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REMINDER: MANY HOSPITALS WILL BE REQUIRED TO REPORT LAB PRICE DATA AS PART OF PAMA CHANGES

In 2014, Congress enacted the Protecting Access to Medicare Act ("PAMA"), changing the landscape of Medicare reimbursement for lab services. PAMA required the Centers for Medicare & Medicaid Services ("CMS") to establish a single, national Clinical Laboratory Fee Schedule ("CLFS") based on current charges in the private health care market. Below, we provide background on PAMA as well as changes made by CMS at the end of 2018 that will require more laboratories, especially hospital laboratories, to report private payor data to CMS in early 2020. It is important to note that failure to report data as required by the changes to PAMA could subject laboratories to fines of up to $10,000 per day.

BACKGROUND

From routine blood tests to complex genetic and molecular assays, laboratory tests play an essential role in health care to prevent, diagnose and treat disease. As one of the largest payors of clinical lab services, Medicare payments totaled $7 billion for lab tests in 2014 and in 2015—approximately three percent of all Medicare Part B payments. From 1984 to 2017, the methodology used to determine Medicare's lab test payment rates remained largely unchanged. Under this prior system, each Medicare claims processing contractor established a local fee schedule based on local charges to Medicare in 1984 and 1985, and there were 57 local fee schedules.

In 2014, Congress enacted PAMA, which required CMS to establish a single, national CLFS based on current charges in the private health care market. In general, the payment amount is equal to the weighted median of private payor rates and is based on data collected from laboratories that meet certain statutory requirements. For most tests, the private payor rate-based CLFS must be updated every three years to ensure that Medicare reimbursement rates consistently reflect the rates laboratories receive from private payors. Under this new system, CMS has projected a government savings of $3.9 billion by 2028.

Under PAMA's scheme for triennial updates to the CLFS, "applicable laboratories" must collect and submit their private payor data to CMS every third calendar year prior to the determination and release of a new CLFS. An applicable laboratory is defined as a laboratory that:

- Is CLIA certified;
- Bills Medicare *Part B* under its own National Provider Identifier ("NPI") or as hospital outreach;
- Receives more than 50 percent of its total Medicare revenues from payments under the CLFS and/or Physician Fee Schedule ("PFS") to qualify as an applicable laboratory ("Majority of Medicare Revenues Threshold"); and
- Receives at least $12,500 in Medicare revenues from the CLFS during the established data collection period to qualify as an applicable laboratory ("Low Expenditure Threshold").

While CMS had originally defined applicable laboratory to encompass labs that bill Medicare Part B lab services under their own unique NPI that meets the majority of Medicare revenues and low expenditure thresholds, various lab advocacy groups quickly took issue with this approach since most hospital outreach labs do not have their own NPI and were therefore excluded from the reporting requirement. According to these groups, the NPI-based definition skewed pricing, leading to deeper cuts to the CLFS than Congress intended. However, after running various simulations in the determination of the 2018 CLFS, CMS stated that increased reporting by hospital, office and independent laboratories would have no significant impact on CLFS rates and may even reduce reimbursements for lab tests. Nevertheless, in an apparent response to stakeholder concerns, CMS revised its definition of applicable laboratory for calendar year ("CY") 2019, increasing the number of laboratories required to collect and report private payor data for use in setting CLFS payment rates.

CHANGES TO PAMA LABORATORY REPORTING OBLIGATIONS

Under the Medicare PFS Final Rule for CY 2019, labs must be aware of two regulatory changes that may affect their status as applicable laboratories and accordingly trigger PAMA reporting obligations. First, although the definition of applicable laboratory will continue to be NPI-based, Medicare revenues under the Form CMS-1450 14x Type of Bill ("14x TOB") has been added as an additional consideration. The 14x

TOB is used by hospitals to bill for non-patient or hospital outreach laboratory services. This change means that applicable laboratory status may be based on Medicare Part B revenues attributable either to a lab's unique NPI or using hospital outreach laboratory revenues.

Notably, under either the NPI or the hospital outreach methods, the two requirements described above – the majority of Medicare revenues and the low expenditure thresholds – continue to apply in the determination of applicable laboratory status. From a practical standpoint, most hospital laboratories providing outreach services will meet the majority of Medicare revenues requirement since Medicare revenues either attributable to a hospital's own NPI or to the 14x TOB are received largely (if not entirely) from the CLFS and/or PFS. Accordingly, if a hospital laboratory also has revenues in excess of the low expenditure threshold of $12,500 in Medicare revenues billed as outreach lab services, the hospital laboratory will face the same burden as large independent labs in identifying and reporting private payor data.

The second regulatory change affects the majority of Medicare revenues threshold requirement. Although Medicare Advantage ("MA") payments under Medicare Part C were previously included as total Medicare revenues (the denominator), MA plan payments are now excluded from total Medicare revenues, thereby decreasing the denominator and increasing the likelihood that a lab will qualify as an applicable laboratory. CMS estimates that this change will result in a 49 percent increase in the number of reporting labs. Meanwhile, MA payments will continue to be considered as private payor data for the purpose of establishing the CLFS.

The next private payor rate-based CLFS update will be effective January 1, 2021. The six-month *data collection period* for this update ended June 30, 2019 and is now followed by a six-month *review and validation period*, in which reporting laboratories should assess whether they qualify as an "applicable laboratory" as described above. In other words, laboratories should collect laboratory service data from January 1 through June 30, 2019 to determine if they meet the majority of Medicare revenues and the low expenditure thresholds. If a hospital or other lab meets the criteria for an "applicable laboratory" during this period, it would need to submit pricing data to CMS during the 2020 *data reporting period* between January 1 to March 30, 2020.

PRACTICAL TAKEAWAYS

- In the wake of recent regulatory changes for 2019, significant numbers of hospital outreach labs are expected to have reporting obligations under PAMA, and laboratories should determine whether their applicable laboratory status has been impacted.
- Laboratories should utilize the next several months – through December 31, 2019 – to determine their status using private payor data collected from January 1 through June 30, 2019.
- If a laboratory utilizes either a separate NPI to bill Medicare or bills for hospital outreach laboratory services, it must determine whether it also meets the majority of Medicare revenues threshold and the low expenditure threshold.
- A laboratory meeting these criteria is an applicable laboratory within the meaning of PAMA and must report its private payor data to CMS by March 30, 2020.

If you have questions or would like additional information about this topic, please contact:

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