Changes to the Clinical Laboratory Fee Schedule in the 2019 Medicare Physician Fee Schedule Proposed Rule

On July 12, the Centers for Medicare & Medicaid Services (CMS) published its 2019 Medicare Physician Fee Schedule Proposed Rule (Proposed Rule) covering a wide range of topics. In our series of articles, we have summarized and offered our insights on several key provisions. Note that comments on the Proposed Rule were due to CMS by September 10, 2018, and we expect CMS to publish the Final Rule later this fall. Of the 15,313 comments CMS received on the Proposed Rule, 1,212 of them included the acronym MIPS. You can review all the comments here.

In 2016, Medicare paid $6.8 billion to Medicare-enrolled laboratories for more than 1,300 types of clinical laboratory tests included on the Clinical Lab Fee Schedule (CLFS). Prior to January 1, 2018, a provider furnishing a lab test reimbursed under the CLFS was paid the lesser of (1) the amount billed by the provider, (2) the local Medicare Administrative Contractor’s established fee schedule amount, or (3) a national limitation amount (NLA). Most tests were paid at the NLA.

The Protecting Access to Medicare Act of 2014 (PAMA) mandated significant revisions to the methodology for calculating CLFS rates. Specifically, PAMA requires a test’s CLFS rate generally to be equal to the weighted median of the private payer rates determined for that test, based on the data that is collected
during a data collection period and reported to CMS during a data reporting period. These rates are not subject to other geographic, budget neutrality, or annual update adjustments.

The data collection and reporting process is defined by CMS regulations. A laboratory is required to collect applicable information for reporting to CMS if, by its own billing National Provider Identifier (NPI), it meets (1) the “majority of Medicare revenues” threshold (receives more than 50% of its total Medicare revenues from the CLFS and/or the Medicare Physician Fee Schedule), and (2) the low-expenditure threshold (receives at least $12,500 in Medicare revenues for CLFS services) during a data collection period.

In establishing these criteria, CMS intended to achieve a balance between collecting sufficient data and minimizing the reporting burden for entities. According to CMS, approximately 95% of physician office laboratories and 55% of independent clinical labs were excluded from the data collection and reporting requirements because they did not meet the low-expenditure threshold.

For the new rates effective January 1, 2018, laboratories collected private payer data from January 1, 2016, through June 30, 2016, and reported it to CMS between January 1, 2017, and May 30, 2017. CMS received data from 1,942 laboratories with over 4.9 million records of applicable information representing a volume of almost 248 million laboratory tests.

CMS then calculated the new Medicare rates (equal to the weighted median of private payer rates for each test), which were published in November 2017. CMS estimates these new rates will save Medicare (through reduced provider reimbursement) $670 million in 2018, which would be a 10% reduction compared to 2016.

CMS will update the CLFS payment rates for most tests every three years to reflect market rates paid by private payers. Rates for certain advanced diagnostic laboratory tests furnished by a single laboratory, however, will be updated annually.

In the Proposed Rule, CMS addresses modifications to the regulations, defining those laboratories required to collect and report private payer data to CMS. First,
CMS proposes to exclude Medicare Advantage (MA) payments for purposes of the “majority of Medicare revenues” threshold. If finalized, this change would result in more laboratories being subject to the data collection and reporting requirements in the next update.

Second, CMS solicits comment on potential changes to the low-expenditure threshold (currently $12,500 in Medicare revenues for CLFS services) as set forth below:

*Increase by 50% to $18,750 to eliminate the reporting requirements for many physician office and small independent laboratories. CMS believes these entities may lack staff resources and/or systems to report required data, so increasing the threshold would effectively be removing that requirement.*

*Decrease by 50% to $6,250 to increase the number of entities reporting, thereby increasing the data set on which CMS will determine CLFS rates. CMS is particularly interested in operational and administrative impacts to small physician practices and independent laboratories.*

While the proposed changes for 2019 are relatively minor following the implementation of the new rates this year, expect more significant changes in future years as CMS refines its processes for the next data collection and reporting cycle.

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*Read other related insights about the MPFS Proposed Rule here*

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