

1.1 2017 Minnesota Legislative Symposium




1.4 President Trump

President Trump

Tweets making headlines

@Politico's Tweet was featured in Slate Magazine



Trump says "Nobody Knew Health Care Could Be So Complicated"

Here is a thing that Donald Trump said about health care reform during a press conference Monday: "I have to tell you..."

President Trump said Monday that "nobody knew that healthcare could be so complicated," as Republicans have been slow to unite around a replacement plan for Obamacare.

"I have to tell you, it's an unbelievably complex subject," Trump said after a meeting with conservative governors at the White House.

1.2 2017 PAMA Review

2017 PAMA Review

2017 Laboratory Legislative Symposium
Rick Panning
ASCLS Government Affairs Committee

1.5 PAMA

PAMA

Preserving Access to Medicare Act

1.3 Talking Points

Talking Points

- ▶ Basic education on PAMA
- ▶ The impact of PAMA implementation on the entire lab industry, especially small hospitals and specialty labs
- ▶ Issues with implementation so far

1.6 OIG Data Brief –Laboratory Tests in 2015

OIG Data Brief -Laboratory Tests in 2015

- ▶ "Medicare Part B paid \$7 billion for lab tests in 2015 - no change from 2014"
- ▶ The top 25 lab tests by Medicare payments totaled \$4.1 billion
- ▶ The top 8 lab tests totaled \$2.7 billion
- ▶ Medicare paid 19% more for all drug tests in 2015 than 2014"

1.7 Top 25 Medicare Lab Tests

Table 1. Top 25 Lab Tests Based on Medicare Part B Payments in 2015

Test Description and Procedure Code*		National Limitation Amount	Number of Tests (Millions)	Medicare Payments (Millions)	Changes From 2014 Payments (Millions)	
1.	Blood test, thyroid-stimulating hormone (TSH) (84443)	\$22.87	21.2	\$475	↓	\$3
2.	Blood test, comprehensive group of blood chemicals (80053)	\$14.37	40.6	\$458	↑	\$5
3.	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	\$10.58	41.5	\$428	↓	\$3
4.	Blood test, lipids (cholesterol and triglycerides) (80061)	\$18.22	27.2	\$379	↓	\$8
5.	Vitamin D-3 level (82306)	\$40.29	8.7	\$337	↑	\$13
6.	Hemoglobin A1C level (83036)	\$13.21	18.6	\$241	↑	\$5
7.	Opiates (drug) measurement (G6056)	\$26.48	8.1	\$208	↑	\$35
8.	Drug screen, qualitative; multiple drug classes by high-complexity test method (e.g., immunoassay, enzyme assay), per patient encounter (G0431)	\$98.96	2.3	\$208	↑	\$15
9.	Blood test, basic group of blood chemicals (80048)	\$11.51	13.8	\$134	↓	\$3
10.	Blood test, clotting time (85610)	\$5.35	21.9	\$117	↓	\$11
11.	Parathormone (parathyroid hormone) level (83970)	\$56.17	2.1	\$114	↑	\$4
12.	Cyanocobalamin (vitamin B-12) level (82607)	\$20.51	5.5	\$110	↑	\$3
13.	PSA (prostate specific antigen) measurement (84153)	\$25.03	4.2	\$103	↓	\$1
14.	Chemical analysis using chromatography technique (82542)	\$24.58	4.3	\$97	↓	\$24
15.	Thyroxine (thyroid chemical) measurement (84439)	\$12.27	6.8	\$81	↑	\$2
16.	Bacterial colony count, urine (87086)	\$10.99	7.4	\$80	↑	\$1
17.	Benzodiazepines level (G6031)	\$25.17	3.2	\$77	↑	\$10
18.	NEW TO TOP 25 Drug confirmation (G6058)	\$18.03	4.3	\$75	↑	\$63
19.	Natriuretic peptide (heart and blood vessel protein) level (83880)	\$46.19	1.5	\$68	↓	<\$1
20.	Ferritin (blood protein) level (82728)	\$18.54	3.5	\$64	↑	\$1
21.	Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) common variants (81226)	\$450.46	0.1	\$62	↓	\$105
22.	Complete blood cell count (red cells, white blood cell, platelets), automated test (85027)	\$8.81	6.8	\$58	↑	<\$1
23.	NEW TO TOP 25 Amphetamine or methamphetamine (G6042)	\$21.15	2.9	\$58	↑	\$13
24.	Folic acid level (82746)	\$20.01	2.8	\$55	↑	\$1
25.	Methadone level (G6053)	\$22.22	2.5	\$53	↑	\$1
Total Medicare Part B Payments: \$4.14 billion						

1.8 Protecting Access to Medicare Act

(PAMA)

Protecting Access to Medicare Act (PAMA)

- ▶ Passed April 1, 2014
- ▶ Section 216 reforms the Clinical Laboratory Fee Schedule (CLFS)
- ▶ Final Rule June 23, 2016
- ▶ CMS guidance documents SE 1619 and SE 1620 issued Sept 2016
- ▶ OIG progress report Sept 2016

1.11 Another Delay?

Another Delay?

- ▶ Some laboratory industry are asking for yet another delay
- ▶ Outcome is uncertain and unlikely
- ▶ The laboratory industry is asking once again that more hospital and clinic data be included in the applicable laboratories - redefine "applicable laboratory"
- ▶ **Note: On March 30, 2017, the data submission deadline was extended 2 months to May 31, 2017.**

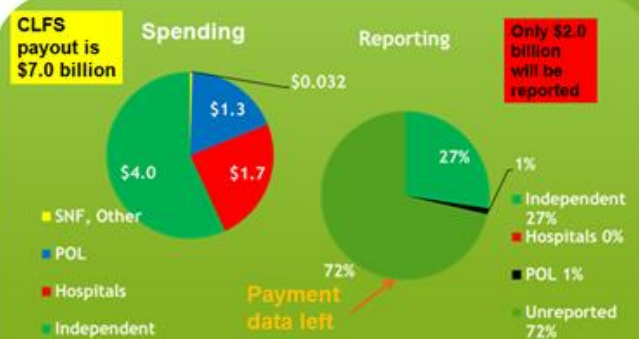
1.9 Final Rule

Final Rule

- The implementation date moved from January 1, 2017 to January 1, 2018
- Revised the definition of advanced diagnostic tests to also include proteins
- Definition of Applicable Laboratory changed

1.12 Who is Required to Report?

Who is Required to Report?
5% of POLs, 44% of Independents and 0% of hospitals



1.13 Applicable Laboratories That Must Report Data

1.10 Current Timeline

Current Timeline

April 1, 2014	PAMA passed
June 30, 2015	Deadline for PAMA proposed rule
October 1, 2015	PAMA proposed rule is published
November 24, 2015	Deadline for comments
June 17, 2016	Final rule is published
August 17, 2016	Rule takes effect (60 days)
Jan 1 – June 30, 2016	Data collection period
Jan 1 – Mar 31, 2017**	Data reporting period
April 1 - Sept 2017	CMS calculates new rates
Sept- Nov 2017	CMS publishes new rates
Jan 1, 2018	New rates are effective

Data collection will repeat every 3 years except for new tests

****Extended to May 31, 2017 on March 30.**

Applicable Laboratories That Must Report Data

1. CLIA certificate
 2. Bill using **their own** lab NPI (CMS indicated in November it could also be a shared NPI, but meeting step 3 below would be difficult)
 - ▶ January 19, 2017 update in CMS PAMA FAQs broadens this definition.
 3. More than 50% of Medicare revenue from the PFS and CLFS
 4. Medicare CLFS payments >\$12,500 for the 6 month reporting period
- ▶ Assumes the lab bills applicable payors

1.14 Majority of Medicare Calculation

**Majority of Medicare Calculation
(At NPI Level)**

$$\% = 100 \times \frac{\text{All PFS + CLFS Revenue}}{\text{All Medicare Revenue}}$$

1.17 Four Fields Reported

Four Fields Reported

- ▶ **HCPCS Code** - The HCPCS/CPT code used to identify the procedure. The applicable HCPCS codes are published on the CMS Clinical Laboratory Fee Schedule website
- ▶ **Payment rate** - The unique private payor rate for each test. For example, if a laboratory has 100 private payers, each HCPCS code would have 100 lines of payment prices. Must have been "paid" during reporting period (NOT ordered or collected).

1.15 Applicable Payers

Applicable Payers

- All private payers including group health plans, Medicare Advantage and Medicaid MCO plans
- Does not include Medicaid fee for service
- Does not include other governmental payors
- Does not include capitated plans

1.18 Four Fields Reported


Four Fields Reported

- ▶ **Volume** - The number of tests paid at each unique private payor rate
- ▶ **National Provider Number (NPI)** - the unique 10-digit identifier for each applicable laboratory reporting under the TIN number
- ▶ Test name removed on latest version

1.16 MLN Matters SE 1620

▶ A "Quick User Guide" for the "Fee-For-Service Data Collection System (FFSDCS)

Gives the most complete instructions on how to apply for a password, how to submit data, etc.



1.19 Applicable Information Does Not Include

Applicable Information Does Not Include

- Unresolved appeals
- Payments that do not reflect specific HCPCS code-level amounts
- Remittances where the payer has grouped test-level payments into an encounter (claim-level) payment
- Denied payments

1.20 Frequency of Reporting

Frequency of Reporting

- For most laboratory tests, every three years
- Annually for advanced diagnostic laboratory tests (ADLTs)

1.23 Payment Reduction Limits

Payment Reduction Limits

- PAMA requires a savings but each HCPCS code is limited to 10% reduction each year for 3 years and 15% the next 3 until the rate gets down to the median
- This is a potential decrease of 27% the first 3 years and 55% over 6 years

1.21 Certification of Data

Certification of Data

- ▶ Certification information is contained in the CLFS User Manual
- ▶ Agree to the following
- ▶ Example: At HealthPartners the submitter was Senior Administrative Director for Laboratory Services and Certifier was the VP of Primary Care

Warning: Once the CLFS Certifier has certified the data for the current period, data submission is closed and no more data can be entered for that applicable laboratory. Be sure that all applicable information is entered, accurate, and complete before certifying the data.

Figure 7-6. Data Certification Statement

Data Certification Statement

I certify that the reported applicable information is accurate and that all information and statements made in the submission are true, complete, and current to the best of my knowledge and belief and are made in good faith. I understand that information contained in this submission may be used for Medicare reimbursement purposes.

☐ I agree to the above certification statement

Certify

1.24 Payment Reduction Cont.

Payment Reduction Cont.

- Each MAC may currently have a different price on a HCPCS
- CMS will use the NLA to do the calculation of 10% or 15% decrease and not the MAC levels

1.22 Rate Setting Process

Rate Setting Process

- CMS will calculate the weighted median price for each code (midpoint of the data set)
- Rate will be national without geographical variation
- Will be in effect for 3 years with no inflation update or productivity decrease - except ADLTs annually
- Will still be subject to sequestration
- If no data is received for a given HCPCS, CMS will use cross walking or gap filling to price the test (example: most G codes)

1.25 CMS Reduction Estimates

CMS Reduction Estimates

- An estimated \$390 - \$540 million reduction in FY2018 payments.
- Private payor rates estimated 20% lower than Medicare overall
- 5 year Medicare fee payments scored at almost \$4 billion by CBO (OIG now says \$5.4 billion)

1.26 Laboratory Impact

Laboratory Impact

1.29 Survey Continued

Survey Continued

- ▶ Nursing home patients accounted for 12% of one laboratory's volume
- ▶ Some laboratories cater to nursing homes where the volume approaches 100% - almost all of the patients are Medicare or Medicaid

1.27 New Fees Apply to:

New Fees Apply to:

- All laboratories receiving payment from Part B Medicare whether they supplied data or not
- This affects all POLs and hospital outreach
- Potentially other payors using the MC fee schedule as a base

1.30 Survey

Survey

- ▶ Health systems in the Midwest report that 100% of outreach is paid based on the MCLFS
- ▶ It is very common to see hospital outreach and independent laboratory contracts tied to the Medicare fee schedule
- ▶ Problem is that none of the hospital outreach data and few physician office labs will be submitting data.

1.28 Many Commercial Payor Rates are

Many Commercial Payor Rates are Linked to the Medicare Clinical Laboratory Fee Schedule

- ▶ Spot Survey Data
 - ▶ Typical for providers to have almost 60% of volume paid by government contracts (Medicare, Medicaid, Medicare Advantage)
 - ▶ For independent laboratories, 91% of tests billed are either at the Medicare rate, or tied to the Medicare rate

1.31 Death Spiral ?

Death Spiral ?

- ▶ If the commercial rates that are tied to Medicare rates go down over the next three years, the next CMS data collection period will be measuring even lower private payor rates.

1.32 XIFIN Client Data

XIFIN Client Data

- ▶ Independent labs are paid 19.6% less than Medicare
- ▶ Hospital labs are paid 25.6% more than Medicare - this data is excluded from submission.
- ▶ Molecular testing labs are paid 27.3% more than Medicare
- ▶ Toxicology and Pain Management labs are paid 50.4% more

1.35 PAMA Impact Predictions

PAMA Impact Predictions

- ▶ Speculation at this point, but almost certainly we predict:
 - ▶ 2018 CLFS fees will decrease
 - ▶ Certainly for the top 25 tests
 - ▶ May see an increase in more esoteric tests
 - ▶ Decrease is capped at 10% per year per test
 - ▶ OIG and CMS have estimated an overall decrease of 5.6% in year 1.
 - ▶ Smaller community laboratories that depend on Medicare volume will struggle with new payments

1.33 XIFIN Analysis

XIFIN Analysis

(As reported by the Dark Report)

- ▶ Prediction is this could trigger the single most financially disruptive event to hit the clinical laboratory industry in the past three decades
- ▶ Experts predict the reductions could force many labs into bankruptcy

1.36 How much could rates change?

How much could rates change?

- The new rates that are based on the weighted medians of private payor rates will stay in place until the year after the next reporting period (three years for a CDLT)
- Law includes a limit for each of the first six effective years of the law for how much a rate can be reduced from the prior year (based on the CY 2017 NLA) – CMS included this in the regulations and pushed everything back a year to account for delayed implementation

2018	2019	2020	2021	2022	2023
10%	10%	10%	15%	15%	15%

Example

CY 2017 NLA	Weighted Median	10% Max. Reduction	CY 2018 Rate	10% Max. Reduction	CY 2019 Rate	10% Max. Reduction	CY 2020 Rate
\$20.00	\$15.00	\$2.00	\$18.00	\$1.80	\$16.20	\$1.62	\$15.00

1.34 What Could This Mean for Clinical Laboratories?

What Could This Mean for Clinical Laboratories?

- ▶ When the Medicare fee schedule goes down the private payor rates will go down also as they are tied together
 - ▶ Means less money for raises and benefits, hard to acquire staffing
 - ▶ Less testing done in-house with more sent to reference labs will result in local loss of jobs
 - ▶ Etc., etc.

1.37 What Does this Mean?

What Does this Mean?

- ▶ Independent labs could see a decrease of 20% over the next 2 years
- ▶ Hospital labs are paid more than independent labs and have been intentionally left out of the applicable reporting labs
- ▶ The data from the specialty labs, MolDx and toxicology may cause an increase in those payments to everyone
- ▶ Fasten your seatbelt and hold on

1.38 Predictions

Predictions

- ▶ OIG estimates that 2018 payments will go down \$400 million and \$5.4 billion over the next 10 years after the annual decrease limits are exhausted. This is twice what Congress projected when PAMA was passed in 2014
- ▶ Smaller laboratories will be bought by the two large commercial laboratories, or they will step in after the smaller labs go out of business
 - ▶ We are seeing news reports of this happening already
 - ▶ PeaceHealth in Oregon, Connecticut Health and PAML in Spokane, WA.

1.41 NPI Confusion

NPI Confusion

CMS 1621 F Updated 9 Mar 17

"For example, if a group practice did not separately apply for an NPI for its POL and did not include the laboratory as part of the practice when applying for an NPI, the laboratory would not be assigned an NPI. In this instance, the POL cannot qualify as an applicable laboratory. Or, if an independent laboratory that has not been assigned an NPI uses another laboratory to bill for its laboratory services, the laboratory that does not have an NPI cannot qualify as an applicable laboratory."

1.39 Implementation Issues

Implementation Issues

1.42 Deadline to Submit 3-31-2017

Deadline to Submit 3-31-2017 (extended to May 31, 2017)

- ▶ Penalties to labs that are applicable labs
- ▶ With the confusion, many labs don't know if they are an applicable lab or not
- ▶ Penalty for not submitting data is \$10,000 per day
- ▶ Unknown if you report by mistake when you are not an applicable laboratory

1.40 CMS Applicable Laboratory Confusion -NPI

CMS Applicable Laboratory Confusion -NPI

- ▶ 21 Sep 2016- "In order to be an applicable laboratory it must have its own assigned NPI
- ▶ 19 Jan 2017 - "If the physician group practice did not separately apply for an NPI for its CLIA certified laboratory, then the POL is assumed to share the NPI of the group practice."
- ▶ 9 Mar 2017 - In response to a published FAQ for PAMA - " ..when applying for an NPI, if the group practice identifies the POL as part of the practice, the POL is presumed to share the NPI of the group."
- ▶ "If the group practice bills for its laboratory services, then in essence, the laboratory's services are being billed under its own NPI"

1.43 March 30, 2017 announcement of data submission extension to May 31, 2017

March 30, 2017 announcement of data submission extension to May 31, 2017

- ▶ Applies to entities that are subject to the data reporting requirements adopted in the Medicare Clinical Diagnostic Laboratory Tests Payment System final rule published on June 23, 2016 (81 FR 41036).
- ▶ Industry feedback suggests that many reporting entities will not be able to submit a complete set of applicable information to CMS by the March 31, 2017 deadline, and that such entities require additional time to review collected data, address any issues identified during such review, and compile the data into CMS's required reporting format.
- ▶ Intent is to maintain the rest of the timeline.

1.44 Provider Upload Portal Problems

Provider Upload Portal Problems

- ▶ Members have related issues with the reporting web portal
 - ▶ Website unavailable
 - ▶ Data format mismatches

1.47 Our Concerns

Our Concerns

- ▶ Only 5% of labs are required to report data. Most hospital laboratories are left out even though they receive 31% of the Part B payments
- ▶ Smaller community laboratories have a higher cost per test because they are a local source and don't have as much volume to spread overhead cost to
- ▶ Commercial insurance fees are often tied to the Medicare rate. If the Medicare rate goes down, the commercial rate will also decrease.

1.45 OIG Concerns

OIG Concerns

- ▶ Certain aspects could limit savings
 - ▶ NLA may be higher for some tests
 - ▶ Individual fees, no bundled tests
- ▶ Portal capacity

1.48 Any Chance for PAMA Changes with New Congress?

Any Chance for PAMA Changes with New Congress?

- ▶ CLMA and ASCLS have met with staff at House Budget Office
- ▶ Surprised to learn that majority of private payers have fee schedules based on the Medicare Clinical Fee Schedule.
- ▶ CLMA's Legislative, Compliance and Regulatory and Committee (LCRC) is working on a survey to determine what percentage of a facilities private payers use a fee schedule based on MCLFS as well as what percent of non-Medicare tests billed are reimbursed off of a fee schedule based on the MCLFS.
- ▶ Data will be presented during Legislative Symposium Hill visits in March and with key Congressional members.

1.46 OIG Concerns

OIG Concerns

- ▶ No assurance of complete and accurate data
- ▶ CMS does not plan to:
 - ▶ Identify applicable labs
 - ▶ Identify whether all labs reported
 - ▶ Verify quality and accuracy of data
- ▶ Advisory Panel financial interests

1.49 Ask for Delay

Ask for Delay

- ▶ Many laboratory organizations are asking for a delay including ACLA, NILA, CLMA, ASCLS, AMT and ASCP
- ▶ Concerns are:
 - ▶ The portal capacity this week to report
 - ▶ Still confusion on the NPI and applicable labs
 - ▶ Not enough time for providers to review the new prices and make the major budget changes for next year

1.50 Is there an Alternative to PAMA?

Is there an Alternative to PAMA?

- ▶ Other fee schedules have been modernized and updated without market data (ambulance, radiology)
- ▶ CLFS is the oldest fee schedule that had never been reviewed since its inception in 1986
- ▶ HZR 6761 in 2014 was introduced to update the fee schedule using negotiated rulemaking
 - ▶ Introduced by Bart Stuppek (MI) and Michael Burgess (TX), a physician

1.53 Questions ?

Questions ? Discussion !

Rick.L.Panning@HealthPartners.com

1.51 How do reimbursement cuts impact you at home?

How do reimbursement cuts impact you at home?

- Unable to hire personnel, fill positions.
- Working short-staffed, longer hours and overtime
- With rising supply and labor costs, continued reimbursement cuts result in budget cuts that threaten your ability to provide high quality, safe laboratory services
- Threatens access to quality patient care in rural and underserved areas.
- ...and on and on!

1.52 Talking Points

Talking Points

- ▶ Basic education on PAMA
- ▶ The impact of PAMA implementation on the entire lab industry, especially small hospitals and physician office labs
- ▶ Issues with implementation so far
- ▶ Ask for a delay so that calculated fees can be based on complete and accurate data

2.1 Laboratory Developed Tests (LDTs)

LABORATORY DEVELOPED TESTS (LDTs)

Kathy Hansen
Permanent Advisor to the ASCLS
Government Affairs Committee
khansen3@fairview.org

2.4 Slow progress on regulation of LDTs

SLOW PROGRESS ON REGULATION OF LDTs

- 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.

2.2 What is an LDT?

WHAT IS AN LDT?

- LDTs are defined by the FDA as in vitro diagnostic tests that are designed, manufactured, and used within a single laboratory.

2.5 Reaction to proposed regulation

REACTION TO PROPOSED REGULATION

- Laboratory organizations differed in their response to the 2014 proposed regulation.
- Some argued that "CLIA is enough" and oversight of LDTs should be left to CLIA inspectors and accredited organizations such as CAP
- Others agreed with FDA that regulation under CLIA was not sufficient – but that the standards proposed were difficult for a single clinical lab to meet.
- ASCLS submitted written comments to 2014 proposed regulation and responded to a committee hearing in 2016.

2.3 Should LDTs be regulated?

SHOULD LDTs BE REGULATED?

- FDA has proposed regulation of LDTs since 2010 or earlier
- We as clinical laboratory professionals agree that laboratory developed tests (LDTs) must be regulated to ensure their accuracy and overall patient safety.
- 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.
- 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

2.6 Next step from FDA

NEXT STEP FROM FDA

- 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.
- Leg Day participants carried a position paper to their Congressional and Senate offices outlining the response of ASCLS, ASCP, and CLMA to the discussion paper.

2.7 Comments to FDA - risk

COMMENTS SUBMITTED TO FDA - RISK

- 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.

2.10 Comments to FDA - feasibility

COMMENTS SUBMITTED TO FDA - FEASIBILITY

- 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.

2.8 Comment to FDA - validity

COMMENT SUBMITTED TO FDA - VALIDITY

- 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.

2.11 Comment to FDA - inspections

COMMENT SUBMITTED TO FDA - INSPECTIONS

- 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.
- 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.

2.9 Comments to FDA - molecular

COMMENTS SUBMITTED TO FDA - MOLECULAR

- 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 have 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.

2.12 Comments to FDA – practical considerations

COMMENTS SUBMITTED TO FDA – PRACTICAL CONSIDERATIONS

- 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 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.

2.13 Comment to FDA

COMMENT SUBMITTED TO FDA

- We share the FDA's goal to balance patient protection with continued access and innovation.

2.16 Proposal seems to combine regulation of LDTs and vendor developed tests

PROPOSAL SEEMS TO COMBINE REGULATION OF LDTs AND VENDOR DEVELOPED TESTS

- **Risk Classification:** Each test will be classified as high-risk, moderate-risk, or low-risk.
- **Pre-Market Requirements:** To market an IVCT, the developer must establish a reasonable assurance of analytical validity and clinical validity for the intended use. Premarket submission/listing requirements will be based on risk classification with no premarket submission required for low-risk IVCTs. The 510(k)/predicate system, used for therapeutic devices, is not part of the new submission process.

2.14 New developments since Leg Day

NEW DEVELOPMENTS SINCE LEG DAY

- On Monday, March 20, Representatives Larry Bucshon, M.D. (R-IN) and Diana DeGette (D-CO) released a discussion draft of the **Diagnostic Accuracy and Innovation Act (DAIA)**, which would provide a predictable and timely path to market for innovative diagnostic tests.
- *In vitro* clinical tests (IVCTs) would have their own regulatory structure under the Food, Drug, and Cosmetic Act—separate and apart from traditional medical devices—that was developed with their unique attributes in mind from the outset. To eliminate duplicative regulation, the legislation clearly establishes FDA jurisdiction over test development and manufacturing activities and maintains oversight of laboratory operations under the Centers for Medicare and Medicaid Services (CMS) pursuant to an updated Clinical Laboratory Improvement Amendments (CLIA) framework.

2.17 Proposed bill features

PROPOSED BILL FEATURES

- Requires time frames for FDA response to submissions
 - 120 days for high risk
 - 75 days for moderate risk
- If FDA does not meet deadlines, test can be legally marketed without approval
- Bill asks for “modernization” of CLIA – eg, a major re-write

2.15 Definitions in proposed legislation

DEFINITIONS IN PROPOSED LEGISLATION

- The DAIA applies to any *in vitro* clinical test (IVCT), which includes both finished products (e.g., test kits and platforms) and laboratory test protocols (often referred to in the past as “laboratory develop tests” or LDTs).
- IVCTs will be a new category and regulatory structure under the Food, Drug, and Cosmetic Act, and will not be regulated as devices, drugs, or biologics. Laboratory operations will be regulated exclusively by CMS/CLIA.

2.18 Conclusions

CONCLUSIONS

- Proposed bill has not been officially introduced and does not have a bill number as of 4/10/17.
- Documents on the web site for this presentation:
 - Legislative Day leave-behind paper
 - Copy of FDA discussion document
 - Summary of proposed DAIA bill

3.1 Clinical Laboratory Workforce Crisis

UNIVERSITY OF MINNESOTA
CENTER FOR ALLIED HEALTH PROGRAMS

MEDICAL
LABORATORY SCIENCES

**CLINICAL LABORATORY
WORKFORCE CRISIS**

Donna Spannaus-Martin, PhD, MLS (ASCP)^{CM}
Professor
ASCLS-MN Government Affairs Committee and
Political Action Committee Representative
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3.2 ASCP's 2015 Wage Survey of Medical Laboratories in the United States


 **STRONGERTOGETHER**

The American Society for Clinical
Pathology's 2015 Wage Survey of Medical
Laboratories in the United States

3.3 Overview

Overview

- US Bureau of Labor Statistics Data
- ASCP 2015 Wage Survey
- Legislative "Asks"

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3.4 U.S. Bureau of Labor Statistics

U.S. Bureau of Labor Statistics

- Occupational Employment Outlook (2014-2024):
 - As of October 2016, overall unemployment rate = 4.9%
 - Overall employment projected to grow at approximately 7.0%
 - Median annual wage for all workers = \$35,540
- Health Occupations Outlook (2014-2024):
 - Projected to grow 19.0% = 2.3 million new jobs
 - Median annual wage = \$61,710


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3.5 U.S. Department of Bureau and Labor Statistics

**U.S. Department of Bureau and Labor
Statistics**

**Medical and Clinical Laboratory Technologists
and Technicians:**


- Number of jobs, 2014 = 328,200
- Job outlook = 16% (much faster than average)
- Employment Change, 2014-24 = 52,100

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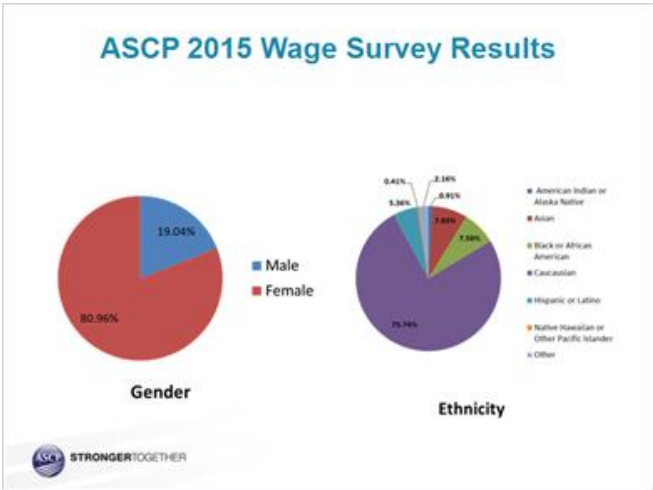
3.6 2015 ASCP Wage Survey

**2015 ASCP Wage Survey
Summary of Findings**

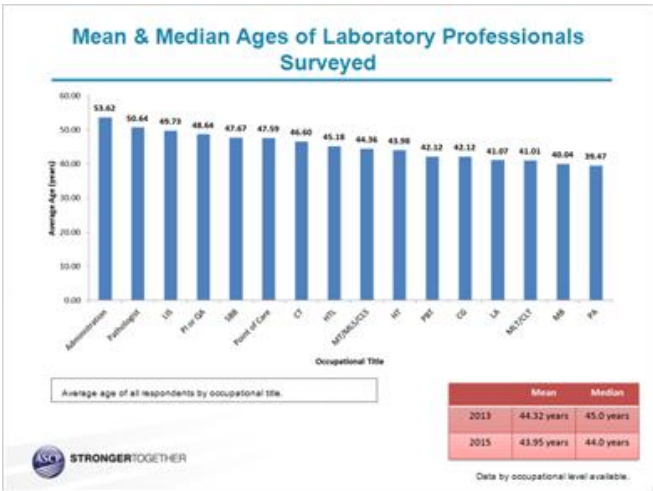
- Participation:
 - 16,661 respondents representing a 27.1% increase in participation compared to the 2013 wage survey
- Additional Occupational Titles:
 - Administration
 - LIS
 - Point of Care
- Additional Categories Researched in 2015 Wage Survey:
 - Gender
 - Ethnicity
 - Certification bodies
 - Budget for salaries

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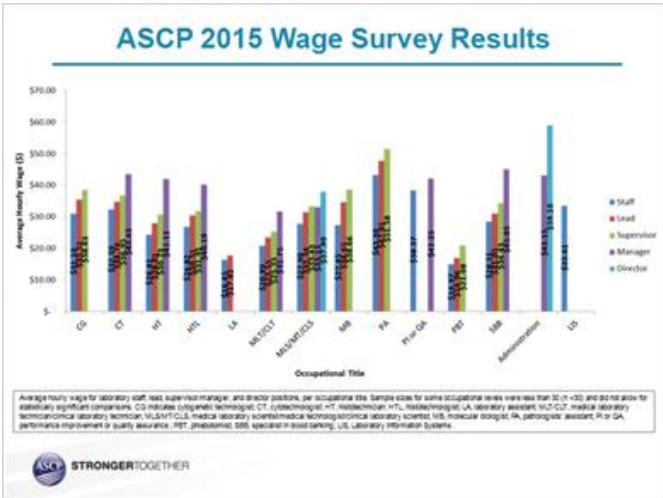
3.7 ASCP 2015 Wage Survey Results



3.8 Mean & Median Ages of Laboratory Professionals Surveyed



3.9 ASCP 2015 Wage Survey Results



3.10 ASCP 2013 vs 2015 Wage Survey Results

ASCP 2013 vs 2015 Wage Survey Results

Staff	2015	2013	% Change
CG	\$ 31.10	\$ 28.63	8.6%
CT	\$ 32.39	\$ 31.45	3.0%
MT/CLS/MLS	\$ 27.90	\$ 27.13	2.8%
LA	\$ 16.45	\$ 16.03	2.6%
MLT/CLT	\$ 20.89	\$ 20.49	2.0%
HT	\$ 24.41	\$ 23.96	1.9%
MB	\$ 27.45	\$ 26.96	1.8%
SBB	\$ 28.51	\$ 28.07	1.5%
HTL	\$ 26.82	\$ 26.83	0.7%
PBT	\$ 14.97	\$ 15.60	-4.0%
PA	\$ 43.30	\$ 46.32	-6.5%
Phlebotomist	\$ 38.37	N/A	N/A
LIS	\$ 33.61	N/A	N/A

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3.11 ASCP 2013 vs 2015 Wage Survey Results

ASCP 2013 vs 2015 Wage Survey Results

Lead	2015	2013	% Change
CG	\$ 35.51	\$ 32.22	10.22%
HTL	\$ 30.51	\$ 28.76	6.07%
MLT/CLT	\$ 23.55	\$ 22.38	5.22%
HT	\$ 28.01	\$ 26.81	4.48%
MT/CLS/MLS	\$ 31.54	\$ 30.81	2.36%
PBT	\$ 16.96	\$ 16.71	1.49%
CT	\$ 34.74	\$ 35.20	-1.30%
SBB	\$ 31.05	\$ 32.11	-3.31%
LA	\$ 17.82	N/A	N/A
MB	\$ 34.65	N/A	N/A
PA	\$ 47.81	N/A	N/A

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3.12 ASCP 2013 vs 2015 Wage Survey

Results

ASCP 2013 vs 2015 Wage Survey Results				
Supervisor	2015	2013	% Change	
MLT/CLT	\$ 25.33	\$ 22.60	12.10%	
PA	\$ 51.58	\$ 48.74	5.83%	
MT/CLS/MLS	\$ 33.43	\$ 32.82	1.87%	
SBB	\$ 34.43	\$ 34.44	-0.04%	
CT	\$ 36.95	\$ 37.09	-0.38%	
HTL	\$ 31.91	\$ 32.41	-1.55%	
HT	\$ 30.73	\$ 31.29	-1.80%	
CG	\$ 38.63	\$ 39.95	-3.32%	
MB	\$ 38.06	N/A	N/A	
PBT	\$ 21.08	N/A	N/A	

3.15 Wage Comment Analysis

Wage Survey Comment Analysis

- “We are an unknown entity within the medical world, yet no one could do their jobs without us.”
- “Our professional status is not well recognized by most people in general, and by other medical professionals in particular.”
- “As laboratory professionals we must stand as one collective unit to passionately demand increased wages, deserved recognition from our colleagues as professional resources, and adequate compensation for improving patient care every hour of every day.”



3.16 Summary

3.13 Wages Summary

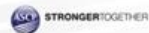
Summary

- Compared to the 2013 ASCP wage survey, salaries are up for all staff-level laboratory professionals except PBT and PA which have a -4.0% and -6.50% change in annual hourly wage, respectively.
- Supervisors' annual hourly wages however, are down except for MLT/CLT, PA and MLS/MT/CLS, at 12.10%, 5.83%, and 1.87% respectively.
- The average wage of laboratory professionals based on age shows that salaries continue to increase considerably for every age range except LA and PBT.



Summary

- There is a need for recruiting younger laboratory professionals, the youngest group are the PAs with an average age of 39.47.
- Employee development such as training, continuing education and mentoring can prove beneficial in retaining staff.
- **Strategic focus on RECRUITMENT AND RETENTION needed!**



3.17 Link to Survey:

3.14 Wage Comment Analysis

Wage Survey Comment Analysis

Number of Comments Received: 2230

Top-Five Categories

1. Underpaid/Underappreciated
2. Need for increased Wages/Raises
3. Suggestions for Future Surveys
4. Advocacy
5. Benefits



Link to Survey:

<https://academic.oup.com/ajcp/articlelookup/doi/10.1093/ajcp/ajqw220>

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3.18 Medical Laboratory

Medical Laboratory Sciences

UNIVERSITY OF MINNESOTA
CENTER FOR ALLIED HEALTH PROGRAMS

Medical Laboratory Workforce Shortage

- BLS estimates the need for new medical laboratory professionals to be 12,000 per year
- Decline in the number of medical laboratory academic programs
- Decline in the number of clinical sites

3.21 Contact Information

*Contact Information

*In Minnesota:

- *Senator Amy Klobuchar
<https://www.klobuchar.senate.gov/public/>
- *Senator Al Franken
www.franken.senate.gov
- *Your Representative depends on where you live
www.gis.leg.mn/iMaps/districts

3.19 VA Healthcare Workforce Shortages

Medical Laboratory Sciences

UNIVERSITY OF MINNESOTA
CENTER FOR ALLIED HEALTH PROGRAMS

VA Healthcare Workforce Shortages

- VA Office of Inspector General determined the largest critical need healthcare occupations were for Medical Officers, Nurses, Psychologists, Physician Assistants, Physical Therapists, and **Medical Technologists (medical laboratory personnel)**

3.22 Be The Voice!



3.20 What Can We Do?

Medical Laboratory Sciences

UNIVERSITY OF MINNESOTA
CENTER FOR ALLIED HEALTH PROGRAMS

What Can We Do?

- Ask that Congress authorize and appropriate funding for a program within the Public Service Act to ensure training for citizens seeking to enter the clinical laboratory workforce
- Title VIII of the Public Service Act has an Allied Health Special Projects and Grants Program that has not been funded in several years
- Authorize the Government Accountability Organization (GAO) to study the shortage of clinical laboratory personnel and make recommendations to Congress