

# Legislative Symposium

## Protecting Access to Medicare Act (PAMA)

Washington, DC

March 19, 2018

**Rodney W. Forsman**

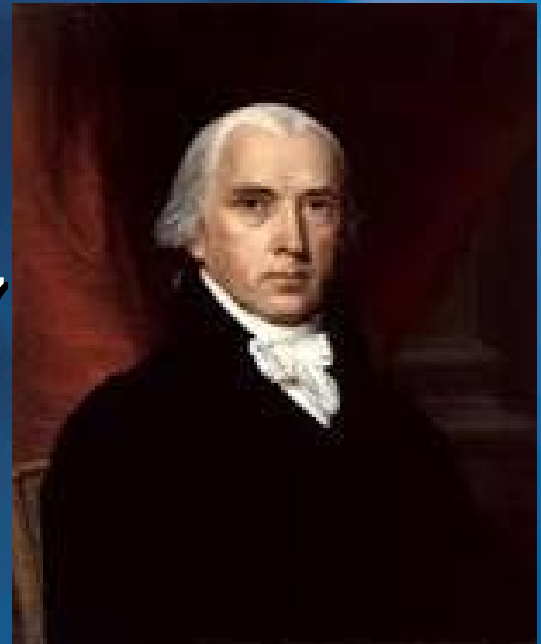
CLMA LCRC, FAAC Member

Assistant Professor Emeritus,  
Laboratory Medicine and Pathology,  
College of Medicine, Mayo Clinic



***“It will be of little avail to the people that the laws are made..., if the laws be so voluminous that they cannot be read, or so incoherent that they cannot be understood.”***

**James Madison, President 1809-1817**



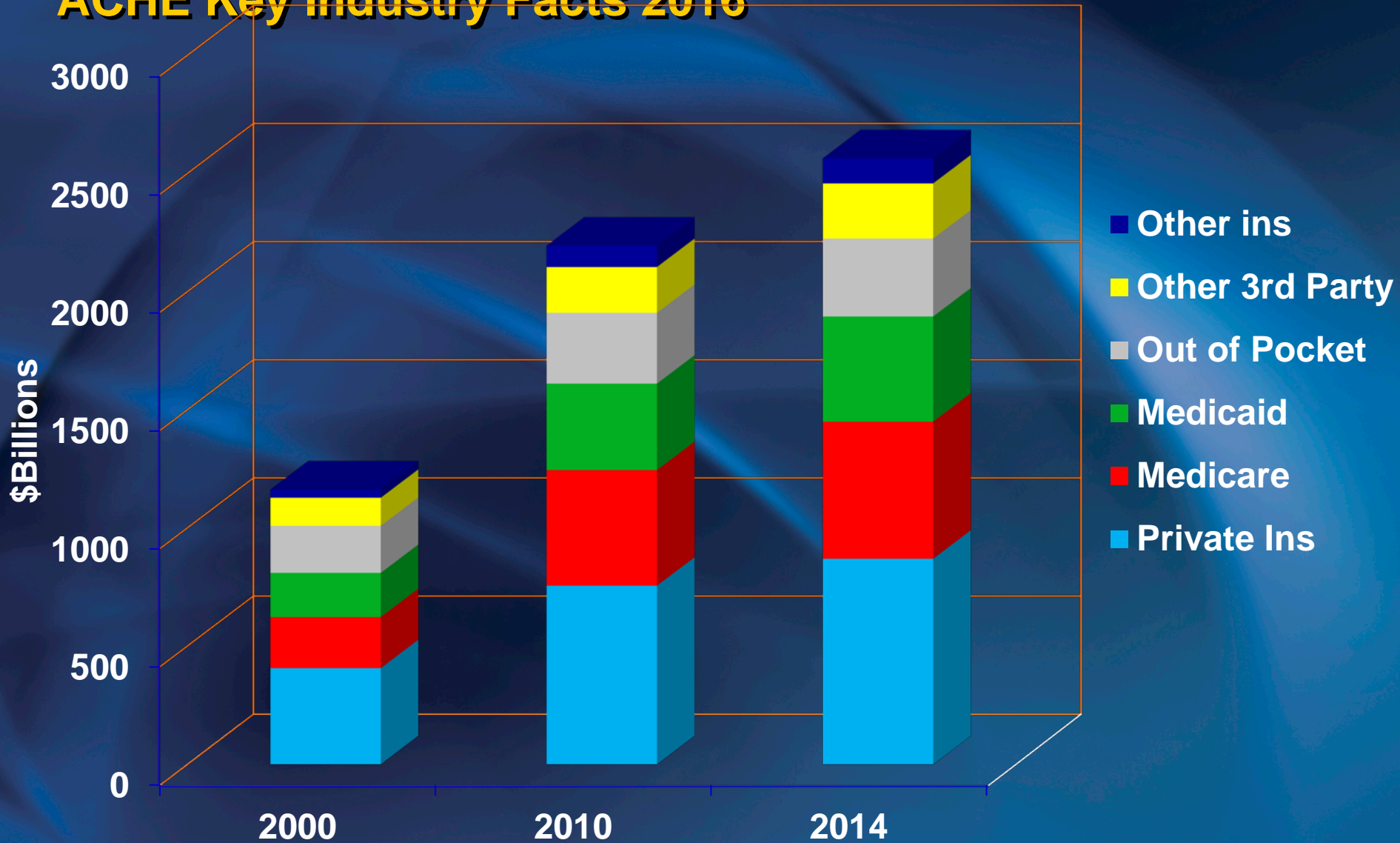
***“When Congress makes a joke,  
it’s a law and when Congress  
makes a law, it’s a joke.”***



**Will Rogers**

# Personal Health Care Expenditures

## ACHE Key Industry Facts 2016



**July 30, 1965**



# First Beneficiary

DHEW - SOCIAL SECURITY ADMINISTRATION

488-40-6969-A

APPLICATION FOR ENROLLMENT  
in the  
Supplementary Medical Insurance Program  
Under the Social Security Act

PLEASE READ THE ENCLOSED LEAFLET

Harry S Truman  
Independence, Missouri

*Do not write in the space above*

TO GET MEDICAL INSURANCE



CHECK



YES

The Federal Government will pay half the cost of this insurance. Your share of the cost (\$3) will be deducted from your monthly social security benefits.

IF YOU DO NOT WANT  
THIS MEDICAL INSURANCE



CHECK



NO

SIGN  
HERE

*Harry S Truman*

Signature by mark (X) must be witnessed below.

SIGNATURE  
OF WITNESS

*[Witness Signature]*

ADDRESS  
OF WITNESS

# Protecting Access to Medicare Act (PAMA)

- Passed April 1, 2014 for the “Doc Fix”  
Section 216 reforms the Clinical Laboratory  
Fee Schedule (CLFS)
- Final Rule June 23, 2016

# 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 from TIN to NPI



# Applicable Laboratories That Must Report Data

1. Have a CLIA certificate
2. Bill using their own lab NPI
3. Bill using the physician NPI if no lab NPI
4. More than 50% of Medicare revenue from the PFS and CLFS
5. Medicare CLFS payments >\$12,500 for the 6 month reporting period
  - Assumes the lab bills applicable payors

# **NPI Requirements Jan 23, 2004**

- **All health care providers that are HIPAA covered entities must have an NPI**
  - 1) **Type 1 – Individuals**
  - 2) **Type 2 – Organizations**
  - 3) **Type 2 Subparts conducting HIPAA transactions separately**

# **“Majority of Medicare” Calculation**

## **At NPI Level**

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

# Reporting Laboratories

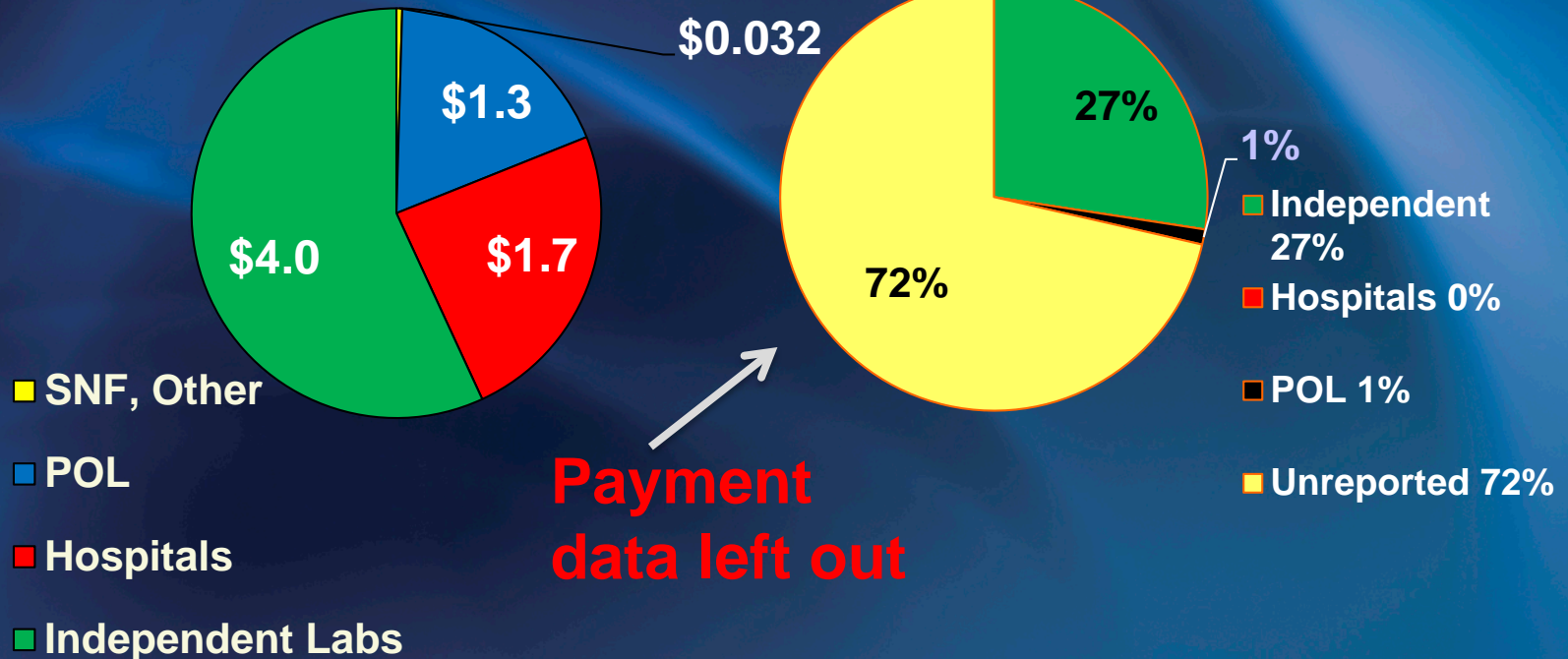
5% of POLs, 44% of Independents and 21 hospitals

CLFS  
payout is  
\$6.8 billion

Spending

Reporting

\$2.0 billion



# 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

# Frequency of Reporting

- For most Clinical Diagnostic Laboratory Tests (CDLTs), every three years
- Annually for advanced diagnostic laboratory tests (ADLTs)

# Collection and Reporting Periods

## Data collection period:

January 1, 2016 through June 30, 2016

## 6-Month window:

July 1, 2016 through December 31, 2016

## Data reporting period:

January 1, 2017 through March 31, 2017

## Implementation date:

January 1, 2018

# Collection and Reporting Periods

- Updates for CDLTs every three years
- For update year CY 2021:
  - Collection = January 1, 2019 –June 30, 2019
  - Reporting = January 1, 2020 –March 31, 2020
- Annually for ADLTs



# 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
- In effect for 3 years with no inflation update or productivity decrease – except ADLTs annually
- Subject to sequestration
- If no data is received for a given HCPCS, CMS will use cross walking or gap filling to price the test

# 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
- New median rates will result from data analysis every three years

# Payment Reduction Limits

- 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

# Potential CLFS Reductions

## Projected Savings \$3.91B First 5 Years



Federal Register, the Daily Journal of the United States Government. Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System. A Rule by the Centers for Medicare & Medicaid Services on 6/23/2016. <https://www.federalregister.gov/documents/2016/06/23/2016-14531/medicare-program-medicare-clinical-diagnostic-laboratory-tests-payment-system>

# **CMS Reduction Estimates**

- **Projected \$390 million reduction in FY2018 payments**
- **Private payor rates are 20% lower than Medicare overall**
- **\$670 million actual reduction FY2018**

# Top 10 PAMA Fees

		NLA	Actual	PAMA	Difference
84443	TSH	\$22.89	\$22.42	\$14.87	\$162,295,000
85025	CBC	\$10.59	\$10.31	\$6.88	\$144,040,000
82306	Vit D	\$40.33	\$38.89	\$26.37	\$112,670,000
80053	Comp metabolic panel	\$14.39	\$11.19	\$9.08	\$88,640,000
83036	HgbA1C	\$13.22	\$13.16	\$8.50	\$88,500,000
80061	Lipid panel *Note no NLA	\$17.86	\$14.17	\$11.23	\$85,330,000
G0483	Drug test def 22 or more	\$215.23	\$241.00	\$193.71	\$47,290,000
G0479	Drug test, presumptive	\$79.25	\$73.67	\$62.14	\$34,580,000
80048	BMP	\$11.52	\$9.50	\$8.06	\$20,160,000
G0482	Drug test, def, 15-21	\$166.03	\$127.00	\$132.00	\$5,000,000
	Decrease, leaving out TSH				\$616,210,000
	Decrease with TSH				\$778,505,000

# Process for New Tests

- New CDLTs will be priced similar to existing process using cross-walk and gap fill until the next data reporting cycle
- These will be discussed by the PAMA payment advisory panel
- Opportunity for public comment

# Advanced Diagnostic Laboratory Tests (ADLT)

- Tests offered by a single lab and must meet one of the following criteria:
  - Include DNA or RNA and use an algorithm to yield a single-patient specific result
  - Test meets other similar criteria established by the Secretary (none at this time)
  - FDA cleared or approved



# ADLTs

- A small number of tests and labs
- Details can be found in the June 23, 2016 Federal Register

# **OLG Concerns 2016**

- **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**

# **OLG Data Brief Year 3**

- **Medicare Part B paid \$6.8 billion for lab tests in 2016 – down from \$7B 2014-15**
- **The top 25 lab tests by Medicare payments totaled \$4.3 billion**
- **The top 6 lab tests totaled \$2.4 billion**

***“The government has dabbled in medical affairs at an enormous expense for what has been accomplished.”***



**Dr. Charles H. Mayo - 1919**