



AGENDA

ASCLS/CLMA/ASCP/AMT/AGT LEGISLATIVE SYMPOSIUM

March 20 - 21, 2017 | Hilton Old Town Alexandria

MONDAY, MARCH 20

- 7:30 – 8:00 REGISTRATION AND CONTINENTAL BREAKFAST
- 8:00 – 8:15 **Welcome**
- 8:15 – 8:30 **Meeting Overview**
 Jim Flanigan, ASCLS
- 8:30 – 9:15 **Overview of the Political Environment in Washington**
 Patrick Cooney, ASCLS
 Michael McCarty, AMT
 Matt Schultz, ASCP
- 9:15 – 10:00 **Laboratory Developed Tests (LDT)**
 Bob Newberry, AMT
 Judy Davis, ASCLS
- 10:00 – 10:30 BREAK
- 10:30 – 11:30 **Patient Access to Medicare Act (PAMA) and Laboratories**
 Presenter: Paul Keoppel, CLMA
 Presenter: Mary Jo Bonifas, CLMA
 Panelists:
 Paul Keoppel, CLMA
 Rick Panning, ASCLS
 John W. Sherer, AMT
 Julie Allen, NILA
- 11:30- 12:00 **Clinical Laboratory Workforce**
 Edna Garcia, ASCP Wage Data Study
 Patrick Cooney, ASCLS

- 12:00** **Political Action Committee**
ASCLS PAC Board of Trustees
- 12:15 – 1:30 LUNCH
- 1:30 – 2:15** **Preparing for Congressional Visits**
- Review of Issues, Leave Behinds and “Talking Points”
 - Walk Through of Voter Voice Feedback System
Patrick Cooney, ASCLS
Jim Flanigan, ASCP
- 2:15 – 3:00** **Update on CMS Rule on Nursing Equivalence**
Matthew Schulze, ASCP
- 3:00 – 3:45** **Congressional Update**
Nicholas Uehlecke, Professional Staff Member
U.S. House of Representatives, Ways and Means Committee
- 3:45 – 4:15 BREAK
- 4:15 – 4:45** **Preparing for Congressional Visits**
- Role Playing - Practicing Your Message / Making a Difference
- 4:45 – 5:30** **How Best to Work with Congressional Offices**
- How Congressional Offices Work
 - How Legislative Staff View Your Visit
 - How to Communicate Your Message Effectively
- 6:00 – 7:00 RECEPTION
- TUESDAY, MARCH 21
- 7:00 – 9:00** **Breakfast (Plaza Level)**
- 8:30** **Travel to Capitol Hill and Appointments**

Flawed Attempt to Set Market-Based Fee Schedule Will Jeopardize Access to Quality Care

Position

The clinical laboratory community urges Congress and the Administration to ensure access to quality clinical laboratory services within the Medicare program will not be impeded by fee schedule cuts authorized within the Protecting Access to Medicare Act (PAMA) of 2014. Final regulations promulgated by the Obama Administration should be reviewed by the Trump Administration to ensure they do not destabilize the clinical laboratory testing market and impede access to care. We urge the Trump Administration to:

- ✓ Extend the deadline for data collection and reporting periods for the clinical laboratory fee schedule (CLFS) under Medicare by **twelve (12) months to March 31, 2018**
- ✓ Delay enforcement of the updated CLFS until **January 1, 2019**
- ✓ Revise the definition of “applicable laboratory” to mean a facility identified by a Clinical Laboratory Improvement Act (CLIA) number, so that true market-based reimbursement rates can be calculated

Rationale

PAMA requires “applicable laboratories” to report private payor payment rates and the associated test volume for those laboratory services defined by CMS. This data will be used by CMS to calculate the new Clinical Lab Fee Schedule (CLFS). The intent of the PAMA was to ensure true market-based pricing by setting the fee schedule to a weighted median of the collected data. To determine a true, market price, laboratories reporting data should be representative of the broad scope of the laboratory market, including hospital and physician office laboratories.

PAMA directed CMS to establish parameters for payment rate reporting by June 30, 2015, and required the market-based payment system to start on January 1, 2017. However, in the Final Rule, CMS delayed the data collection and reporting requirement pushing back the effective implementation date to January 1, 2018. CMS originally estimated \$390 million in savings in 2018, \$1.7 billion over five years, and \$3.9 billion over ten years, but **recent industry estimates indicates that cuts will go well beyond these figures.**

As recently as March 13, 2017, CMS gave conflicting definitions “applicable laboratories,” leaving many laboratories still in doubt as to their status. **The current definition ignores the intent of Congress by excluding virtually all hospital laboratories, physician office laboratories, and over 50 percent of independent laboratories.** This results in unnecessarily limited payment data captured from laboratories performing just \$2 billion of the total \$7 billion Medicare spends on laboratory services each year.

Excluding pricing data from a broad representation of the laboratory community forces CMS to base payment rates on data drawn almost exclusively from large reference laboratories.. These laboratories provide narrower menus of services with less urgent time constraints to deliver results. In contrast, hospital and physician office laboratory service deliver services in urgent, acute, and long term care settings not served by commercial laboratories, which naturally leads to higher costs in those settings. CMS is missing necessary data to address this difference.

In September of 2016, the Department of Health and Human Services (HHS) and the Office of Inspector General (OIG) released reports updating stakeholders on the Centers for Medicare & Medicaid Services' (CMS) implementation of Medicare's new system. The OIG's report noted the potential for skewing of median payment information based on the collection plan. The OIG also raised concern that once laboratories reported, CMS did not plan to verify the data's completeness or accuracy. **Without these safeguards, CMS is unable to determine whether labs complied with reporting requirements or whether the data on which new Medicare lab payment rates will be complete and/or accurate.**

Impact

The accuracy of an updated CLFS is now in doubt if existing regulations on data collection and reporting are not revised. The estimated impact to the clinical laboratory market could go well beyond what Congress had envisioned when it enacted PAMA and may impact access to laboratory services not just for Medicare beneficiaries, but for all patients as the vast majority of private payors peg their reimbursements to the CLFS.

Indiscriminate cuts in the CLFS will ripple through the entire laboratory system.

Without immediate action, the administration will implement a brand new payment system, based on potentially flawed and incomplete data that is likely to impact the availability of critical laboratory services in communities all over the country.

The anticipated cuts are already causing consolidation. In recent weeks, PeaceHealth Outreach Laboratory was sold to Quest Diagnostics, and Pathology Associated Medical Laboratories was purchased by LabCorp. The result will be the loss of hundreds of jobs, significant local economic displacement, and compromise locally available laboratory services.

Community laboratories are typically very small operations and will be extremely vulnerable to Medicare cuts to the CLFS. Medicare fee decreases of 10 percent for a community laboratory that has 60% Medicare patients will result in closures or bankruptcies. Even laboratories with a lower percentage of Medicare patients will be affected by private payor links to the CLFS.

Laboratories will respond by reducing staff and cutting back on capital investment, leaving clinicians without important tools to quickly diagnose and treat patients. Access to care for both the community and nursing homes served by the community-based, hospital laboratory outreach programs will be compromised.

Setting the new CLFS based on the flawed and incomplete data has the potential to be the single most financially disruptive event for clinical laboratories, which have already been subjected to repeated and severe reimbursement cuts for three decades.

Background

Under PAMA, CMS can lower the price of individual tests up 10% in 2018, 2019 and 2020. PAMA then allows price cuts up to 15% in 2021, 2022 and 2023.

PAMA requires “applicable laboratories” to report to CMS, and defines an “applicable laboratory” as a laboratory that receives a majority of its Medicare revenue during the data collection period from the CLFS or the Physician Fee Schedule. In the proposed rule, CMS defined applicable laboratories based on an entity’s IRS Taxpayer Identification Number (TIN). In the Final Rule, in response to comments, CMS modified the definition of an applicable laboratory to be at the National Provider Identifier (NPI) level, not the TIN level. CMS stated that this would allow the inclusion of hospital outreach laboratories in the definition of “applicable laboratories.” However, that interpretation does not consider that most of those laboratories do not have separate NPI numbers.

In the Final Rule, CMS elected to shorten the data collection period to six months to give laboratories a six-month window to ensure the completeness and accuracy of data. The data collection period is now from January 1 through June 30 for CDLTs with specific HCPCS codes. CMS stated in the Final Rule that it would re-evaluate the length of the data collection period in future rulemakings, including whether the six-month review period before the reporting period is necessary. Laboratories must report the data to CMS by March 31, 2017. CMS will provide sub-regulatory guidance to specify the manner and form for reporting applicable information before the first reporting period. Although CMS will use NPI to determine an applicable laboratory, reporting will still be done by the TIN level entity.

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*Access to Clinical Laboratory Services in Jeopardy
Due to CMS Implementation of PAMA*

Talking Points

The Ask: Congressional Support for Administrative Delay of Implementation of Sec.126 of PAMA until January 2018.

Sec. 126 of PAMA – Protecting Access to Medicare Act – requires CMS to calculate and establish a new Medicare Clinical Lab Fee Schedule (CLFS) based on private payer payment data submitted by “applicable labs”. The intent was to revise the CLFS based on true market based pricing. The project as laid out by CMS is flawed and does not reflect true market based reimbursement rates as intended by Congress.

Concerns:

1. New reimbursement rates will be set based on incomplete and inaccurate data
 - a. CMS’s current definition of “applicable lab” excludes virtually all hospital labs and physician office labs and about half of independent labs.
 - b. Per the OIG, Medicare spend is \$7B. Because of how CMS defined “applicable lab”, only \$2B of payment data is being reported and will be used to set new payment rates leaving out 72% of payment data.
 - c. New CLFS will apply to all labs, not just those who reported data
 - d. As recently as March 13, 2017 CMS was still providing conflicting information to labs as to whether they were an applicable lab and should report their data. The deadline to report is March 31, 2017.
2. The new CLFS will not just affect Medicare and Medicaid. Almost all private payors base their contracted fees for lab services on the Medicare CLFS. If the Medicare CLFS is decreased by 10%-15%, the private payor rates will also be lowered, cutting ALL reimbursements.
3. The OIG in September 2017 voiced significant concerns regarding PAMA
 - a. Only 5% of labs would be reporting data, skewing the data used to calculate the new fee schedule
 - b. CMS has no plans to conduct audits to:
 - i. identify applicable labs
 - ii. identify whether all labs reported
 - iii. verify completeness or accuracy of data
4. CMS promised the lab community transparency in their calculation of new payment rates, but has yet to specify how they would provide this
5. The Medicare CLFS is the oldest fee schedule and has not been seriously reviewed and revised since it was implemented in 1986! Using the flawed data collection process set under PAMA is not the way to rationalize and modernize the CLFS.
6. Under PAMA, CMS can lower current reimbursement rates up to 10% in 2018, 2019 and 2020 and up to 15% in 2021, 2022 and 2023. If PAMA is allowed to move forward, it has

the potential to be the single most financially disruptive event for clinical labs, already subjected to repeated and severe reimbursement cuts for the last three decades!

7. The financial impact on clinical laboratories if PAMA is implemented is significant, especially for community based hospitals, rural hospitals and nursing homes. With typical profit margins of 3% to 5%, a 10% to 15% cut in reimbursement will mean:
 - a. No money for raises, inability to be competitive and recruit staff
 - b. No money for new equipment and new technology
 - c. Less testing done in-house and more sent to outside reference labs – possible layoffs if less testing
 - d. Increased delay in getting results if sent out causing delay in diagnose and in inpatient, increased length of stay
 - e. Labs no longer financially viable - possible lab closings and bankruptcy
 - f. Selling off the lab business to a national reference lab – already seen in the industry with PAMAL and others. This results in a loss of hundreds of high paying, technical jobs as well as significant local economic impact and loss of locally available lab services.
8. Access to care for both the community and nursing home patients served by the community hospital lab will be compromised – less access to quality lab services – exactly the opposite of PROTECTING Access to Medicare – the name of the regulation.

For all these reasons, setting a new Medicare CLFS based on the flawed data collection process under PAMA must be delayed.



Laboratory Developed Tests Should Be Carefully Regulated

Position:

We as clinical laboratory professionals agree that laboratory developed tests (LDTs) must be regulated to ensure their accuracy and overall patient safety. Patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions. Inaccurate or false test results, or accurate measurements with an invalid claim regarding the test results' relationship to a disease, can lead to substantial patient harm. LDTs play an increasingly important role in the provision of high-quality health care, and many laboratories perform proper validation of their LDTs and provide high-quality, professional management of their operations. However, currently, patients and providers cannot uniformly rely on all tests offered for clinical use as some are not subject to active premarket oversight to ensure they provide accurate measurements and valid claims. Furthermore, the Centers for Medicare and Medicaid Services' (CMS) evaluation of clinical utility, as part of a coverage determination, would typically follow from Food and Drug Administration (FDA) review of analytical and clinical validity.

Background:

LDTs are defined by the FDA as in vitro diagnostic tests that are designed, manufactured, and used within a single laboratory. In 2014, the FDA released draft guidance to provide enhanced oversight of LDTs. FDA proposed a three-tier risk-based framework for this oversight. High-risk (Class III medical devices) and moderate-risk (Class II) LDTs would be subject to premarket review requirements (i.e., premarket notification, or 510(k) submissions), FDA registration, listing, and reporting requirements. Low-risk LDTs (Class I) and LDTs for rare diseases or unmet medical needs would be under FDA enforcement discretion for applicable premarket review and quality systems requirements; they would be required to comply with registration and adverse event reporting within six months of the release of FDA's final guidance.

On January 13, 2017, the FDA released a discussion paper on LDTs and announced that it would not issue a final guidance on the oversight of LDTs at the request of various stakeholders to allow for further public discussion on an appropriate oversight approach, and to give congressional authorizing committees the opportunity to develop a legislative solution.

Comments on the New Discussion Paper:

- The clinical laboratory personnel community appreciates the elucidation of the distinction between clinical validity and clinical utility. We define clinical validity as how well the test determines the presence, absence or potential risk of disease (i.e. the test's ability to detect the clinical condition for which the test is intended). We agree with FDA's assessment that clinical validity is very different from the clinical utility that CMS uses to determine coverage decisions and that CMS needs the information about clinical validity from FDA to protect the public.
- We agree that molecular tests are essential tools in diagnosis, prognosis, and therapy decisions, putting them in the category of high-risk tests. These LDTs require oversight. However, one might question whether the full burden of data required by the PMA process is even achievable. A balance needs to be struck between full regulation and providing potentially useful information to providers and patients with rare diseases.
- We agree that a risk-based approach to oversight is necessary and appropriate. We believe that a risk-stratified approach to regulation is also appropriate. Very low-risk traditional LDTs should not require full PMA/510k documentation.

- We support a phased-in process proposed. However, we do disagree with the Year One exemption of traditional LDTs from reporting of serious adverse events. While we feel that traditional LDTs are low-risk and unlikely to create serious adverse events, if such an event were to occur, it should be reported. Laboratories are familiar with the adverse event reporting process as it applies to FDA-approved tests and equipment, and reporting of all adverse events should not be a burden for either laboratories or the FDA.
- On the subsequent years of the phase-in, our previously stated concern about whether the full burden and quantity of data required by the PMA process are necessary or achievable. A modification of the PMA should be considered.
- There are several statements in the document that laboratories that conduct proper validation should not need to collect more data or incur new costs for LDT regulation. We feel this statement is too optimistic; the rigor and volume of data required by the PMA process are greater than the typical validation acceptable by CMS of an in-house test.
- We urge the FDA to address the issue of health system laboratories that may use the same methods and equipment. If an LDT is validated in one laboratory within a health system, we urge that the other system laboratories be allowed to adopt the method without repeating the full validation.
- We are concerned about what groups or agencies will be identified by FDA with which to expand its third party premarket review program. We do not believe that many of the CLIA accredited organizations have the expertise or experience needed to perform premarket reviews. Allowing and encouraging clinical collaboratives will be an excellent way to expedite data collection and sharing; all of which will enhance innovation rather than stifle it.
- We question whether it is realistic that a laboratory would be able to anticipate future changes needed to a test that is brand-new and has not been performed in a clinical setting yet. Some latitude should be incorporated into any oversight to avoid the need to re-submit a test following minor changes.
- We support the use of CLIA's quality system requirements for LDTs. We reiterate our stance that, if third party entities can inspect for the FDA requirements that are in addition to CLIA, that extensive education of State Department of Health and inspectors is necessary.
- We share the FDA's goal to balance patient protection with continued access and innovation.

For further information on this issue, please contact Patrick Cooney at 202-347-0034 x101 or via email at Patrick@federalgrp.com.



Growing Crisis in the Clinical Laboratory Workforce

Position

To ensure access to quality health care services the healthcare system must have an adequate supply of clinical laboratory personnel. Today that supply is in serious question. This shortage hampers the ability of clinical laboratories to meet patient testing demands, posing problems for patient health and welfare. Growing numbers of patients and the number and complexity of medical laboratory tests are putting strains on a profession growing modestly.

We call upon Congress to address this concern within the Veterans Health Administration and to begin to address the concern throughout our nation's health care system.

Congress must do the following:

- ✓ Enhance recruitment and retention efforts within the Veterans Health Administration
- ✓ Authorize and appropriate funding for a program to within the Public Health Service Act to ensure training for citizens seeking to enter the clinical laboratory workforce
- ✓ Authorize the Government Accountability Organization (GAO) to study the shortage of clinical laboratory personnel and make recommendations to Congress

Rationale

The Bureau of Labor statistics anticipates needed growth of 12,000 new medical laboratory professionals per year to meet growing demand. However, academic programs currently produce just 5,000 graduates per year.

Another cause for concern is the average age of the laboratory workforce, which has been increasing steadily. In 2004, the average age of a certified medical technologist was 43.7 (which was slightly older than of nurses (43.3) and is aging at a 78 percent faster rate than the entire U.S. labor market.

On September 28, 2016, the VA Office of Inspector General (OIG) conducted its third determination of VHA occupations with the largest staffing shortages as required by Section 301 of the Veterans Access, Choice, and Accountability Act of 2014. They determined that the largest critical need occupations were Medical Officer, Nurse, Psychologist, Physician Assistant, Physical Therapist, and Medical Technologist (clinical laboratory personnel).

This crisis is the result of a decades-long decline in MLS and MLT producing academic programs. From 1970 the number of accredited programs declined from nearly 1,000 to less than 450 in 2006. Since 2008, the number of programs has rebounded modestly from 427 to 479 in 2015. That increase has not been nearly enough to address the increasing demand. Further the shortage exacerbates the challenge in securing clinical sites for training.

Background

Clinical laboratory personnel are critical to our nation's health care. They provide a wide-range of diagnostic, technical, therapeutic and direct patient care and support services. These professionals are critical to physicians and nurses with whom they work and to the patients they serve. In total, clinical laboratory personnel and other allied health professions account for an estimated 60 percent of the entire health care workforce.

More than 4 billion medical laboratory tests are performed each year in the United States, the single highest volume medical activity. Approximately 70% of physicians' patient interactions are influenced by laboratory test data.

New laboratory tests are being developed all the time to improve early detection and diagnosis of diseases, more accurately monitor conditions and better protect outcomes (prognosis). One area of significant growth, molecular diagnostics detects and measures the presence of genetic material or proteins associated with a specific health condition or disease, helping to uncover the underlying mechanisms of disease and enabling clinicians to take care at an individual level, facilitating the practice of "personalized medicine."

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