

Sound Health Policy Objectives Achieved

Key Success Factors in Reporting Under PAMA *Critical Insights for Clinical Laboratories*

January 2020

Sponsored by Hologic

+ What Will I Learn In This Webinar?











What is PAMA?

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+ Protecting Access to Medicare Act of 2014

	Prompted Section 216 of the Protecting Access to Medicare Act (PAMA), which overhauls the Clinical Laboratory Fee Schedule (CLFS)		Exceeds \$760 million
Congressional Involvement		Estimated Savings	
Congress realized that private payor rates for laboratory services were lower than Medicare rates and it was determined not to allow Medicare to subsidize private payor contracts	Section 216	CMS originally estimated changes would save: \$390 million	Actual Savings

+ Medicare Lab Reimbursement: Background

- + In 1984, Medicare CLFS was established
- + Payment rates were originally based on laboratory charges
- + For a new test, payment was set using either crosswalk or gapfill
- + Under the CLFS, once a rate was established, other than inflation updates, there were no changes to the rates

CROSSWALK	GAPFILL
 Crosswalking is used if it is determined that a new test is comparable to an existing test(s). Looks for similar characteristics (e.g., analyte, methodology) between assays CMS assigns, to the new test code, the fee schedule amounts that apply to the comparable existing test(s) 	 Gapfilling is used when no comparable existing test(s) is available. Gapfill rates are set by local contractors, considering the following factors, if available: 1) Charges for the test and routine discounts; 2) Resources required to perform the test; 3) Payment amounts determined by other payors; After 1 year, CMS establishes a national rate at the median of all gapfill rates.

+ PAMA Highlights



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Applicable Laboratories

- · Applicable laboratories must report private payor rates
- Reported private payor rates determine new CLFS payment rates

Payment System

• PAMA created a new payment system effective January 1, 2018

CLFS Payments

- In 2018 2020, reductions capped at 10% per year
- In 2021 2023, reductions capped at 15% per year
- In 2024 and beyond, payment will be set at the weighted median

Three-Year Cycle

• Most data is collected and reported to CMS on a three-year cycle though certain advanced diagnostic lab tests follow an annual cycle

+ Changes Since Implementation

+ CMS implemented changes in a few key areas after the 1st 3-year cycle

ORIGINAL POLICIES	REVISED POLICIES
 Medicare Advantage (MA) revenues <u>considered</u> when determining if a lab	 Medicare Advantage (MA) revenues <u>excluded</u> when determining if a lab is
is an "applicable lab"	an "applicable lab"
 Very few hospital outreach labs	 More hospital outreach labs to be
reported data	reporting data
 Rate reductions capped at <u>10% per</u> <u>year</u> (2018 – 2020) 	 Rate reductions capped at <u>15% per</u> <u>year</u> (2021 – 2023)

+ It is unclear how many additional labs will now qualify as "applicable labs" and how that additional data may impact the rates for CY 2022 and beyond



+ Changes Since Implementation: The LAB Act

- + As part of the 2019 end-of-year spending package, Congress passed the Laboratories Access for Beneficiaries Act, referred to a the LAB Act, on Dec. 19, 2019.
- + The LAB Act (Sec. 105) has two main provisions:
 - Delaying the data reporting period for the current cycle until 2021
 - Requiring the Medicare Payment Advisory Commission (MedPAC) to conduct a study to review the methodology that CMS has implemented for determining the private payor-based CLFS rates
 - Report is due by June 2021

+ The LAB Act: Implications

+ The LAB Act has implications for Medicare and for laboratories

ORIGINAL	REVISED
Data reporting period: January 1 through March 31, 2020	Data reporting period: January 1 through March 31, 2021
First data collection and reporting period set payment rates for CLFS for 2018 – 2020	First data collection and reporting period set payment rates for CLFS for 2018 – 2021
New private payor based CLFS rates as of January 1, 2021	New private payor based CLFS rates as of January 1, 2022

- + A few things have remained unchanged with the LAB Act:
 - Data collection period <u>remains</u> at January 1 through June 30, 2019
 - Guardrails remain the same: 10% for 2018 2020, 15% for 2021 2023
 - Three-year cycle remains going forward

+ Flawed Implementation

Some stakeholders have argued that CMS implemented PAMA in a way that ignores Congressional intent and threatens beneficiary access.

PAMA'S INTENT	PAMA AS IMPLEMENTED	Імраст
Market based system	Highest volume/lowest price tests dominate the data	Data is not reflective of either the private payer or the Medicare market
Data from all market segments	Data excluded significant markets	Over 99% of labs were prohibited from reporting
Predictable and sustainable	Arbitrary and unsustainable	Implementation resulted in unpredictable and unsustainable rate decreases
Fair and accurate rate setting	Rate cuts 3 – 4x predictions	Top 25 tests cut by 32%; rural hospital labs cut by 28.5%
Ensure continued access to diagnostic tests	Access is threatened by dramatic rate cuts	Beneficiaries at risk of losing access to lab services

+ Data Excluded Large Market Segments



Patient Access at Risk

Proposed rate cuts will likely force clinical labs in rural and underserved areas to close and limit the lab tests they offer, resulting in test result delays for Medicare Beneficiaries.

The US clinical lab market is composed of nearly 250,000 labs, including hospital labs, physician office labs, and independent labs. In 2016, the Department of Health & Human Services estimated that 12,500 labs would report their private market lab data to calculate the new Medicare rates. Ultimately, *fewer than 2,000 labs reported rates*, creating a dataset that is unrepresentative of the private market.

Less Than 1% of All Labs Reported Data

61,040 – (Number of Labs Billing Medicare)

246,133

(Number of Labs in U.S.)

12,547 – (2016 Estimate of Labs

That Should Report Data)

1,942

(Actual Number of Labs That Reported Data)

*Industry data on file: AdvaMed Dx, ACLA and AMA



+ Flaws in Reported Data

Hospital labs contributed 1% of data but have 24% share of lab spending

Physician Office Labs contributed 7.5% of data but have 20% share of spending

CMS wrongly presumed adding more data from other labs is not going to change the results

3.7 million data points were "outliers"

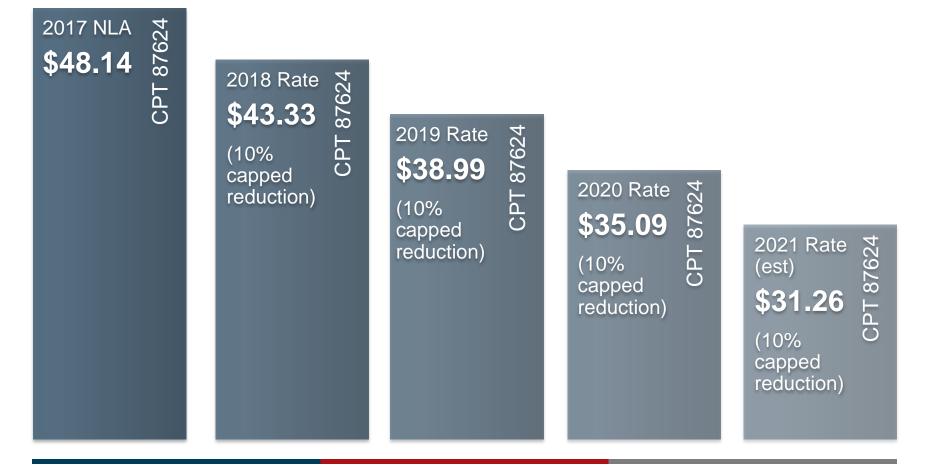
Data set excludes 99.3% of market

2.4 million \$0.00 claims reported



+ Example of PAMA Impact

HIGH RISK HPV (CPT® 87624)





Proprietary

+ Why Does This Matter?

All Data Matters

Private payor rates are used to set Medicare rates

Private Payor Rates

Medicare Rates

Some private payors set their rates as a percentage of Medicare

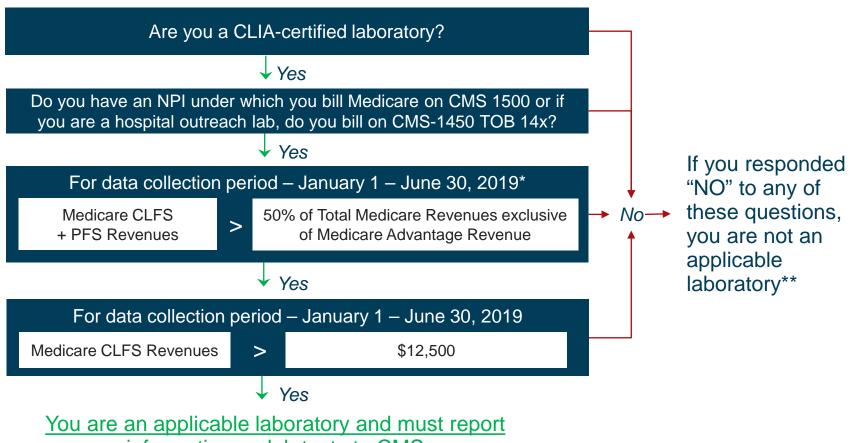


Am I an Applicable Lab?

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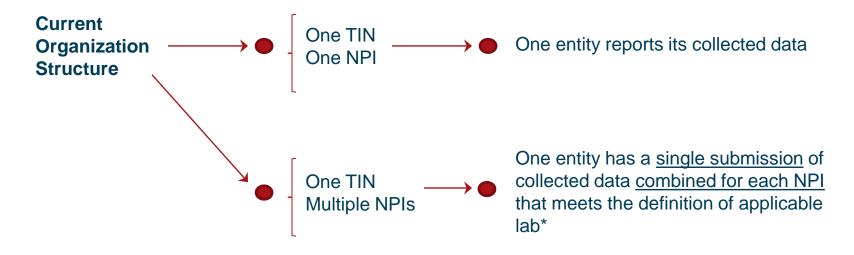
information on lab tests to CMS

* Most independent labs and physician office labs will meet this criterion.

** Exception in place for laboratories that offer sole-source laboratory tests called Advanced Diagnostic Laboratory Tests

+ Which Entity is Required to Report?

- + For the upcoming data reporting period, CMS is allowing entities to do a "condensed data reporting" option
- + So you may be wondering what that means ...



* Applicable lab requirements:

- Meets minimum threshold of Medicare CLFS revenues > \$12,500 for data collection period
- Medicare CLFS + PFS Revenues > 50% of Total Medicare Revenue

+ Checklist: Am I an Applicable Laboratory?

Checklist: Am I an Applicable Laboratory? Protecting Access to Medicare Act Section 216 Toolkit

Identification

1. Are you a laboratory?

A "laboratory" is defined under 42 CFR 493.2 as a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.



2. Are you CLIA-certified?

Note: a facility that receives any CLIA certificate (including a CLIA certificate of waiver) is considered a laboratory

Yes No

3. Are you a hospital outreach laboratory? Yes, proceed to question 4A.

No, proceed to question 4B.

Download this entire checklist: Checklist - Am I an Applicable Laboratory (2019) [mcdermottplus.com]



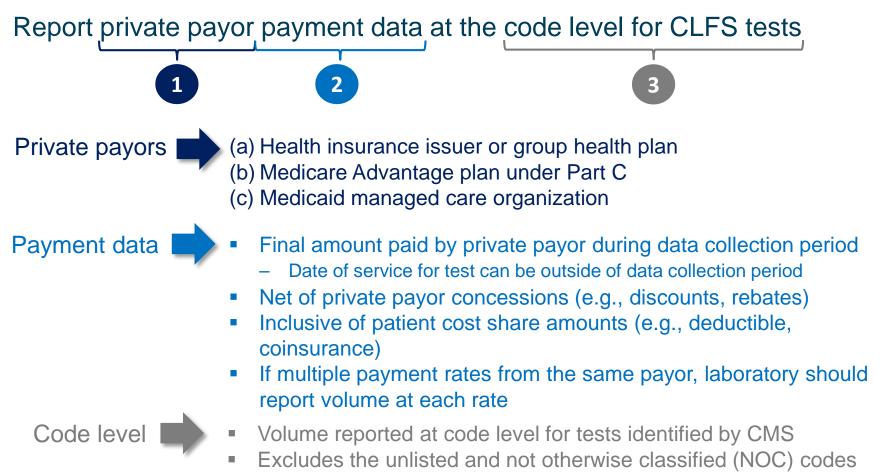


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What Do I Have to Report?

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+ What Applicable Information Must I Report?

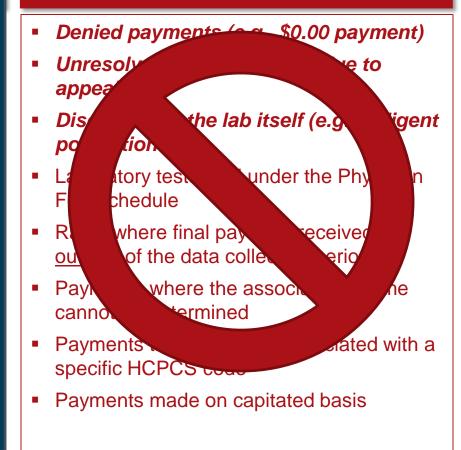


Excludes tests paid under the Medicare Physician Fee Schedule

+ Applicable Information - Payment Data

- Denied payments (e.g., \$0.00 payment)
- Unresolved payments (e.g., due to appeals)
- Discounts by the lab itself (e.g., indigent populations)

What's Not Reportable





+ Applicable Information - Data Elements

+ Required data elements to be reported by applicable labs

Field Name	Field Definition	Values	Required Field
HCPCS Code	CPT [®] code / Standardized coding system associated with the test	Alphanumeric (maximum length of 5)	Yes
Payment Rate	Private payor final rate for each test	Only numeric values with 2 decimal places.	Yes
Volume	Number of lab tests paid at each unique private payor payment rate	Only numeric values.	Yes
National Provider Identifier	Unique 10-digit identification number required by HIPAA for all health care transactions by providers in the United States	Numeric digits (length of 10)	Yes

Source: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1620.pdf

+ You may need to collect additional information in order to verify the data (e.g., paid date, appeals status, etc.)

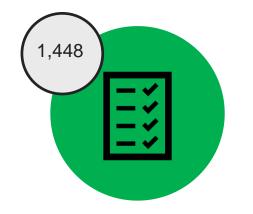


+ Applicable Information – Example

Sample Data for 80000-Series HCPCS Code

HCPCS Code	Payor	Private Payor Rate*	Date Performed	NPI	Final Payment Date		Excluded: Final payment date occurred before collection period
	Private Payor Plan #1	\$100	11/30/2018	1234567890	1/30/2019		
Ð	Private Payor Plan #1	\$100	3/22/2019	1234567890	4/2/2019		
ð	Private Payor Plan #1	\$100	11/30/2018	1234567890	12/9/2018	┥┥┥	Excluded: Final payment date
Ó	Private Payor Plan #2	\$95	4/25/2019	1234567890	5/7/2019		occurred after collection period
S	Private Payor Plan #2	\$90	12/4/2018	1234567890	1/9/2019		
S	Private Payor Plan #3	\$90	6/1/2019	1234567890	6/30/2019		
Ŭ	Private Payor Plan #3	\$90	6/1/2019	1234567890	7/3/2019	╵╉╾┙┍	Excluded: Claims in appeals
Ē	Medicare Advantage Plan #1	\$105	12/5/2018	1234567890	1/2/2019		
Ð	Medicare Advantage Plan #2	\$80	5/1/2018	0987654321	Unresolved		
Š	Private Payor Plan #1	\$100	3/3/2018	0987654321	3/17/2019		
•••	Private Payor Plan #1	\$100	11/30/2018	0987654321	1/30/2019		Excluded: Medicaid Fee for
0	Private Payor Plan #2	\$95	4/3/2019	0987654321	4/17/2019		Service
0	Private Payor Plan #4	\$100	5/7/2019	0987654321	5/26/2019		
Õ	-Medicaid, FFS	\$75	3/22/2019	0987654321	4/4/2019		Excluded: Capitated payment
0	Medicaid, MCO Plan #1	Capitated	4/3/2019	0987654321	4 /20/2019	┥╺┯┛	
∞	Medicaid, MCO Plan #2	\$65	6/11/2019	0987654321	6/23/2019		
	Private Payor Plan #5	\$0	1/2/2019	0987654321	2/1/2019		
	•	• • • •					Excluded: Zero-dollar claims

+ To What Codes Does This Apply?



If Not on the List, Don't Report



CMS Lists Applicable Codes

List of 1,448 codes for which information should be collected and reported

List of applicable codes can be found on the CMS website at:

• <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html</u> under the link to "CMS Applicable Information HCPCS Codes"



+ Reporting Applicable Information

- + 3-month period for reporting data collected on private payor rates
 - Data collection period was from January through June 2019
 - Upcoming reporting period begins
 January 1, 2021 (Recently changed from 2020)



- + Subsequent data collection and reporting periods run every three years (2023-2025, 2026-2028, 2029-2031, etc.)
 - Some laboratories performing a special class of sole source tests called advanced diagnostic laboratory tests (ADLTs) report annually

+ Reporting Applicable Information







Reporting applicable information is **mandatory**

for "applicable labs"

 Reporting is <u>not</u> <u>discretionary</u> CMS has authority to impose civil monetary penalties (CMP) up to \$10,000 per day for non-compliance

No voluntary reporting

 Reporting by labs that do not meet criteria of "applicable laboratory" is <u>strictly prohibited</u>



+ Checklist: Am I Ready to Report?

Checklist: Am I Ready to Report Applicable Information?

Protecting Access to Medicare Act Section 216 Toolkit

The Centers for Medicare & Medicaid Services has a portal for reporting Applicable Information. The purpose of this checklist is to help Applicable Laboratories understand what is included in Applicable Information and to assess whether they are prepared to submit Applicable Information.

Identification

Are you an Applicable Laboratory (see "Checklist: Am I an Applicable Laboratory?") Yes Download this entire checklist: <u>Checklist - Am I Ready to Report</u> <u>Applicable Information (2019)</u> [mcdermottplus.com]

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CONTINUE, if you answered YES to the question above.

No

STOP, if you answered NO to the question above. You are not permitted to submit Applicable Information.

Preparedness Assessment

Note: Applicable Information will be reported by the Taxpayor Identification Number (TIN) level for each of its component National Provider Identifier (NPI)-level entities that meet the definition of an applicable laboratory.

Question	Explanation	YES	NO
1. Do you have data on final paid claims for the period January 1, 2019 through June 30, 2019?	You may maintain such data in paper, electronic, or a combination of paper and electronic files.		
2. Are you able to extract data from these databases?	You may have systems in place to electronically extract data, or you may have to rely on manual review. If you maintain data in multiple systems, you may have to aggregate across systems.		
3. Are you able to extract data by individual NPI meeting the criteria for Applicable Laboratory?			
Are you able to extract the following data elements from these			
A. Payments on claims identifying specific HCPCS/CPT [®] codes?	See "PAMA Codes" tab for full list of codes for which reporting is required.		
B. Deriving from 4A, whether or not claims reflect final payments?	Final payment: (1) Is the final amount that is paid by a private payor for a CDLT after all private payor price concessions are applied and does not include price concessions applied by a laboratory. (2) Includes any patient cost sharing amounts, if applicable. (3) Does not include information about denied payments.		
	See the 'What's Included/Excluded'' section below for a full list of data inclusions and exclusions.		



When Do I Report Data?

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+ Timeline



- + Data to be reported are for claims for which <u>final payment was</u> received between January 1, 2019 and June 30, 2019
- + Data reporting period pushed out one year by the LAB Act
- + For most lab tests, there is a three-year cycle
 - Collect: Year 1
 - Report: Year 2
 - Rate: Years 3 5

+ The LAB Act: Data Collection and Reporting

+ Review of data collection and reporting periods

CDLT Rates	Data Collection Period	Data Reporting Period	Reduction Cap
CY 2020	1/1/16 — 6/30/16	1/1/17 — 5/31/17	10%
CY 2021	1/1/16 – 6/30/16	1/1/17 — 5/31/17	15%
CY 2022	1/1/19 — 6/30/19	1/1/21 – 3/31/21	15%
CY 2023	1/1/19 – 6/30/19	1/1/21 – 3/31/21	15%
CY 2024	1/1/19 — 6/30/19	1/1/21 – 3/31/21	No cap

* In the most recent guidance, CMS noted that it will resume a three-year cycle, starting in 2025. Based on the communication, the next data collection period would be January through June in 2023 with the subsequent data reporting period in 2024 for rates effective January 1, 2025.

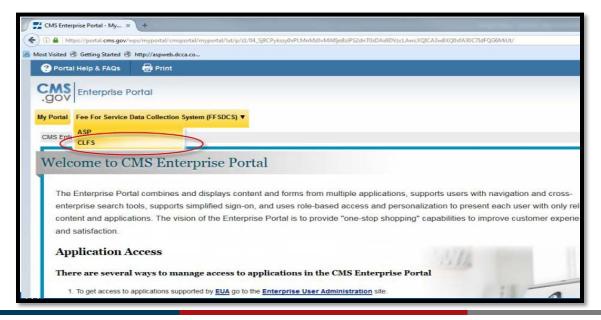
How Do I Report Data?

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+ How Do I Report Applicable Information?

- + CMS operates a web-based portal referred to as the Fee-For-Service Data Collection System (FFSDCS)
- + Data collection system at http://portal.cms.gov
 - Users must register or re-activate previously registered account as either a submitted or a certifier before you can access the system



+ How Do I Report Applicable Information?

- + Will accept data manually by data entry via an online interface or electronically through csv file upload
 - Data reporting template was published by CMS in November 2016 at <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-</u> <u>Payment/ClinicalLabFeeSched/PAMA-Regulations</u>

Clinical Lab	Fee Schedule	Upl	oad Applica	ble Informatio	n	. •			7 - (= =)	-			_		CLF	S.csv - Micro	soft Excel	
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	80417	81.00	9999100	1245319599	Volume format 9999	2	1.1.4											



+ Groups Who May Help







CMS.gov Centers for Medicare & Medicaid Services













Proprietary

How Does PAMA Impact Our Industry?



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Proprietary

+ Payment Rate Calculation

- + Accurate payment rates rely on accurately reported data from labs
- + Inclusion of data that should not be reported can skew the median payment rate calculation
- + Scrub out any data that should not be reported

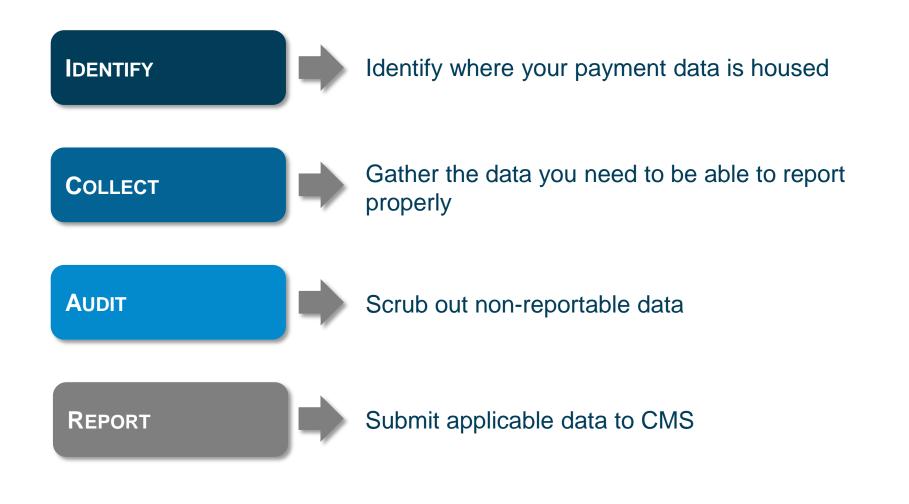
HCPCS Code	Private Payor Rate	Volume of Tests	National Provider ID		HCPCS Code	Private Payor Rate	Volume of Tests	National Prov ID
	\$105	1	1234567890		Φ	\$105	1	123456789
code	\$100	2	1234567890		code	\$100	2	123456789
					CS CS	\$100	3	098765432
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Summary

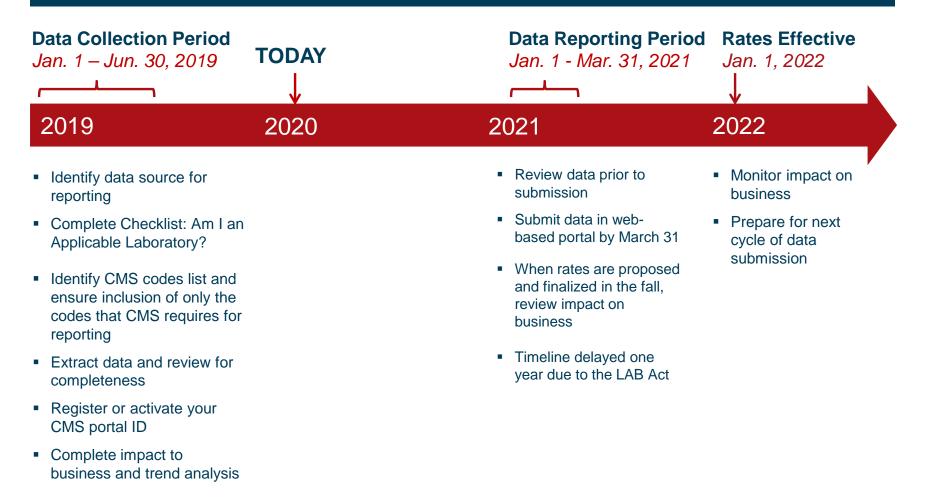
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+ Keys to Successful Reporting

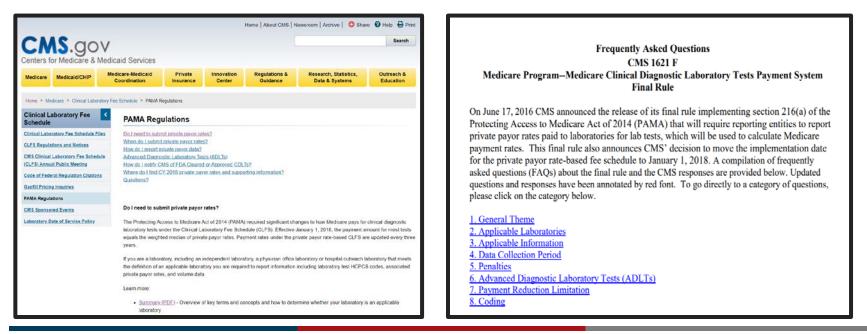


+ What Do I Need to Do?



+ Resources

- + These slides and the checklists are available to download at:
 - <u>https://www.mcdermottplus.com/insights/hologic-pama-webinar/[mcdermottplus.com]</u>
 - PAMA Resources_Checklists_Codes_FAQ (2019) [mcdermottplus.com]
- + CMS documents, including fact sheets, FAQs and the portal guide (when available) can be found on CMS's website:
 - <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html</u>



+ Resources: LAB Act

- The Laboratory Access for Beneficiaries Act Section 105(a)(1) of the Further Consolidated Appropriations Act of 2020
 - HR 1865 Further Consolidated Appropriations Act of 2020
 - <u>https://www.congress.gov/bill/116th-congress/house-bill/1865/text</u>
- + Medicare Part B CLFS: Revised Information for Laboratories on Collecting and Reporting Data for the Private Payor Rate-Based Payment System:
 - <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html</u>



Future Webinars

DECEMBER 2019											
Monday	Tuesday	Wednesday	Thursday	Friday							
2	3	4	5	6							
9	10	4 ⁰⁰ ET/ 11 1 ⁰⁰ PT	2 ⁰⁰ ET/ 12 11 ⁰⁰ PT	13							
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23	24	25	26	27							
30	31										

Questions?

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