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PAMA: Reporting Dates Approaching

The Protecting Access to Medicare Act of 2014 (PAMA) was implemented requiring applicable laboratories to report private payor payment rates which is used to determine rates for Clinical Diagnostic Laboratory Tests (CDLT) under the Clinical Laboratory Fee Schedule. Recently, CMS made several revisions regarding the approaching data reporting period. The first revision is that the reporting period has changed, per the below table. The data collected January 1st, 2019 - June 30th, 2019 was originally due to be reported in early 2021, but was postponed due to Covid. The revised reporting date for this data will be January 1st, 2022 - March 31st, 2022. This 2019 data submitted will impact the rates determined for 2023-2025.

Below is the revised schedule published by CMS (revisions in red). It can also be found by clicking here.

Data Collection Period	Six-Month Review and Validation Period	Data Reporting Period	Used for CLFS Rate Years
1/1/2019-6/30/2019	7/1/2019-12/31/2019	1/1/2022-3/31/2022	2023-2025
1/1/2024-6/30/2024	7/1/2024-7/31/2024	1/1/2025-3/31/2025	2026-2028
Continues every third subsequent calendar year	Continues every third subsequent calendar year	Continues every third subsequent calendar year	New CLFS rate every third year

The second revision is that CMS is extending the payment reduction start date until 2024. CMS indicated that there will be a 0.0 percent reduction for 2021 thus, extending the payment reduction until 2024.

ADLT (Advanced Diagnostic Laboratory Test)

An ADLT (Advanced Diagnostic Laboratory Test) according to CMS is a "CLDT covered under Medicare Part B that is offered and furnished only by a single laboratory. Additionally, an ADLT cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, it must meet one of the following criteria":

- The test is an analysis of multiple biomarkers of DNA, RNA, or proteins;
- When combined with an empirically derived algorithm, the test yields a result that predicts the probability that an individual patient will develop a certain condition or conditions, or respond to a particular therapy or therapies;
- Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
- May include other assays.

ADLTs are to be reported annually and require an application to CMS. A small list of currently approved ADLTs and the application process can be found by clicking here.

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What is an Applicable Lab?

There are 4 steps in determining the requirements of an applicable lab:

- Is the laboratory certified under CLIA (Clinical Laboratory Improvement Amendments)? This certification applies to all laboratories that perform tests on human specimens for health purposes and is required to receive payment from CMS.
- Does the CLIA-certified laboratory bill Medicare Part B under its own NPI (National Provider Identifier)? The NPI is the standard, unique health identifier used by health care providers for billing Medicare and other payors.
- Does the laboratory meet the majority of Medicare revenues threshold? A laboratory qualifies if it receives more than 50% of its total Medicare revenues from payments under the Medicare CLFS and/or Medicare PFS (Physician Fee Schedule).
- Does the laboratory meet the low expenditure threshold? A laboratory qualifies if it receives more than $12,500 in Medicare revenues from the CLFS during the data collection period.

What's Next:

If you are an applicable lab, the 2019 data is to be submitted to the CMS Data Collection System. CMS has indicated that this portal will be available soon. APS is monitoring the go live date of this new system and will present instructions prior to January 1, 2022. For clients who are in the APS billing system from 2019, the data has been formatted according to CMS requirements and is ready to be supplied to the CLFS Submitter. APS will be reaching out to its clients in December establishing two separate individuals, as the Certifier and Submitter for each group.

<u>To clarify these roles</u>

- A CLFS Submitter is required to be registered in PECOS as CMS will reference this data. Their role will entail registering in the CMS portal and uploading the data.
- A CLFS Certifier is typically a CEO or CFO. This individual will register in the CMS portal and verify the accuracy of the data.

APS will keep you informed of any updates regarding PAMA. Should you have any questions, please contact your APS Practice Manager.