CMS Needs to Fix Payment Policies For Clinical Labs

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Congress ordered the Centers for Medicare and Medicaid Services (CMS) to come up with a new payment system for the more than 400 million clinical laboratory tests that Medicare pays for each year so that prices would be more closely aligned with those paid by private insurers.

But the new system relies on data that are not broadly representative of market rates, putting access to clinical services for many seniors in jeopardy. Seniors who live in rural areas and those in nursing home facilities are among those most at risk.

Here's the back story: CMS launched a new system for paying for clinical diagnostic laboratory services in January under a rule written by the Obama administration. The new clinical laboratory fee schedule (CLFS) reduces payments this year by 10% compared to 2017 for tests that represent nearly two-thirds of Medicare's outlays for lab tests. Similar cuts are slated over the next two years.

Cuts of this magnitude will "have extreme consequences for community and regional clinical laboratories," impacting services for beneficiaries, "especially those in small and rural communities, and those who receive home health care or reside in assisted living or skilled nursing facilities," according to a study by the National Independent Laboratory Association (NILA).

CMS' implementation of the Protecting Access to Medicare Act jeopardizes the nation's laboratory infrastructure and affects labs of all sizes and circumstances—large and small independent labs as well as hospital-based labs and those engaged in specialty services, such as home and nursing facility care.

So why would CMS do this? Medicare already is a jumble of overlapping and sometimes conflicting payment policies for medical goods and services. Within that, Medicare reimburses tens of thousands of laboratories for hundreds of millions of tests for nearly 30 million beneficiaries every year.

Clinical lab payments represent about 2% of Medicare Part B spending. In 2016, the HHS Office of Inspector General estimates that Medicare paid $6.8 billion for 437 million tests for 28 million beneficiaries. Some 58,593 labs received Medicare payments in that year, with payments per lab averaging $115,546.

To add to this complexity, CMS has established payment codes for more than 1,300 tests and, on average, each "applicable laboratory" will bill multiple insurers, which often pay varying rates.

Clearly, the clinical laboratory world is vast and diffused, serving patients in virtually every corner of the country.

Collecting even representative data is a daunting task indeed. Congress specified that the agency was to collect data from all "applicable laboratories." What CMS chose to do was to define applicable laboratories in such a way as to disproportionately represent large independent labs while excluding from the definition most smaller independent labs, physician laboratories, and hospital outreach laboratories. Its methodology excluded virtually all hospital laboratories from the calculations.

"CMS chose to collect data from only a small segment of the clinical laboratory sector, giving disproportionate weight to rates paid by private insurers to the two largest clinical laboratory chains," according to a new paper for the Galen Institute by Doug Badger. "The inescapable

outcome of the CMS methodology is that the market data upon which Medicare reimbursement is based does not reflect the market composition of the clinical lab industry."

The result? The new CLFS imposes sizeable cuts in Medicare reimbursement for some of the tests most commonly ordered for Medicare patients.

When fully phased in, the cuts will lead to a 39% reduction in payments for a lipid panel, for example, from $18.41 in 2016 to $11.23 in 2020. Medicare payment for a complete blood count will be cut from $10.59 to $6.88.

"In relieving most laboratories of the reporting burden, it imposed a more onerous burden on many clinical labs: sharp reductions in Medicare reimbursement rates based upon an unrepresentative segment of the clinical laboratory industry," Badger concludes in his paper.

The information CMS collected for purposes of establishing a new Medicare clinical lab reimbursement methodology "vastly overweights data from independent laboratories and vastly underweights data from labs based in hospitals and physician offices. These results suggest a skewed Medicare reimbursement methodology that rests on what appears to be a distorted sample of the overall market," Badger reports.

This has resulted in "sizeable cuts" in Medicare reimbursement for some of the tests most commonly ordered for Medicare patients, with similar cuts on tap for the next two years.

"It could be argued that Congress's real intention was not to base reimbursement for lab services on market rates, but to reduce Medicare spending. The new CLFS appears to be exceeding expectations on cutting spending on this tiny slice of the Medicare program," Badger writes, adding that the cuts "appear to be running deeper than CMS itself expected."

Laboratories told NILA they "might take a range of actions in response to the cuts, including reducing workforces, limited services, and, in some cases, shuttering operations." This could jeopardize access to timely diagnostics for residents of nursing homes, rural communities, and vulnerable populations.

CMS has produced a reimbursement system that does not reflect payments for lab tests in the private marketplace and that does not abide by statutory intent. The American Clinical Laboratory Association, a trade association representing the industry, has sued HHS over its definitions that it says "arbitrarily and capriciously" restricted the types and numbers of entities in its survey.

"If Congress' goal had been to simply reduce Medicare spending on clinical laboratories, it would not have had to order such a complex process. The statute plainly envisions a system that shadows prices paid by private insurers for lab tests in a complex and variegated marketplace. That is an elusive goal under any circumstances. A methodology based on a limited and skewed method of data collection does not achieve it," Badger concludes.

In devising the CLFS, the agency faced a difficult task. Congress required applicable laboratories to report enormous amounts of data and imposed civil money penalties of up to $10,000 a day on laboratories that failed to report.

CMS tried to limit the reporting burden by applying it to only a very small number of labs. The unfortunate result is that all labs will bear the burden of steep cuts imposed by a Medicare reimbursement schedule that doesn't reflect the payments they receive from private insurers.

Both Congress and CMS need to reassess this fledgling CMS plan in order to rationalize payments and not lock in a policy that could well put access to necessary diagnostics in jeopardy for millions of seniors.

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