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Association for Molecular Pathology

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AMP AT WORK FOR YOU

• The Board of Directors recently appointed three Board members to the **Strategic Opportunities Committee** (SOC): **Elaine Lyon** (as SOC Chair), **Roger Klein**, and **Shuji Ogino**. The continuing members of the SOC are **Steve Gutman**, **Marc Ladanyi**, and **Karl Voelkerding**.

• The Training and Education Committee has appointed **Caren Gentile** to serve a two-year term as the **Medical Technologist member**.

ADVOCACY

• CMS has released the final regulations to implement the **Physician Payment Sunshine Act**—Section 6002 of the Affordable Care Act - that requires manufacturers of drugs, biological and medical devices to publically report payments and other "transfers of value" with physicians and teaching hospitals. Fortunately, the final rule excludes accredited CME activities from reporting requirements. In addition, applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a conference where it is difficult to identify those who consumed the food and drink. This will enable manufacturers to continue to support awards and dining events at the AMP annual meeting. The final rule may be downloaded at https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-02572.pdf.

• AMP has a presence on PopVox.com (https://www.popvox.com/orgs/amp), which provides a curating interface for anyone - including Congressional staff, the public and the media - to access and understand AMP's positions. **PopVox is rapidly being adopted as on the intranet in the House and Senate**, enabling staff to easily research the views of stakeholders on issues and pending legislation.

• AMP is **visiting the offices of newly seated members of Congress** to introduce them to AMP, offer expertise, and to educate staff on issues of relevance to our members.

• The LDT Working Group of the Professional Relations Committee (PRC) continues its work drafting a white paper to address the complexities involved with **oversight of LDTs**. AMP contributed to the Personalized Medicine Coalition's drafting of a white paper on the oversight of LDTs. The document summarized the complexity of the policy issue and described stakeholder positions, including AMP's.

• The Economic Affairs Committee framework **proposal for CPT coding for multi-gene sequencing assays** will soon be submitted to the AMA CPT Editorial Panel. AMP will post the proposal on its website and will collect comments to pass along to the panel. AMA has indicated that stakeholders will have the opportunity to engage with them during the development process.

• The **CMS Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meets May 1** to discuss evidence for (1) DNA- or RNA- based tests to predict the likely tissue of origin in patients presenting with a cancer of unknown primary site ('CUP' tests); and (2) Fluorescence *in situ* hybridization ('FISH') tests for cancer/pre-cancer in patients with atypical squamous cells of unknown significance (ASCUS) or low-grade squamous intraepithelial lesions (LSIL) in cytological specimens from the uterine cervix. Information regarding providing oral and written comments is in the *Federal Register* at http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/downloads/id67.pdf.

ALERT...CALL TO ACTION!
SEE BELOW

INNOVATION & IMPROVED PATIENT CARE

• AMP now links to the **FDA webpages for approved molecular diagnostic tests** at: http://www.amp.org/FDATable/. AMP gratefully acknowledges the work by Carol Holland in previously maintaining AMP's own list of FDA approved molecular diagnostic tests.

• Congratulations to **Larissa Furtado** as the newly appointed **Junior Member to the Clinical Practice Committee** for 2013-2014.

EDUCATION

• Need an intense update or a review of Molecular Genetic Pathology? Take the AMP 2013 **Molecular Genetic Pathology Review Course** on April 4-7 in Bethesda, MD! Information is available at: http://www.amp.org/mgp2013/. CME-eligible. Early registration has ended; however, onsite registrations are welcomed.

• And the winners of the **AMP 2012 Annual Meeting photo contest** are...
o First Place, **Dan Farkas**
o Second Place, **Cindy Walker-Peach**
o Third Place, **Jin-Yeong Han**
Visit http://www.amp.org/Emailads/AMP2012PhotoContest2.html to see the winning photos!

• AMP is a sponsor of "**Updates in Molecular Diagnostics and Genomic Medicine**," a one day symposium on April 8 in Newark, NJ, jointly organized by the Department of Pathology and Laboratory Medicine at UMDNJ-New Jersey Medical School and the Departments of Pathology and Medical Education at Saint Barnabas Medical Center. For registration and more information visit: http://www.molecularupdates.com.

• **Webinars coming this spring**:
o AMP Variant Nomenclature Database, **Linda Jeng**
o New Lung Cancer Biomarkers Guidelines, **Neal Lindeman** on behalf of CAP/IASLC/AMP
o MGMT Testing in Gliomas, **Milena Cankovic** and **Neal Lindeman**
o Review of the Gene Patent Supreme Court Case, Sandra Park, ACLU
o Recruitment and Retention of Medical Technologists/Medical Laboratory Scientists, **Sara Taylor**
o The Diagnostic Management Team: Optimizing Personalized Diagnostic Testing for Hematologic Malignancies, Adam Seegmiller

• The AMP Economic Affairs Committee (EAC) presented a webinar, "**Ins & Outs of Coding with the New Molecular Pathology CPT Procedure Codes**," on February 26. AMP members sign in here to access the recorded webinar: https://secure.amp.org/cvweb_amp/MainLogin.shtml

• The AMP 2013 Annual Meeting **Abstract Submission Site will open April 1** and close May 31! Details will be soon posted at: http://www.amp.org.

SPECIAL FEATURE - CALL TO ACTION REGARDING THE FINAL RULE

• In the 2013 Final Rule, CMS directed the regional Medicare Adminstrative Contractors (MACs) to assign reimbursement values to the new molecular pathology CPT codes using whatever information they had access to. This is the "Gap Fill" process. Several MACs have released their preliminary fee schedules that have significantly underpriced many molecular tests. These fee schedules are still subject to modification, but it is important that every molecular pathology laboratory provide its regional MAC with data that can be used to set appropriate reimbursement values. AMP members should endeavor to bring this important issue to the attention of their department chairs and the billing officers of their institutions. Some Medicare contractors have set response deadline as early as March 31, so there is no time to delay.

Regional Medicare Administrative Contractors can be identified at the following site: http://go.cms.gov/YmwpAD. Every Contractor has a Medical Director identified on the above site. You should direct your communications to the Medical Director. The information you submit to the MAC could include the following:

• Test Name
• 2012 Stacking codes
• Tier 1 code
• Z Code (especially if Palmetto is your carrier)
• Cost to perform test, including direct costs (technical inputs), costs of professional interpretation labor, indirect input and medical malpractice inputs
• Other pricing data points (other payer reimbursement)

Be aware that the old stacking codes only inform part of your test costs. It is important to add to that the costs of professional interpretation labor, indirect costs (electricity, rent, etc), and medical malpractice expenses.

Alternatively, you can direct the MAC to use the information submitted by the AMA to CMS for assigning reimbursement values to the new molecular codes. This information is filed in the "2013 Gapfill Process" folder in the CHAMP Open Forum library and posted on the public Economic Affairs Committee web page (http://www.amp.org/committees/economics/). The original source of this information is as follows:

• Direct Costs(technical inputs) at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1590-P.html

• Professional inputs: Federal Register / Vol. 77, No. 222 / Friday, November 16, 2012 / Rules and Regulations at http://www.gpo.gov/fdsys/pkg/FR-2012-11-16/pdf/2012-26900.pdf (12.5 MB), page 110 (69000) and following.

One advantage in using these publicly available data sources is that they include information for all the new molecular codes and not just those performed in your laboratory. Furthermore, these data have been assembled and adjudicated through the standard RUC* mechanism, and to which many AMP members contributed.

In summary, this is what you need to do:
1. Identify your Medicare Administrative Contractor.
2. Engage your department chair and your institutional billing officers in this issue.
3. Communicate with your MAC Medical Director information regarding your laboratory's test pricing or refer to the published RUC data on direct costs, indirect costs, and professional inputs.
4. Communicate your efforts with your senators and congressmen so that they are aware of the jeopardy this issue is bringing to the delivery of molecular diagnostic services and personalized medicine in their legislative districts.

CMS will publish preliminary national pricing by 30 April; a 60-day public comment period will follow.

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