendees who are new to AMP and/or the Annual Meeting this year are invited to attend a specialty lunch on Thursday, November 14. **Lara Brusca** and **Kimberly Lebel** arranged this event to allow "first timers" to meet and greet AMP leaders in a relaxed, informal environment.

Corporate Workshop Day is scheduled for Wednesday, Nov. 13 at the Sheraton Phoenix Downtown from 8:00am - 5:00pm. This event is FREE and requires no registration! For details, visit: http://www.2013amp.org/corporate_workshops.cfm

INNOVATION AND IMPROVED PATIENT CARE



Attend a specialty lunch session that will present a clinical laboratory perspective for **reporting incidental findings from exome and genome sequencing**. Members from the Genetics Subdivision Leadership, the Clinical Practice Committee, and the Whole Genome Working Group, have drafted perspectives on addressing incidental findings and are welcoming feedback and discussion during this lunch session on Friday, November 15. <http://www.2013amp.org/AMP2013SpecialEvents.cfm#EGS>

Note two **ancillary sessions at the Annual Meeting** related to Clinical Practice. For more details, visit: <http://www.2013amp.org/AMP2013SpecialEvents.cfm#EF>

AMP Reference Material Forum, Tuesday, November 12, 201, 8:30am-12:30pm
Location: Phoenix Sheraton Downtown Hotel, Room: Camelback

Open Forum Meeting: **Interpretation of Sequence Variants (ACMG/CAP/AMP)**, Wednesday, November 13, 2013, 5:00pm-6:30pm. Location: Hyatt Regency Phoenix, Room: Ellis Ballroom

Recruitment for a **volunteer junior member to serve on the Clinical Practice Committee** for two years (2014-2015) is underway. Go to http://www.amp.org/Get_Involved/volunteer_at_AMP.cfm to apply.

The Co-Chairs and Expert Panelists on the **ASCP/CAP/AMP Clinical Practice Guideline Development Group** for the Evaluation of Molecular Markers for Colorectal Cancer will be meeting in San Francisco in December to continue reviewing the literature and drafting the recommendations for the guideline. **William Funkhouser** joins **Antonia Sepulveda** (Co-Chair), **Federico Monzon**, and **Noralane Lindor** as AMP representatives.

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