Clinical Laboratory Medicare Reimbursement

Position

The clinical laboratory community urges Congress to fix the flawed implementation of Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014. The convergence of continuing rate cuts, mounting labor costs, and the workload caused by the COVID-19 pandemic is devastating the clinical laboratory system in the U.S. Immediate action is needed before the end of the year to forestall additional cuts that will further hamper access to essential clinical laboratory services for beneficiaries.

Congress Must Take Action

- Congress should freeze any additional PAMA cuts scheduled to take effect on January 1, 2022. No cuts should go into effect until January 1st of the calendar year that begins no sooner than one year after the COVID-19 public health emergency has ended.
- Congress should direct CMS to collect private-payer rates from a proportional sample of the entire laboratory industry, to include representation from all independent laboratories; all hospital laboratories, including rates for unbundled inpatient, outpatient, and non-patient services; and all physician office laboratories.
    - This sample must be representative of the laboratory market and the geographic regions these laboratories serve, and it must take into account different size providers in each market segment—the sample cannot rely on data only from the largest national laboratories. Any laboratory that bills on the CLFS should be eligible for data collection, with the existing exemptions for low volume laboratories retained. Collected data should be extrapolated by CLFS code to ensure that each laboratory test code is accurately represented based on its use in the market.
    - This methodology will guarantee that each type of laboratory is adequately represented and will reduce the number of laboratories required to submit data through a burdensome reporting process. Surveying a representative sample of the laboratory industry will meet Congress' initial intent by producing more accurate estimates of private-payer rates in the laboratory market and reducing the onus of reporting.
    - As smaller and mid-sized laboratories are more likely to struggle under an onerous data reporting process, Congress should consider protections, or incentives, for small to medium-sized laboratories, including guarantees that they will not have to report their data during every reporting period.
    - Private-payer data collected should exclude Medicaid managed care rates that are a result of federal or state budgetary or statutory requirements, which are not reflective of market rates. Laboratories should also be given the option to exclude from reporting paper, manual, and non-electronic claims that collectively constitute no more than 10% of a laboratory's private-payer claims.
    - To stabilize CLFS rates and mitigate the burden of reporting, Congress should increase the length of time between data collection periods from three years to four years.

Background

PAMA completely overhauled the Medicare Part B clinical laboratory fee schedule (CLFS). The goal of PAMA was to establish a single national fee schedule based on private-payer rates. Under PAMA, clinical laboratories are required to report their private-payer rates on a test-by-test basis along with associated test volumes. CMS collected this data and used it to calculate new Medicare Part B CLFS rates. Unfortunately, CMS' implementation of PAMA resulted in extreme reimbursement rate cuts, deeply harming hospital, physician, and independent laboratories.

When payment data was first collected under PAMA it did not accurately represent the laboratory market as required under statute and as intended by Congress. The largest independent laboratories were overrepresented in the first round of data reporting. Independent laboratories provided 90% of the reported data despite representing only 48% of the utilization of Medicare CLFS tests. According to the June 2021 Medicare Payment Advisory Committee (MedPAC) report on PAMA, private-payer rates for hospital outpatient laboratories and physician office laboratories were 45% and 53% higher, respectively, than private-payer rates for independent laboratories, but only represented 9% of the reported private-payer data. This flawed process failed to accurately capture private-payer rates, resulting in drastic, unanticipated payment cuts that threatened the ability of many laboratories to provide essential services.

PAMA-related cuts have been devastating across the laboratory industry, particularly for laboratories that serve rural and underserved communities. PAMA resulted in three consecutive years of 10% CLFS cuts for most high-volume laboratory tests. In fact, some laboratories experienced reimbursement rate cuts of up to 59% on some of the most common laboratory tests.

While the intention of PAMA was to tie Medicare rates to market rates for laboratory tests, Medicare rates have historically been—and continue to be—the marker used for many insurance companies to set their own laboratory payment rates. So, while the private market could reflect an increase in wages and other costs borne by laboratories, it does not. Therefore, as Medicare rates are cut, private-payer rates follow, creating a downward spiral towards categorically unsustainable reimbursement rates.

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