ASCLA, CLMA, ASCP, AGT, AMT, NSH Annual Legislative Symposium: Repair Medicare CLFS Reform under PAMA

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Reform of the Clinical Laboratory Fee Schedule

from the *Protecting Access to Medicare Act of 2014*

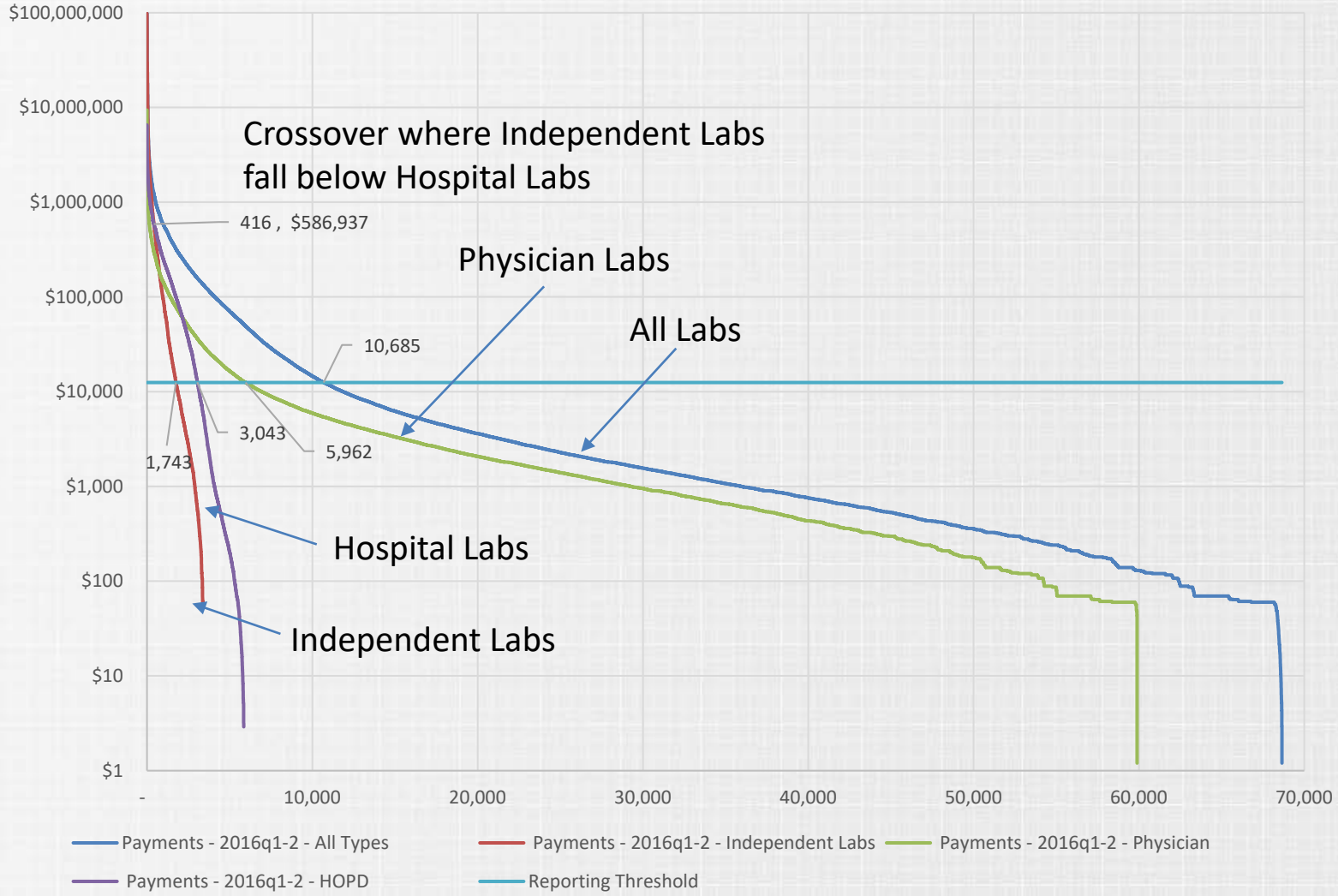
Congress enacted the *Protecting Access to Medicare Act* (PAMA) in 2014, including Section 216, which changes how labs are reimbursed for serving Medicare patients. PAMA changes the Clinical Laboratory Fee Schedule (CLFS) from a static fee schedule to a fee schedule based on the private market rates of Medicare lab providers. CMS, however, has implemented PAMA in an arbitrary way that ignores Congressional intent and threatens beneficiary access.

PAMA's Intent	PAMA as CMS implemented	Detail
Market-based system	Framework resulted in lowest prices from highest volume providers, not market-based pricing	Largest three labs constituted 60% of PAMA data, despite reportedly receiving only 16% of 2016 CLFS claims payments
Data from all market segments	Skewed data excluding whole market segments	Over 99% of laboratories were prohibited from reporting, especially hospital labs, which represented 26% of 2016 CLFS spend
Predictable and sustainable	Unpredictable and unsustainable	Reporting was unpredictably low and rules for applicable labs and data unpredictably applied, resulting in unsustainably low reimbursement
Fair and accurate rate-setting	Rate cuts 3-4x greater than government estimates	Top 25 tests cut by average of 32%, rural hospital labs cut by average of 28.5%
Medicare beneficiary access	Beneficiary access threatened	Vulnerable beneficiaries at greatest risk of losing access to laboratory services, including rural, nursing home and home health patients

Lab Segments Providing Services Under the Medicare CLFS

Clinical Lab Revenue - First Half of 2016 - By Lab Type

Highest Revenue (left) to Lowest Revenue (right)



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1,300 More Hospital Labs Provide Medicare Services in Mid-Sized Laboratory Market

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Clinical Lab Revenue - First Half of 2016 - By Lab Type

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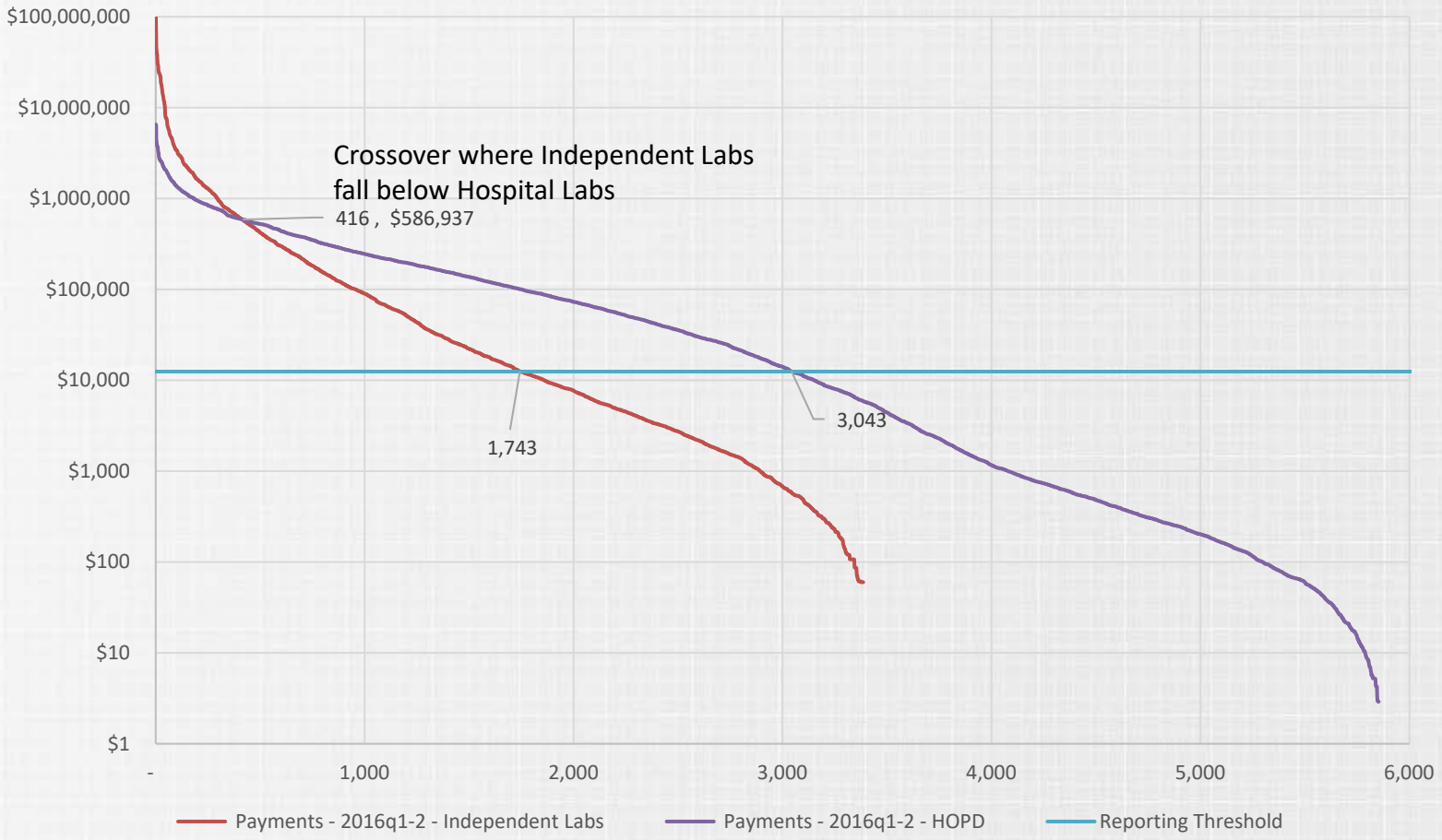
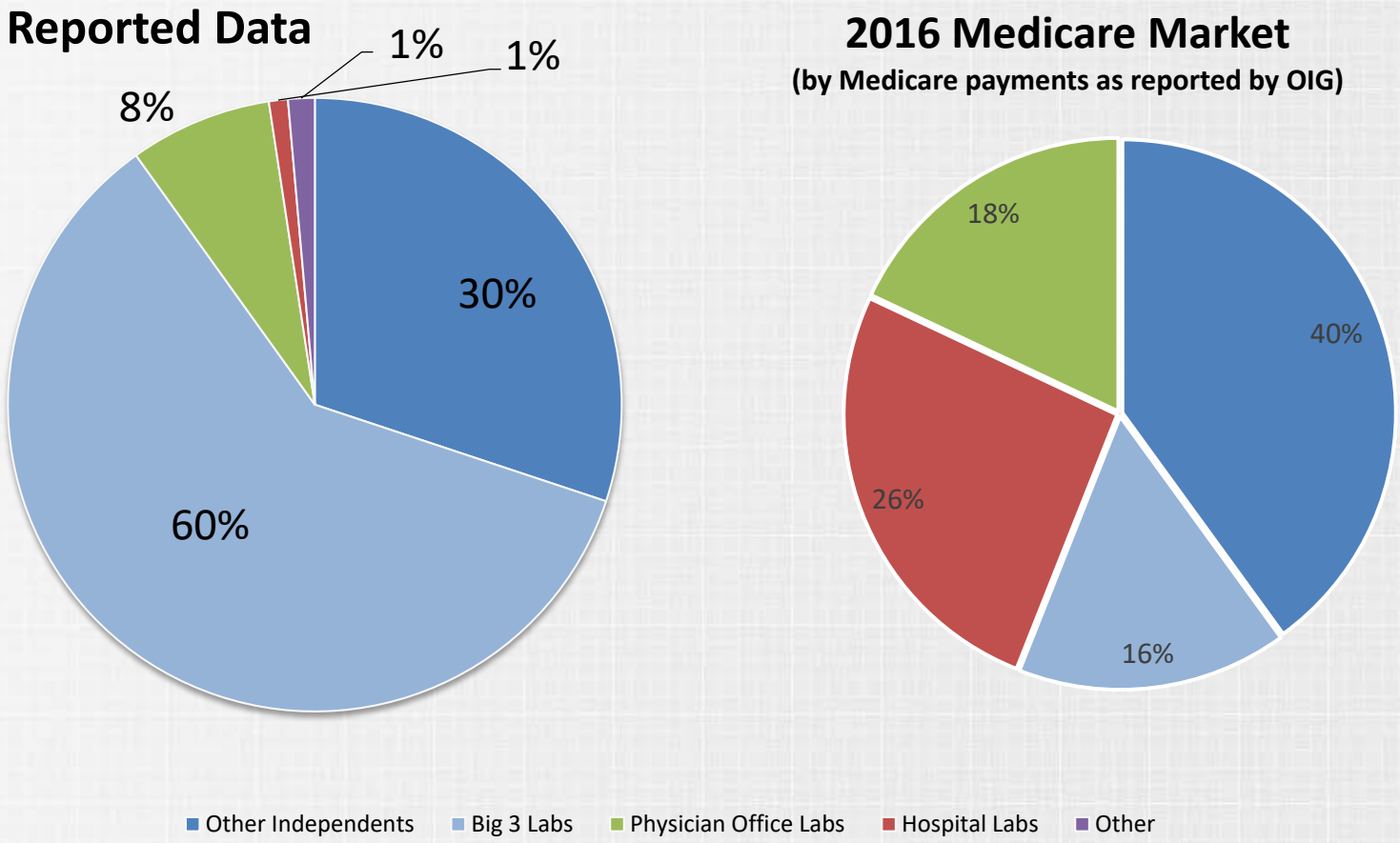


The Big Labs Are Not Representative of the Market



PAMA Data Inadequate

- **Hospital laboratories are significant providers in the Medicare CLFS**
  - 3,043: number of hospital laboratories provided more than $12,500 in *just* CLFS billed services in the first two quarters of CY 2016 (the period used to qualify as an applicable laboratory), without including PFS billed services
  - 1,300: 1,300 more mid-sized hospital labs service the CLFS than mid-sized independent labs
    ("mid-sized" defined as between $568,937 and $12,500 billed in Q1 and Q2 of 2016; 2,627 hospitals and 1,327 independent labs were found to be mid-sized)
  - 26%: Hospital laboratories accounted for 26% of Medicare CLFS payments as reported by the HHS OIG, but were only 1% of data submitted
  - 21: Only 21 hospital NPIs reported data and the actual number of reporting hospital TIN entities is likely even fewer

- **Physician office laboratories significantly expand patient access points**
  - 60,000: Approximately 60,000 physician office laboratories provide services under the CLFS
  - 5,962: Number of physician office labs that exceeded $12,500 in CFLS claims in Q1 and Q2 of 2016
  - 18%: Percentage of Medicare CLFS payments paid to physician offices in 2016
  - 8%: Actual percentage of data reported by physician office labs under PAMA

Independent Analysis of CMS data and summary by Braid-Forbes Health Research

C***MS received data on an extremely small proportion of private sector laboratory payments.***
CMS reported receiving 4.9 million records representing 248 million laboratory tests from 1,942 laboratory reporting entities. In the Medicare claims data alone there are over 78,000 laboratories who billed Medicare in 2016 for lab tests. The 1,942 labs in the CMS data are less than 3% of the total number of labs that currently serve Medicare patients. Private insurance covers 157 million people. Medicare covers 44 million. Medicare paid for over 430 million tests in 2016.

CMS is missing data from an entire important sector of laboratory providers - hospitals.
Over 7,000 hospital labs billed Medicare in 2016. CMS reported collecting information from only 21 hospital NPIs, but since NPIs were bundled under TIN entities, the number of actual hospitals is likely fewer than 21. This leaves hospitals essentially unrepresented in the dataset. Further, it appears that the handful of hospitals that did report are large academic hospitals, which will not be representative of the preponderance of hospital laboratories.

The sample of laboratories that reported is unrepresentative, and cannot be used for unbiased estimation of national payment rates. The sample of laboratories that reported data is extremely small, and entirely excludes important market segments – almost all hospitals, and all non-academic hospitals, and likely other critical laboratory types whose payment rates may differ from others'. Given this, it is not possible to calculate statistically unbiased estimates of the true national payment rates. CMS explored the possibility of reweighting the sample to match nationally representative laboratory characteristics, however even this would not suffice given the complete absence of key laboratory types; this is likely the reason CMS found no significant impact on CLFS spending when it performed its sensitivity analyses.

There is no transparency on the analysis of the sample that CMS performed. CMS stated that the agency performed additional modeling to "determine whether increased participation would significantly affect the payment rates." (p.7) CMS concluded based on its analysis that additional data reporting would not have made significant impact on the payment rates. (p.7) While the data and information released was a positive step in transparency, the agency did not present adequate information on the analyses performed to reach the conclusions presented nor did it make available sufficient data for outside stakeholders to replicate the analysis.

See https://www.kff.org/other/state-indicator/total-population/?dataView=1&currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

Key Legislative Principles to Reform PAMA

1. Savings Bridge to Allow for New Data Collection: Make a statutory adjustment to CLFS payments that provides short term savings but allows time to revise the data collection and rate calculation process conducted by CMS under PAMA. Such an adjustment shall not be greater than the original 2014 PAMA CBO 10-year baseline for the statute. A 10 percent per year cut to a majority of the tests on the CLFS will eliminate testing offered in more costly settings including small and mid-size clinical laboratories, hospital and physician office labs currently serving Medicare beneficiaries.

2. Statistically Valid Sampling of Laboratory Market: Ensure a valid stratified random data sample is collected by CMS that represents all segments of the laboratory market. The sample strata are: hospital laboratories, physician office laboratories, large independent laboratories, and small independent labs, further stratified to assure representation across geographic areas, e.g. MSA, and including urban and rural regions.

3. Streamline Data Reporting: Data collection requirements shall streamline data collection to reduce burden on participating laboratories, and focus on data that is specific to the private market and will impact data calculations. Data collection and reporting requirements shall be applied to private payment rates paid after implementation rules and guidance documents are finalized. Medicaid managed care data that are a result of federal or state budgetary or statutory requirements, which is not reflective of market rates, shall be excluded. Consideration shall be given to allowing laboratories to exclude from reporting paper, manual and non-electric claims that collectively constitute no more than 10% of a lab's private market claims.

4. Fair and Accurate Rate-Setting: Revise PAMA statutory requirements to calculate final CLFS payment rates per code as a weighted mean proportionate to laboratory-type, market share, and geography. All data and calculations will be publicly posted by CMS except where such data would identify specific laboratories and specific proprietary pricing or market data. Annual test fee reductions caps should be put in place. Caps shall be lower than the 10 percent-15 percent limits in the current statute, and spread over a 10-year period.

Key Messages

- Fixing PAMA must be a top legislative priority for Congress this year.
- PAMA cuts are unsustainable and causing real harm to clinical laboratories and the Medicare beneficiaries they serve.
- The hardship will worsen as 10% cuts are scheduled for both 2019 and 2020 for the most commonly ordered laboratory services
- Timely access to these lab services are essential to keeping Medicare beneficiaries healthy and out of the emergency room
- Congress must make a legislative fix to the flawed PAMA system a top priority in 2018.

Comments and Questions