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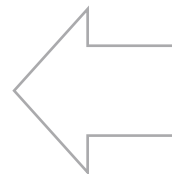
# Medicare Clinical Laboratory Fee Schedule Proposed Cuts to Payment

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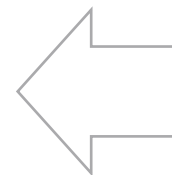
October 2017

*Your* MISSION is *Our* MISSION  
PROPRIETARY AND CONFIDENTIAL

January 1, 2018  
Medicare **patient access** to clinical testing may  
markedly **decrease**



Why?



The Protecting Access to Medicare Act (PAMA)  
will result in steep reductions in payments  
and will not reflect market-based payments as  
intended by Congress

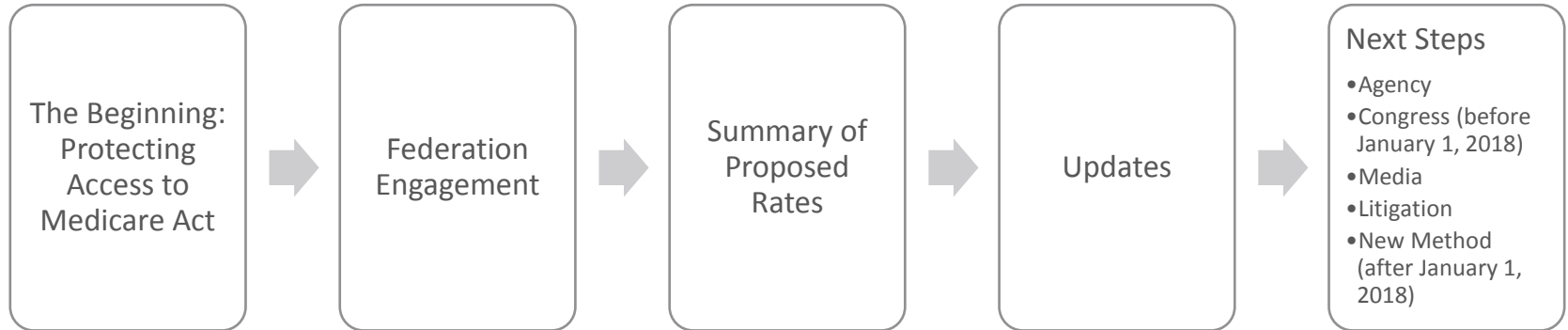
Reimbursement was decreased for a vast majority — 75% — of the various lab tests, with just 10% of the codes getting an increase

The proposed “2018 industry cut is near the worst case, with 2019 likely not providing much relief.”

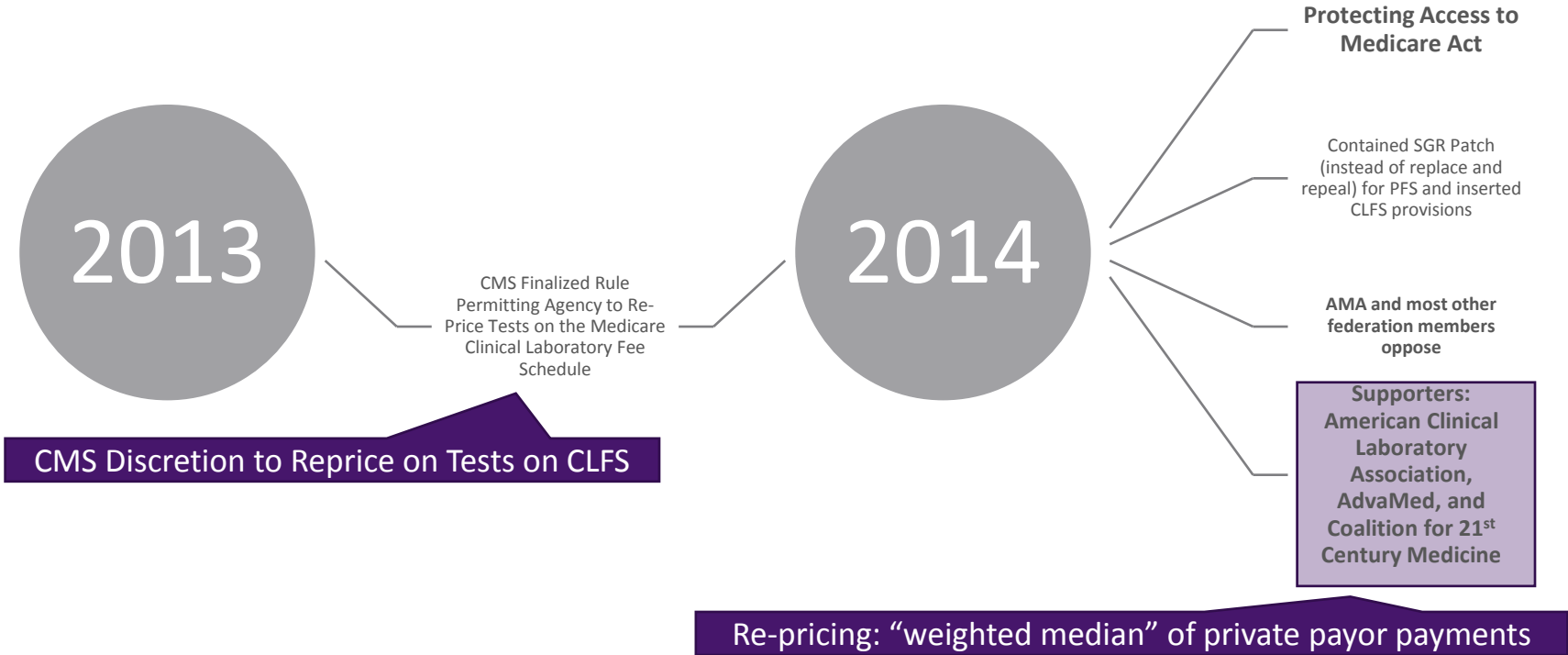
- “In the long run, though, it’s likely that the ‘brunt of the cuts will impact ‘mom and pop’ small labs that lack scale...allowing companies like LabCorp, Quest, and Genomic Health “to consolidate weaker players.”  
– Industry Analyst

- CMS stated that they received data
  - from 1,942 applicable laboratories
  - on nearly 248 million test payments
  - 1,360 tests codes on the CLFS
- The majority of reporting laboratories were located in physician offices (57.0 percent)
- 90.1 percent of the actual reported test volume came from independent laboratories
- Because PAMA establishes a maximum per-year reduction in test rates, 58 percent of tests (those declining by more than 10 percent) will have their reductions phased in over multiple years
- Meanwhile, approximately 10 percent of tests will receive an increase relative to the 2017 CLFS

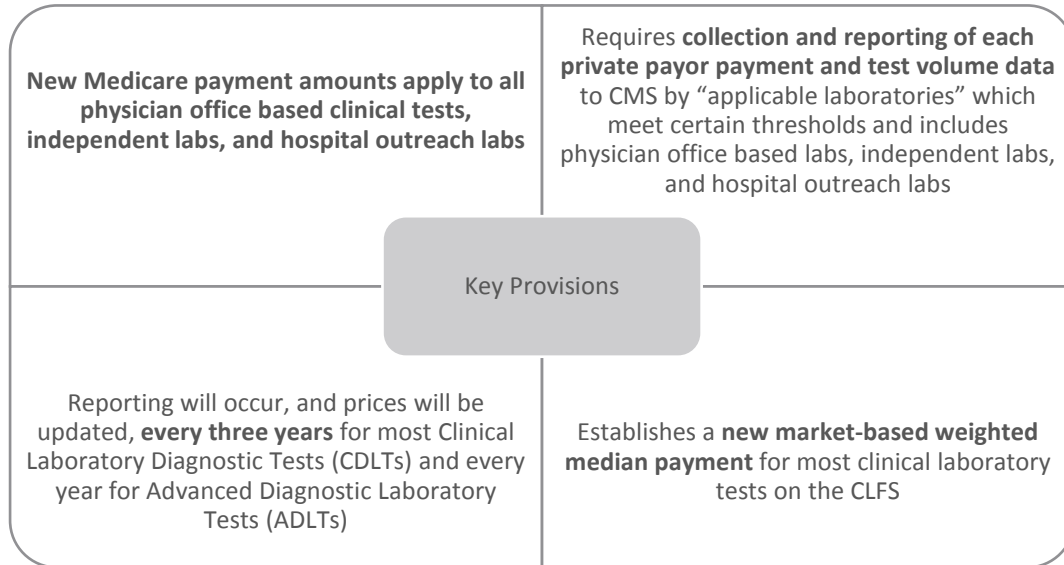
# Road Map



# The Beginning: Legislation



# PAMA requires CMS to establish new Medicare payment rates and the rates will apply to most clinical tests including rapid result testing offered in a physician's office



If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information under this subsection with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty in an amount of up to **\$10,000 per day for each failure to report or each such misrepresentation or omission.**

# The Beginning: Rulemaking

2014: Clinical Laboratory Fee Schedule Annual Public Meeting

- AMA Presentation on potential POL reporting burden

2015: Proposed Rule Issued

- Federation discussions on impact of reporting burden v. too few POLs reporting

2016: Final Rule Issued & Data Collection Required

- Widespread concern with retrospective data collection and six month burden
- Dark Report analysis—projected cuts

2017: Data Submission Mandated, Proposed Rates Issued

- Reports about data collection confusion and challenges: impossibility
- Delays in data submissions

## Key Concerns

- ✓ POL Reporting Burden & Risk of Civil Money Penalties
- ✓ Too Few POLs Report and Weighted Median Too Low

# Regulatory Timeline

- On June 23, 2016 CMS published in the Federal Register the final rule implementing section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA).
- **CMS published preliminary CLFS rates for CY 2018 September 22, 2017.**
  - The public will have approximately 30 days, through early October 23, 2017, to submit comments on the preliminary CY 2018 rates.
- **CMS indicated that it make final CY 2018 CLFS rates available on the CMS website: early November 2017.**
- The final rule also announces CMS' decision to move the implementation date for the private payor rate-based fee schedule to **January 1, 2018.**



# Federation Engagement

- CMS to national medical specialty societies
- Note to all EVPs and Specialties
- AMA Advocacy Updates
- National Specialty Calls
  - Smaller subset of engaged Federation members
- COLA outreach and engagement efforts
- State medical association / national specialty sign-on

# SUMMARY OF PROPOSED RATES

September 22, 2017, CMS Proposed Rates Issued

October 23, 2017, Comment Letters Due to CMS

November 2017, Rates to Be Posted

January 1, 2018, Rates Effective

# COLA ANALYSIS

HCPCS Code	Description	Value to diagnosis & treatment	2017 National Limit Amount	2018 Amount with 10% cap	Weighted Median	Percentage of Cut over 3 years	Number of Tests 2016 (in Millions)
83036	A1C TesT	Treatment of chronic diabetes	\$13.32	\$11.99	\$8.50	-36.7%	19.1
85025	Complete CBC with auto differential	Diagnosis of infection, anemia etc.	\$10.66	\$9.59	\$6.88	-35.46%	41
80053	Comprehensive Metabolic panel	Check major organ function	\$14.49	\$13.04	\$9.08	-37.34%	41
84443	Thyroid Test	Monitoring thyroid function and medication	\$23.05	\$20.75	\$14.87	-35.49%	21.3
85610	Prothrombin Time	Monitoring patients on Coumadin and coagulation disorders	\$5.39	\$4.85	\$4.29	-20%	19.1
83880	Assay of natriuretic peptide	Testing for heart failure	\$46.56	\$41.90	\$39.26	-15.68%	1.4

## Accurate Reporting--Impossibility

Physician organizations strongly urged CMS to establish a data collection period at a minimum six months after the final rule was issued in 2016. This request was based on extensive experience implementing major changes to Medicare programs by physician organizations and physician practices. CMS instead mandated a complicated, detailed, confusing, and voluminous data collection requirement for a mostly retrospective six month data collection period that began approximately six months before the final rule was issued. This constituted an impossibility for a number, if not all, of our members to do accurately and completely. Many clinical laboratories including the largest reference laboratories that have sophisticated payments systems and that hired additional staff, struggled to collect accurate data within the specified data collection timeframe and to submit timely. All of the foregoing underscore that clinical laboratories were required to comply with a regulation that constituted an impossibility.

## Recommendations

We urge CMS to modify the existing PAMA regulations through issuance of an interim final rule effective December 1, 2017, that holds the current rates in place until CMS has conducted targeted market segment surveys (reference laboratories, physician office-base laboratories, independent laboratories, and hospital outreach laboratories) to validate and adjust the final fee schedule payments calculated based on the data collection to ensure congressional intent—payment rates that accurately reflect private market payments across all market segments—is achieved.

# AMA Concerns

- Prevent spread of infectious diseases and pandemics
  - Ensuring the U.S. health system has a strong and comprehensive network of clinical laboratories (including physician office based, independent, reference and hospital community outreach labs) to provide the **first line of detection and defense against an infectious disease outbreak or pandemic in the interest of public health.**
- Strengthen Patient Centered Care through point-of-care testing/near patient testing
  - Advancing **patient-centered care** as part of **21<sup>st</sup> Century medicine initiatives** to leverage innovations in order to ensure care is delivered near to patients (particularly important for Medicare beneficiaries who may have more comorbidities, may be more medically fragile, and may face more barriers (cost and geographic, for example) to accessing clinical care). Point-of-care testing is an important component of such efforts.
- Support delivery pathways that are consistent with MACRA Implementation
  - Improve **patient care continuity and optimize care coordination and efficient communication** to minimize patient burdens associated with fragmented care by facilitating and advancing new payment and delivery models as required under the Medicare Access and CHIP Reauthorization Act of 2015.
- Establish accurate market-based rates
  - Ensuring **congressional intent for market-based rates** is effectuated for clinical tests on the Medicare CLFS.

## Vulnerable Patients: Oncology

“To have testing on the day of treatment, before we start, is very important,” stated an oncologist from Michigan. Laboratory testing at the time of the cancer patient’s treatment visit is often necessary to determine prescription dosages and to assess side effects resulting from chemotherapy medications and any combination of other medications the patient may be taking.

COLA, [www.nearpatienttestingmatters.org](http://www.nearpatienttestingmatters.org) (Reference: 2017 COLA Study, Value of Laboratory Testing to Patient Care)

## Public Health

The public health consequences that result in a significant reduction of near patient testing (including physician office-based and regional testing clinical laboratories) will undermine essential public health infrastructure needed as the front line to detect infectious disease outbreaks

- Our interconnected society makes it vital that our public health professionals get quick, real-time access to diagnostic information when the next epidemic disease breaks out so they can quickly identify the disease and a possible treatment.
- Physicians who provide laboratory services in their practice are able to rule out other potential infections fast in their own laboratory while the patient waits.
- If the infection is not identifiable, the physician can quickly refer the specimen to a reference laboratory or directly to the public health lab.
- The faster these diseases are identified, the faster we can treat these patients and the more likely we will save their lives.



## Rural Patients Losing Access

“It would have a devastating effect in our community.”

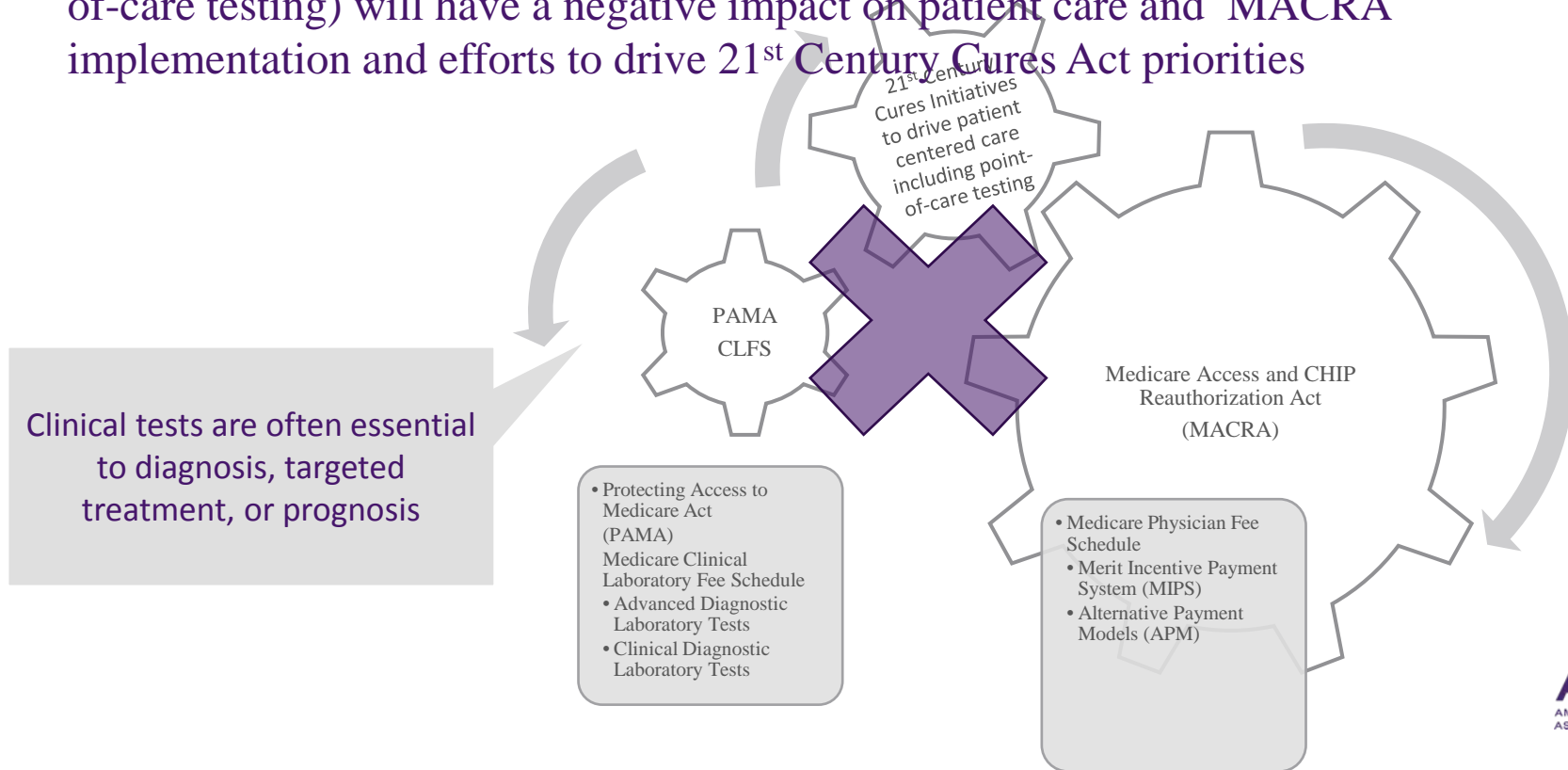
Dr. OK is a family physician practicing in an entirely rural community. During the interview, Dr. OK shared about the scarcity of access to laboratory services in this community.

Dr. OK shared that the closest laboratory is “300 miles away.” If the 3 physician practice no longer provided laboratory services “it would be devastating to our community,” Dr. OK added.

--COLA, [www.nearpatienttestingmatters.org](http://www.nearpatienttestingmatters.org)

## Disrupting MACRA and Innovation

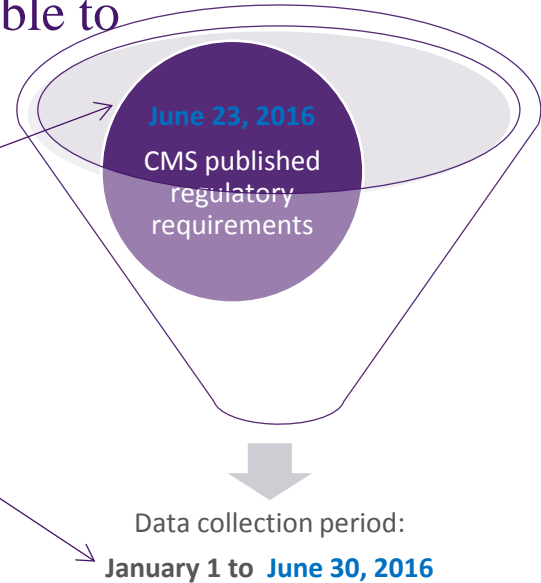
A significant decrease in patient access to clinical testing options (including point-of-care testing) will have a negative impact on patient care and MACRA implementation and efforts to drive 21<sup>st</sup> Century Cures Act priorities



# PAMA PRIMER AND DEFINITIONS

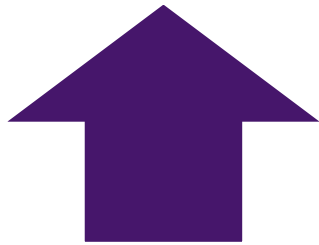
# Implementation was not optimized to collect accurate data and CMS has not specified how stakeholders will be able to ascertain accuracy of final calculated amount

- Based on the CMS regulation (not the statute) clinical laboratories were expected to know nearly six months **before** they were informed what data should be collected
- Many clinical laboratories did not learn of the requirements until well after June 2016 and after the collection of accurate data became an impossibility
- Reports have emerged that inaccurate data was submitted and many clinical laboratories were not aware that they are subject to the reporting requirement because inadequate time was provided to conduct outreach and education
- The Open Payment implementation and data inaccuracies underscore need to validate data in a transparent manner, particularly for first cycle where data integrity remains a widely shared concern

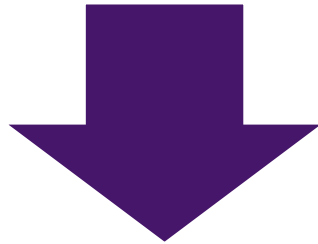


The regulation required too much data, 6 months, when less data would have reduced the regulatory burden and increased ability of applicable laboratories to ensure accuracy

Even large, independent clinical laboratories struggled to submit requested data by the established deadline...while many other clinical laboratories faced additional challenges



Data reporting deadline: March 30, 2017



The deadline was extended by two months to May 30, 2017, because many clinical laboratories including large reference laboratories had difficulty collecting accurate data

# Data Accuracy Problems

- Virtually every laboratory in the country is out of network with a large percentage of private payors. This is for numerous reasons, but the most common reason is that the third party payors wish to contract exclusively with only one or two national or regional laboratories, and all remaining laboratories are effectively excluded from in network status. This means that the laboratories do not have a contract or any other formal documentation of the “allowable” payment rate established by the payor. This makes the reporting of the payment rate for the payor very difficult, if not impossible.
- Even when a laboratory is paid for claims by an out of network payor, the explanation of benefits (EOB) often does not clearly state the payment rate established by the payor. Many laboratories receive different payment rates for the same test (a single CPT code) on the same date of service for patients who live in the same state. Theoretically, these claims should be paid the same amount, but often they are not. This further compounds the difficulty in discerning the payment rate established by the payor.
- Furthermore, the EOBs may not clearly define the patient balance owed on the out of network claim. A laboratory needs to add both the amount paid by the third party payor and the EOB listing of the patient balance in order to determine the payment rate established by the payor. However, if the patient balance is not well delineated, it is not possible for the laboratory to report the payment rate for the out of network payor.
- Additional complications due to bundled payments, paper claims processing.
- Associations and specific labs reported that reconciling payments to test performed was not consistent and was error prone (particularly for paper claims) as payments such as co-pays and co-insurance were not easily reconciled to initial payments and specific tests. In some cases, payments for one test were reported as payments for different tests inadvertently.

# Applicable Laboratory Definition

- “Applicable laboratory” is one that receives a majority of its Medicare revenue under the Medicare Clinical Laboratory Fee Schedule, the Medicare Physician Fee Schedule, or the newly created Section 1834A of the Social Security Act.
- The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory, as the Secretary determines appropriate.
- In the final regulation, the Secretary established a low expenditure threshold for exclusion **which relieved many small, independent clinical laboratories and physician office based laboratories (but not all) from having to report.**
- The final regulation also provided a definition of applicable laboratory that excluded a number of outpatient hospital based clinical laboratories.

# Applicable Data Definition

- The “applicable data” that must be collected and reported is the payment rate that was paid by each private payor for the test during data collection period specified by the Secretary in regulation (six months).
  - The payment rate reported shall reflect all discounts, rebates, coupons, and other price concessions
  - Such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates
  - In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate.
- The applicable data also includes the volume of such tests for each such payor for the period defined in the regulation (six months).



# Payment Amount

- The payment amount to reflect the weighted median determined for the test
- Calculation of weighted median
  - For each laboratory test with respect to which information is reported for a data collection period, the Secretary calculates a weighted median for the test for the period, by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payer and each laboratory.
- Congress intended that the data would be accurate and that implementation would enable the capture of accurate data

# Phase-in Reductions

- Section 1834A(b)(3) of the Act limits the reduction of the payment amount for an existing test as compared to the payment amount for the preceding year.
- For the first three years after implementation, the statute limits the reduction to 10 percent per year, and to 15 percent per year for the following three years.
- CMS finalized the payment reduction limit to correspond to the January 1, 2018 implementation of the revised private payor rate-based CLFS.
- The 10 percent payment reduction limit will apply for CY 2018 through CY 2020, and the 15 percent payment reduction limit will apply for CY 2021 through CY 2023.
- The phased-in payment amount limit per year for existing tests paid under the CLFS prior to January 1, 2018 will be applied using the 2017 national limitation amount (NLA) for the existing test as the baseline payment amount.