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From international law firm Arnold & Porter LLP comes a timely column that provides views on current regulatory and legislative topics that weigh on the minds of today's physicians and health care executives.

CMS proposes sweeping changes for Medicare lab payments: What physicians need to know

--By Thomas A. Gustafson, Paul M. Rudolf and Jennifer B. Madsen

In a long-anticipated proposed rule, CMS recently revealed its preliminary plans for implementing sweeping changes relating to clinical laboratory tests. Practicing physicians should be aware of two key features of these changes.

First, starting as early as the first quarter of 2016, laboratories will be required to report for the first time detailed information to CMS about payments they receive from private payers. Not all physician office laboratories (POLs) will be required to report, but inadequate reporting may result in penalties. Physicians with POLs should stay tuned for more information from CMS and plan ahead for this looming obligation.

Second, Medicare will adopt new rates, based on private-sector rates, for all tests paid on the Clinical Laboratory Fee Schedule (CLFS) starting in 2017. Rates for most tests are likely to be significantly reduced. These changes will affect CLFS payment amounts for all laboratories, including POLs that are not required to report data. Pathology tests paid on Medicare's Physician Fee Schedule (PFS), however, will not be affected.

Will your laboratory face reporting requirements?

You laboratory may be required to report, depending on whether it has revenues above certain proposed thresholds. CMS proposes to require reporting by certain entities, defined at the level of Tax Identification Numbers, that include CLIA laboratories. POLs, free-standing labs and facility-based labs all could be required to report if they meet both of the two proposed revenue tests.

First, CMS proposes that only entities with more than 50% of their total Medicare revenues (from Parts A, B, C and D) from the CLFS or the PFS would be required to report. This test would be met by most physician practices with POLs, but most hospital labs are likely to be excluded from reporting by this test.

Second, for entities passing the first hurdle, CMS proposes to excuse an entity from reporting if it received less than a specified amount of Medicare CLFS revenue in a year. As

a result, most (but not all) POLs and many smaller independent laboratories would not have to report. For the first round of reporting, the threshold amount would be $25,000 in payments under the CLFS from July 1, 2015, to Dec. 31, 2015. In the future, only laboratories receiving CLFS payments greater than $50,000 for a 1-year period would be required to report, and reporting would be required for most laboratories only every third year.

Should practices with POLs do anything now?

Yes. Because the proposed reporting period began July 1, practices with POLs will need to determine whether they are likely to receive $25,000 in revenue, between July 1, 2015, and Dec. 31, 2015, from tests paid off the CLFS. Unless the practice is certain that revenue will fall well short of $25,000, it would be prudent to start to develop the infrastructure to collect the required information for potential reporting in Q1 2016. Unfortunately, CMS has not proposed a process for resolving disputes if CMS concludes that a POL is required to report but the practice disagrees.

What will happen to payments over time?

CMS proposes that first-round reports would be due by March 31, 2016. These reports would provide information on private-payer rates and volumes for services that appear on the CLFS and that were furnished between July 1 and Dec. 31 of this year. CMS's proposed rule was late, and the agency has not yet provided detailed, sub-regulatory guidance that providers will need to comply. Many observers speculate that CMS may, in its final rule, delay the timeline.

HHS has the authority to impose civil money penalties of up to $10,000 per day for each failure to report fully or accurately. The federal government has prosecuted other health care providers under the False Claims Act for noncompliance with similar reporting requirements.

How will Medicare ' s payment amounts change in 2017?

Payment amounts are likely to go down for many routine POL-performed tests such as CBCs and chemistry panels. The new Medicare payment amounts will be based on the weighted median, calculated on a national basis, of the rates paid by private payers for each test. Large payment reductions will be phased in, with rate reductions limited to 10% for each year from 2017 to 2020 and 15% for each year from 2020 to 2022. The expected changes for particular tests are unknown at this time, and while payment amounts could go up in some instances, CMS estimates that overall its payments will fall by 4.5% in 2017 and by 7.4% over the 5-year period from 2017 to 2021. This suggests that payment amounts for most tests will likely fall.

In the future, payment rates will change at least every 3 years (although for tests subject to phased-in reductions and certain “advanced diagnostic” tests, changes will be made annually). For most tests, payment amounts will change (in 2020 and 2023 and so forth) to reflect average payment rates for each test in the private market during the tri-annual interval between reports from labs. Departing from its prior practice, after 2016 Medicare will no longer make any annual across-the-board adjustments for inflation or productivity.

As at present, Medicare will not impose any cost-sharing obligations on CLFS tests. Accordingly, affordability for patients should not be affected by the new payment rates.

What’ s next?

Note that many of the provisions discussed above are proposals, not final policy, so some detailed aspects (such as the definition of laboratories required to report or timelines) may change when CMS publishes its final rule, probably sometime this winter. Physicians and others are welcome to comment on the proposals; the comment window closes Nov. 24. Laboratories should also watch for anticipated sub-regulatory guidance from CMS on specifics, such as exactly what to report and how.

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