HOW WE GOT TO PAMA AND THIS FINAL REPORTING RULE:

Understanding the History, Legislation, and Regulatory Processes Involving the Medicare Part B Clinical Laboratory Fee Schedule

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The Long and Winding Road...

- Pre-PAMA CLFS
- "Technological Changes" (2013)
- PAMA (2014)
- PAMA Rulemaking and Implementation (2016-2017)
- FUTURE THIS WAY
B.P. (Before PAMA)

“My insurance doesn’t cover prehistoric conditions.”
The Clinical Laboratory Fee Schedule as we knew it...

- **CLFS established in 1984** by the Deficit Reduction Act
  - Labs were reimbursed at the lower of the submitted charge or the CLFS rate
  - Actually **56 separate local and state fee schedules**, with small differences in prices between them

- In 1985, Congress established **National Limitation Amounts** for clinical laboratory fees, which gradually decreased from 115 percent of the median of all local fee schedule amounts to 74 percent of the median

- CLFS was **updated annually** around the margins by the CPI-U, multifactor productivity adjustment, etc.; otherwise, largely **static** reimbursement rates through the years
“Technological Changes”

- Statute gave the Secretary of HHS the authority to adjust rates on the CLFS “subject to such other adjustments as the Secretary determines are justified by technological changes.” 42 U.S.C. § 1395l(h)(2)(A)(i) (2013).

- CMS proposal:
  - Define “technological changes” as changes to the tools, machines, supplies, instruments, skills, techniques, and devices by which laboratory tests are produced and used
  - Review a set of codes each year, starting with the codes that had been on the CLFS the longest
  - Review tests using similar methodologies, resources together
  - Public could nominate codes for review
  - Expected most reimbursement rates to decrease

- Despite widespread concern about process transparency, public involvement, adequacy of agency resources and expertise, and potential for sharp reimbursement rate cuts, CMS finalized its proposal in the CY 2014 PFS Final Rule.
NOT SO FAST!!!
Protecting Access to Medicare Act § 216

- Removed the Secretary’s authority to adjust CLFS rates based on “technological changes”
- Established a new “market-based” system for establishing CLFS rates
- During a **data reporting period**, an **applicable laboratory** submits **applicable information** (private payor rates & volumes) about lab tests for which it received payment during a **data collection period**; CLFS rates are based on the **weighted median** of rates reported by applicable laboratories and stay in effect for **three years**
- Authorized **civil monetary penalties** for incomplete or inaccurate reporting, failure to report
- **Limit** on how much rates could be cut in first six years
- Mandated **GAO report** on implementation, **OIG monitoring** of payments
- Called for issuance of **final rule no later than June 30, 2015**
What were they thinking?

- We’ll never know for sure...
- **Very little legislative history** for § 216 (e.g., hearings, floor debate, official legislative summary)
- Colloquy on Senate floor between Sen. Orrin Hatch (R-UT) and Sen. Richard Burr (R-NC), letter to then-CMS Admin. Marilyn Tavenner about Congressional intent to include hospital outreach laboratories
PAMA Rulemaking and Implementation

- CMS issued a proposed rule about three months after the deadline for issuing a final rule
- Statute calls for first data reporting period in 2016 and new CLFS rates in 2017; final rule pushed everything back one year
- Final rule released about two weeks prior to the end of the first data collection period (Jan. 1 – June 30, 2016) - all data collected retroactively
- Data reporting period scheduled for Jan. 1 – Mar. 31, 2017 – extended two months because of “technical difficulties” on CMS’s end
- Preliminary rates released Sept. 2017, final rates released Nov. 2017
- New CLFS rates went into effect Jan. 1, 2018
Key take-aways from the first PAMA reporting cycle

1. Far **fewer labs reported** applicable information than expected:
   - 0.7 percent of labs paid under Medicare Part B in 2015
   - 1,942 out of 261,524 labs

2. Hospital labs reported just **1% of applicable information**

3. Rates for **9 of top 10 lab tests** by CLFS spending **cut by more than 30%; 21 of top 25 lab tests cut by more than 20%**

4. The **actual cuts far exceed Congressional Budget Office estimate** of savings to Medicare program
   - CBO estimate: **$1 billion/3 years**
   - Actual cuts: **$3.6 billion/3 years**
CY 2019 PFS Rulemaking

- Amended the definition of “applicable laboratory” to include hospital laboratories that submit claims to Medicare using a **CMS-1450 14X type of bill** and that have more than $12,500 in CLFS revenue in the first six months of 2019
  - Intended to capture hospital outreach labs that compete in the marketplace with independent laboratories
  - Hospital outreach labs will report information on private payor rates and volumes only for hospital non-patients (those not registered as hospital inpatients or outpatients)
- A few other changes to PAMA regulations...
What’s next for PAMA?

- **American Clinical Laboratory Association v. Azar**
  - Challenges CMS’s implementation of PAMA, failure to comply with Congress’s statutory directives
  - Oral arguments heard in U.S. Court of Appeals for D.C. Circuit on April 23, 2019
  - U.S. District Court ruled in October 2018 that statute precludes judicial review of “establishment of payment amounts”; District Court did not rule on merits of argument

- Next data collection period: NOW! (Jan. 1 – June 30, 2019)
- Next data reporting period: Jan. 1 – Mar. 31, 2020
- New rates go into effect: Jan. 1, 2021
- Will Congress act?

*Stay tuned!*
Thank you!

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