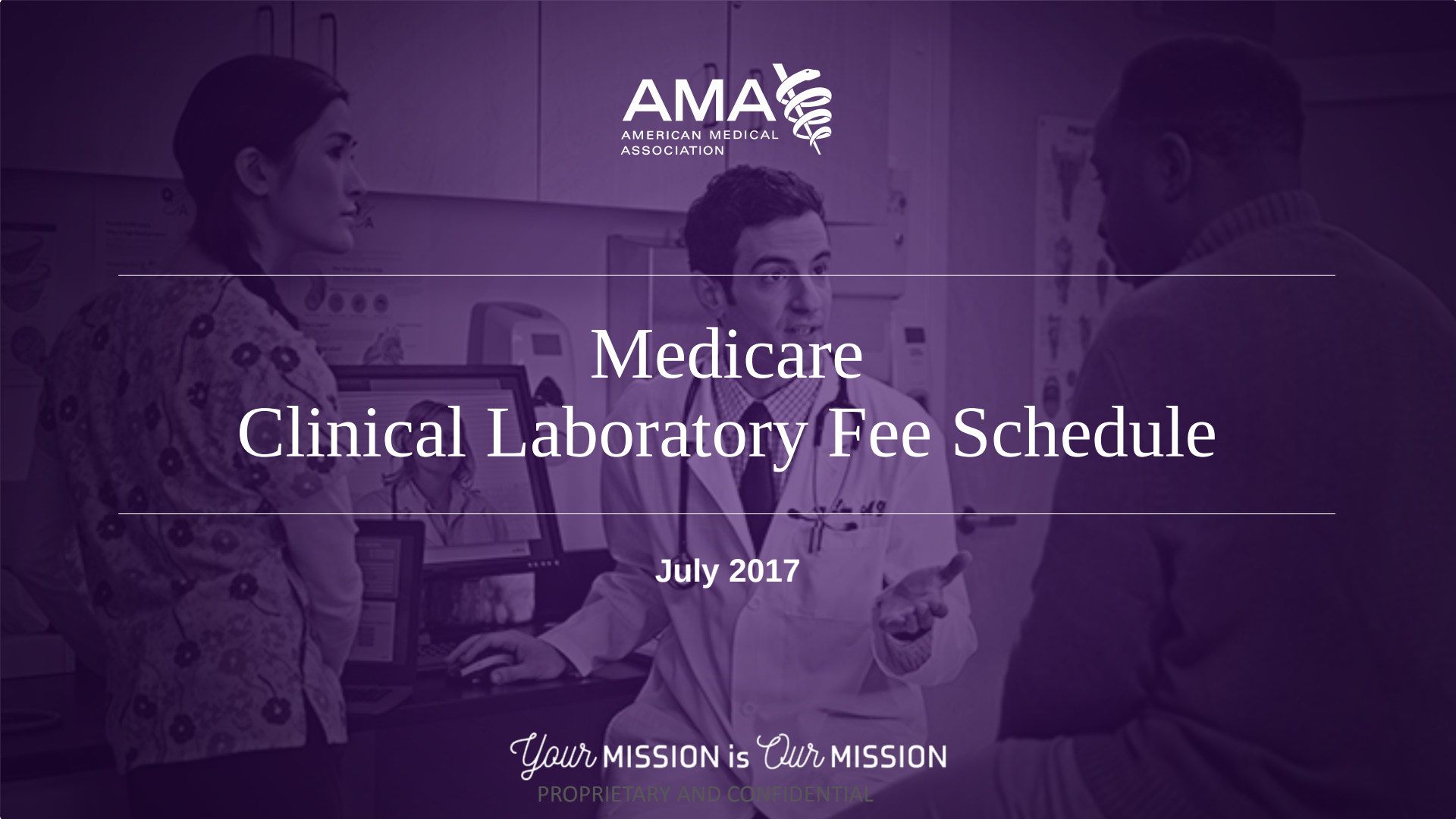

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Medicare
Clinical Laboratory Fee Schedule

July 2017

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Implementation
Clinical Laboratory Fee Schedule Provision
Protecting Access to Medicare Act

BACKGROUND

- 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) that will require reporting entities to report private payor payments paid to laboratories for lab tests, which will be used to calculate Medicare payment rates for clinical tests provide by physicians in their offices to their patients, independent laboratories, and hospital outreach clinical laboratories.

- **CMS indicated it will publish preliminary CLFS rates for CY 2018: early September 2017.**

    - The public will have approximately 30 days, through early **October 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.**

AMA Priorities

- 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**

- Achieving **patient-centered care** as part of **21st 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)

- 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

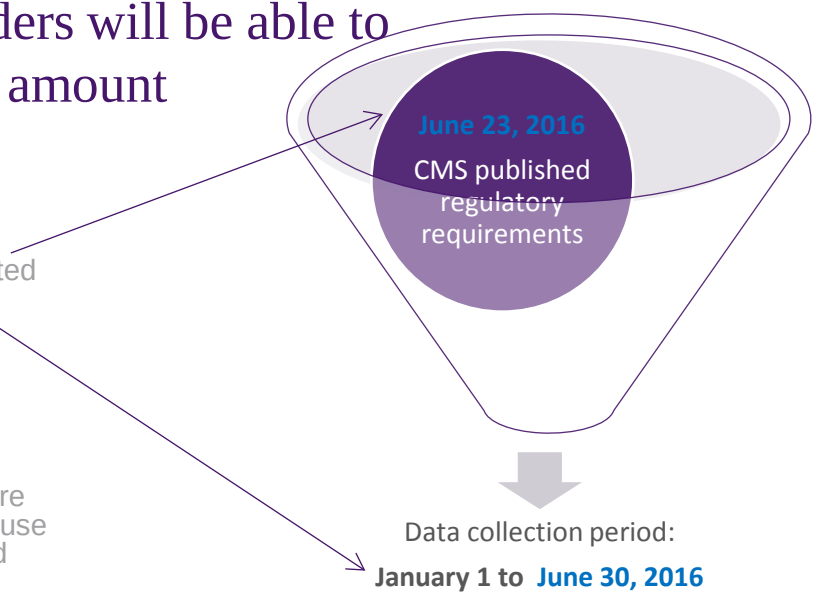
- Ensuring **congressional intent for market-based rates** is effectuated for clinical tests on the Medicare CLFS.

Recommendations

- Publish preliminary information in early August concerning the number of clinical laboratories that have reported based on market segment and geographic locations.
- Publish preliminary CLFS rates for CY 2018 in early September 2017 as the Agency indicated it would do in order to provide physicians and patients time to prepare for any potential disruptions to care delivery resulting from potential significant cuts.
- Issue an interim final rule to
    - Modify existing regulation and provide that CMS will conduct market segment surveys (reference laboratories, physician office–based laboratories, independent laboratories, and hospital community laboratories) **to validate and adjust** the final amount calculated based on the data collection to ensure congressional intent achieved that payments reflect private market payments
    - Allow pricing to proceed as planned on January 1, 2018, based on data collection and submission under existing rule for
        - sole source clinical tests since the data submissions are reasonably expected to be accurate given the limited test menus, the final amount calculated easily validated by the sole source clinical laboratory, and data adequate to establish rate
        - Any additional clinical tests where factors establish high data integrity and transparency of private payer payment calculation

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

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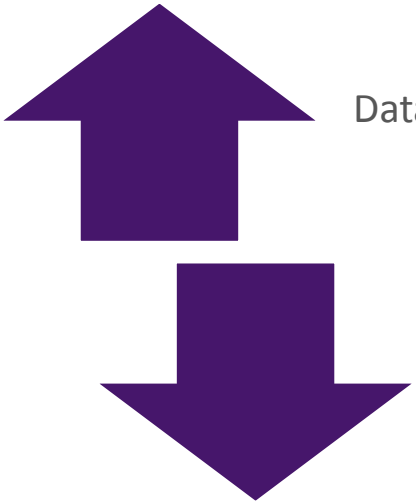
Even large, independent clinical laboratories struggled to submit requested data by the established deadline…while many other clinical laboratories faced additional challenges



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

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.

Oncology Patients

"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. (Reference: 2017 COLA Study, Value of Laboratory Testing to Patient Care)

Table 1 below shows several examples of the projected cuts in Medicare for the most common tests routinely performed by oncologists based upon an analysis of the claims data held by XIFIN. *The list of procedure codes below is not intended to reflect the full menu of testing common to the practice of oncology but is a selection of tests.*

Table 1 — Impact of PAMA on the Clinical Laboratory Fee Schedule

Procedure Code	Test	Private Payer Weighted Average Rate**	Medicare National Limit*	Variance	Percentage Increase/ Decrease
80053	Comprehensive Metabolic Panel	$11.40	$14.39	-$2.99	-20.8%
85025	Complete CBC w/auto diff wbc	$8.11	$10.59	-$2.48	-23.5%
85027	Complete CBC automated	$7.28	$8.81	-$1.53	-17.3%
80061	Lipid Panel	$16.37	$17.73	-$1.36	-7.7%
84439	Thyroxine	$9.54	$12.28	-$2.74	-22.3%
87086	Urine Culture/colony count	$8.27	$11.00	-$2.73	-24.8%
82306	Vitamin D	$28.45	$40.33	-$11.88	-29.5%
82607	B12	$15.09	$20.54	-$5.45	-26.5%
82542	Chromotography quant	$17.80	$24.60	-$6.80	-27.7%
85610	Prothrombin Time	$4.37	$5.36	-$0.99	-18.4%
82728	Ferritin	$13.61	$18.57	-$4.96	-26.7%

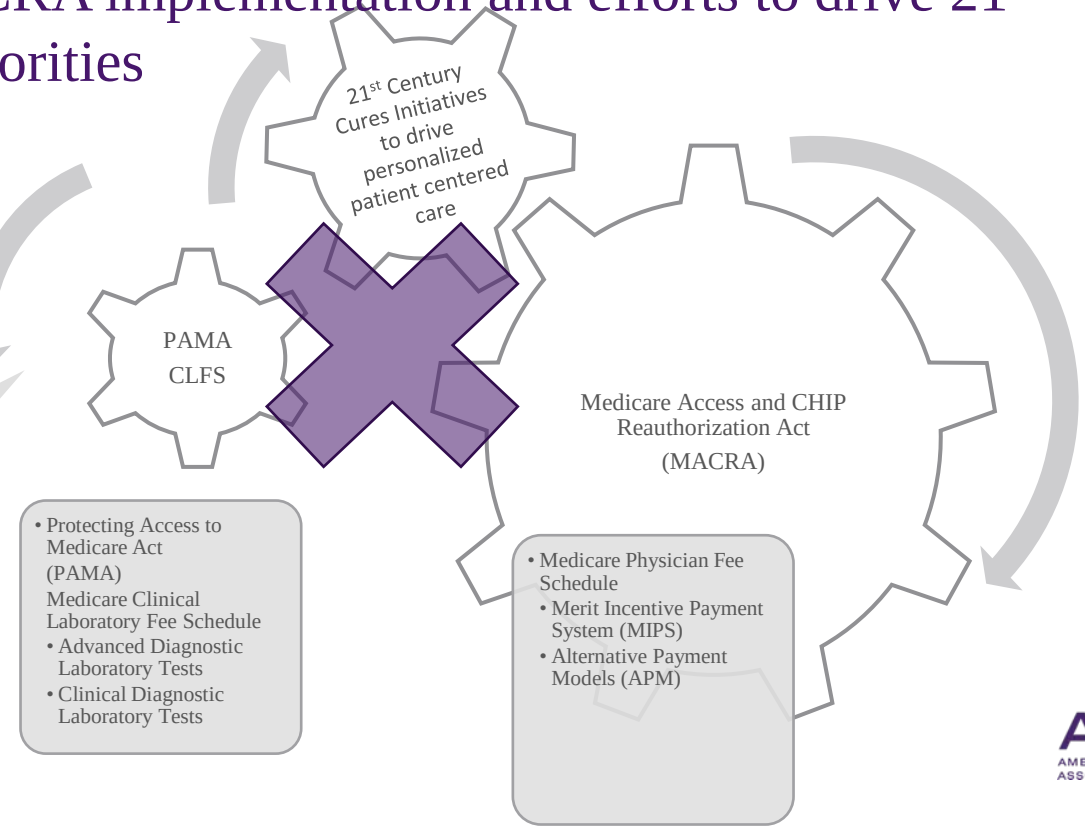
*Medicare Prices as of 2016
**This private payer price data was gathered from XIFIN's database for payments between January 1, 2016 and June 30, 2016
Data comes from approximately 200 labs and between 200 million and 300 million lab test claims
Source: The Dark Report. November 7. 2016. Volume XXIII, Number 15.

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.

A significant decrease in patient access to clinical testing options (particularly near patient testing) will have a negative impact on patient care and MACRA implementation and efforts to drive 21st Century Cures Act Priorities

Clinical tests are often essential to diagnosis, targeted treatment, or prognosis



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