Flawed Attempt to Set "Marketing Pricing" Fails and Jeopardizes Access to Quality Care

Position

The entire clinical laboratory community urges Congress to fix the flawed implementation of Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014, which will restrict access to quality clinical laboratory services, especially for patients living in nursing homes and rural areas. The law required CMS to establish a market-based payment system for laboratories paid on the Clinical Laboratory Fee Schedule (CLFS). However, regulatory requirements included in the final PAMA regulation do not comply with the statute as the data collected reflects just a small sector of the clinical laboratory market. Full implementation of these cuts will cause an irreversible, market shift that threatens access to essential laboratory tests. Congress must step in to mitigate this risk.

1. **Make a statutory adjustment to CLFS payments that provides short term relief and allows time to revise the rate setting process conducted by CMS.** Any adjustment would not be more than the original 2014 PAMA CBO 10-year baseline for the statute. A 10 percent per year cut to a majority of the tests on the CLFS will eliminate testing in small and mid-size clinical laboratories, hospitals and physician office labs currently serving Medicare beneficiaries
2. **Ensure a valid stratified random data sample is collected by CMS that represents all segments of the laboratory market.** The sample strata are: hospital laboratories, physician office laboratories, large independent laboratories, and small independent labs, further stratified to assure representation across geographic areas, e.g. MSA, and including urban and rural regions.
3. **Require that data collection requirements streamline collection to reduce the burden on participating laboratories by focusing on data specific to the private market.** Data collection and reporting requirements must be applied only to private payment rates paid after implementation rules and guidance documents are finalized. Medicaid managed care data that are a result of federal or state budgetary or statutory requirements, which is not reflective of market rates, must be excluded. Laboratories should be allowed to exclude data from paper, manual and non-electric claims that collectively constitute no more than 10 percent of a lab's private market claims.
4. **Revise PAMA statutory requirements to calculate final CLFS payment rates per code as a weighted mean proportionate to laboratory-type, market share, and geography.** Annual test fee reductions caps should be put in place, lowering the 10 percent-15 percent limits in the current statute, and spread over a 10-year period.

Rationale

PAMA required "applicable laboratories" to report private payor payment rates and the associated test volume for those laboratory services defined by CMS. The intent of PAMA was to ensure true market-based pricing by setting the fee schedule to a weighted median of the collected data. Unfortunately, by manipulating the definition of the "applicable laboratory,"

CMS intentionally skewed the data collection and artificially lowered the weighted median of payment rates.

In its 2016 report, the OIG estimated that 3,500 laboratories would report, but actual reporting entities number barely half that. **Paired with the fact that the proposed fee cuts exceed the Congressional Budget Office estimated savings from PAMA by more than 300 percent, it is clear this implementation fails to maintain alignment with Congressional intent.**

After defining "applicable laboratory" in the narrowest possible terms, the Agency collected 90 percent of reported data from independent laboratories. Hospitals and physician office laboratories, which provide 44 percent of laboratory services under Medicare, represented just 8.5 percent of the reporting entities. Less than one percent of hospitals and physician office laboratories reported data. CMS admits that just 1.85 percent of data was collected from laboratories serving rural areas.

Hospital laboratories represent 24 percent of the laboratory billing from the CLFS, but data was collected from just 21 of the 6,994 hospital laboratories. Physician office laboratories represent 20 percent of the laboratory billing for Medicare, but only 1,106 out of approximately 236,000 POLs reported. (OEI-09-16-00040)

Impact

Smaller, local, independent, physician office and hospital laboratories, functioning closest to the patient and clinician, provide services for nursing home residents, patients requiring frequent testing for management of chronic conditions like diabetes and hypothyroidism, same day information for oncologists to treat their patients undergoing chemotherapy or those suffering from infections that require rapid detection and identification for proper monitoring and treatment.

To serve the needs of their patients, local laboratories provide more rapid results drawn from more specialized test menus without economies of scale. The methods used by CMS to collect and interpret an incomplete dataset without validation excluded the possibility of measuring those differences. Laboratories are responding by reducing staff and cutting back on capital investment, leaving clinicians without important tools to quickly diagnose and treat patients. Access to care for both the community and nursing homes served by the community-based, hospital laboratory outreach programs will be compromised.

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