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Protecting Access to Medicare Act Implementation

July 2017

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January 1, 2018
Medicare patient access to clinical testing expected to decrease

Why?

It is anticipated that implementation of the clinical testing provisions of the Protecting Access to Medicare Act (PAMA) will result in significant reductions in payments
and will not reflect market-based payments as intended by Congress

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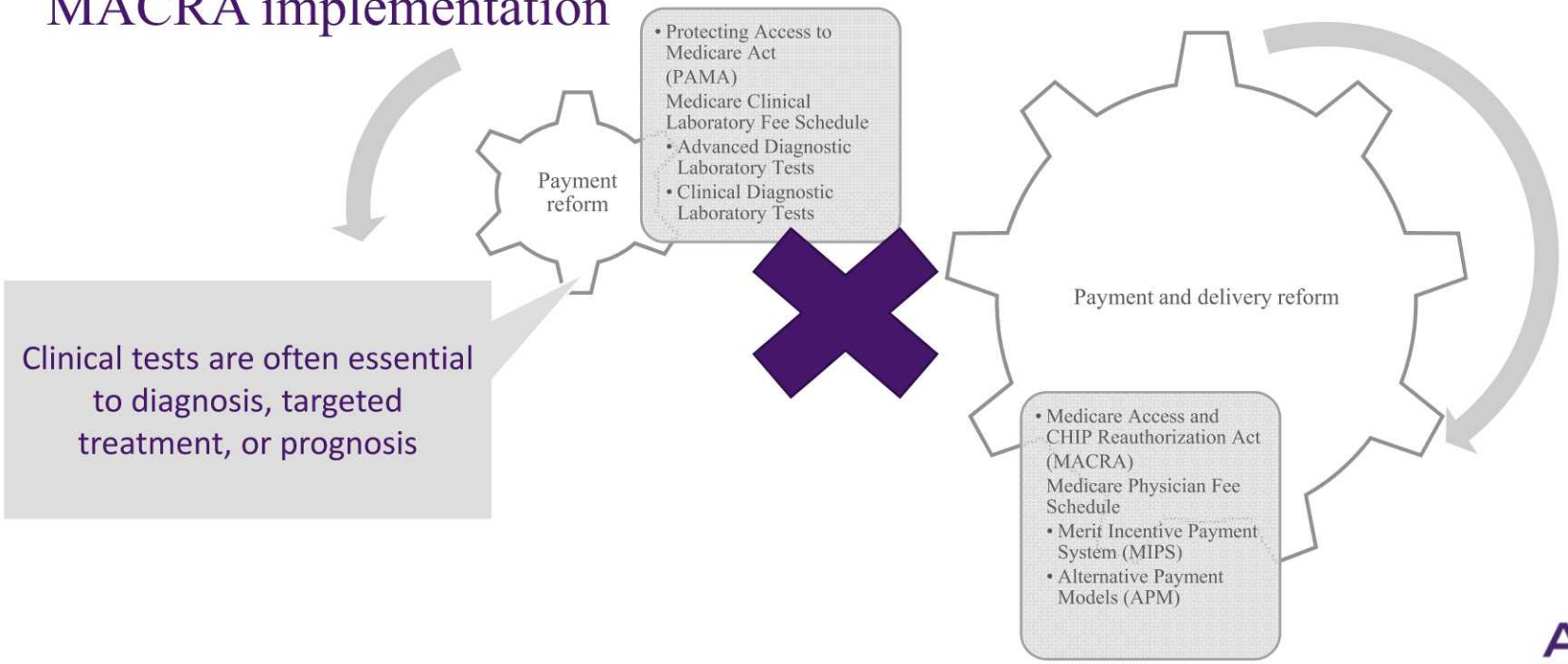
The anticipated decrease in patient access to clinical testing options (particularly near patient testing) is very likely to negatively impact MACRA implementation



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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

New Medicare payment amounts apply to all physician office based clinical tests, independent labs, and hospital outreach labs

Requires **collection and reporting of each private payor payment and test volume data** to CMS by "applicable laboratories" which meet certain thresholds and includes physician office based labs, independent labs, and hospital outreach labs

CMS issued Final Rule

June 23, 2016

Reporting will occur, and prices will be updated, every three years for most Clinical Laboratory Diagnostic Tests (CDLTs) and every year for Advanced Diagnostic Laboratory Tests (ADLTs)

Establishes a **new market-based weighted median payment** for most clinical laboratory tests on the CLFS

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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.

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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).

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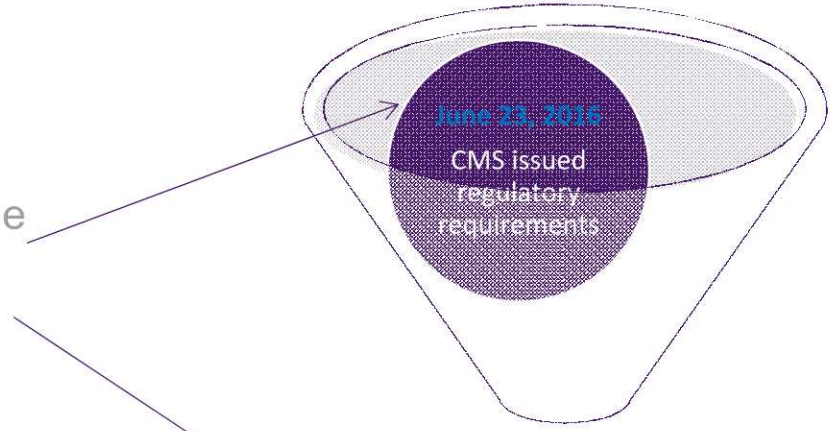
Implementation was not fashioned to collect accurate data

- Based on the CMS regulation (not the statute) clinical laboratories were expected to know nearly six months **before** CMS told them 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



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

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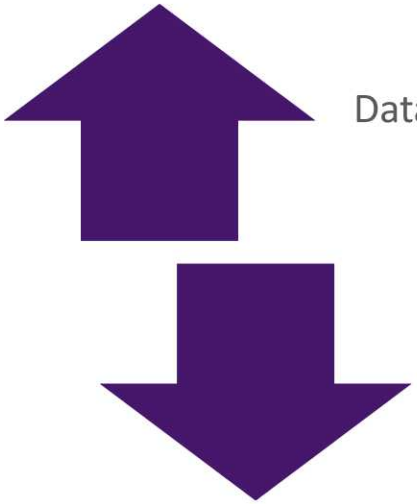
Even large, independent clinical laboratories struggled to submit requested data by the established deadline…while many other clinical laboratories faced additional challenges



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

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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 payor and each laboratory.
- Congress intended that the data would be accurate and that implementation would enable the capture of accurate data

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There are concerns that the widely reported difficulties capturing the specified data will precipitate even larger cuts than were initially expected and imperil patient access

- Physicians rely upon rapid laboratory results in order to appropriately treat their patients.
- The maximum amount of each expected cut:
  - January 1, 2018 – CMS makes no more than 10% cut
  - January 1, 2019 – CMS makes no more than 10% cut
  - January 1, 2020 – CMS makes no more than 10% cut
  - Years 4, 5, and 6 – CMS makes no more than an additional 15% cut per year
- These cuts will hurt **all** specialties' ability to properly care for patients.

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