Bloomberg Law

Medical Devices Law & Industry Report™

Reproduced with permission from Medical Devices Law & Industry Report, 11 MELR 10, 05/10/2017. Copyright © 2017 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com

Medicare

Implementation of the Medicare Clinical Laboratory Fee Schedule Overhauls Hits a Snag

By Joyce Gresko

Implementation of Section 216 of the Protecting Access to Medicare Act (PAMA) hit a snag recently, and it is too early to tell whether the problems will have further ripple effects. The law overhauls the way that clinical laboratory tests are priced on the Medicare Clinical Laboratory Fee Schedule (CLFS), basing the new rates on the weighted medians of private payor rates reported by laboratories. When Congress passed PAMA in April 2014, it gave the Centers for Medicare & Medicaid Services (CMS) until June 30, 2015 to issue a final rule to implement Sec. 216. CMS missed the statutory deadline by almost a year, issuing the final rule on June 17, 2016, but since then, implementation had continued apace. That is, until March 30, 2017, when CMS made an announcement on the day before the first data reporting period was to come to a close that it effectively would extend the data reporting deadline by two months, to May 30, 2017.

Section 216 of PAMA (Pub. L. 113-93) calls for Medicare reimbursement for clinical laboratory tests to be based on the weighted medians of private payor rates for those same tests, a major departure from the way CLFS rates have been set for the last several decades.

Joyce E. Gresko is an attorney with Alston & Bird's Health Care Group in Washington.

Under the law, ''applicable laboratories'' are to report ''applicable information'' to CMS – essentially, payment information about clinical laboratory tests for which they received final payments during a specific data collection period, including each private payor rate for each test and the associated volume of tests at each rate. CMS then calculates a weighted median of all applicable laboratories' private payor rates for each test, and the weighted median is to become the new CLFS rate starting January 1, 2018. An applicable laboratory that does not report its applicable information, or that reports incomplete or inaccurate information, may be liable for civil monetary penalties of up to $10,000 per day for each failure to report, each misrepresentation, or each omission. (For more detailed information on the law and the final rule, see the author's prior article, ''CMS Releases Final Rule Implementing New CLFS Payment Law,'' published in July 2016 in the Medical Devices Law & Industry Report (10 MELR 15, 7/20/16).)

CMS had planned that by this time, it would have started the process of poring over the mounds of data submitted by laboratories and calculating a new Medicare payment rate for each test on the CLFS. But a number of insurmountable difficulties–both on the part of CMS and on the part of reporting laboratories–led the agency to adjust its implementation timeline once again. It remains to be seen whether CMS will be able to collect all of the required information and calculate new CLFS rates in time for them to go into effect at the

start of the next calendar year, or whether there may be further delays in the offing.

What is an ''applicable laboratory''?

Each applicable laboratory is required to report private payor rates and associated volumes to CMS during a data reporting period, and an entity that does not qualify as an applicable laboratory may not report that information to the agency. An ''applicable laboratory'' is defined as an entity that: (1) is a laboratory, as defined under the Clinical Laboratory Improvement Amendments (CLIA) and its implementing regulations, or has at least one component that is a laboratory; (2) bills Medicare Part B under its own National Provider Identifier (NPI); (3) in a data collection period (*e.g.*, Jan. 1 through June 30, 2016), receives a majority of its Medicare revenue from the CLFS and/or the Medicare Physician Fee Schedule (PFS); and (4) that receives more than $12,500 in Medicare revenue under the CLFS during that same data collection period (other than for ''advanced diagnostic laboratory tests'' (ADLTs)). 42 C.F.R. § 414.502.

The universe of laboratories that qualify as ''applicable laboratories'' is a small fraction of the total number of laboratories in the U.S. that are certified under CLIA and its implementing regulations, but it still is a large number of entities. In a report released in September 2016, the U.S. Department of Health and Human Services Office of the Inspector General estimated that just five percent of laboratories would be considered applicable laboratories for the first data reporting period and that those labs accounted for roughly 70 percent of Medicare payments for lab tests in 2015. On the other hand, five percent of laboratories still amounts to more than 12,000 entities reporting applicable information to CMS, and each of those labs will report the volume of tests paid at each and every private payor rate during the first six months of 2016. Importantly, regardless of whether an entity qualifies as an ''applicable laboratory,'' all entities that receive Medicare reimbursement under the CLFS will be subject to the new rates that CMS calculates, based on the data reported by the estimated five percent of laboratories.

Naturally, the definition of ''applicable laboratory'' encompasses independent clinical laboratories, which generally receive a majority of their Medicare revenue from a combination of the CLFS and PFS and have high enough test volume that they would have surpassed $12,500 in CLFS revenue in the first data collection period. The definition also sweeps in larger physician group practices that have physician office laboratories (POLs), when those POLs exceed the CLFS low-dollar threshold during the data collection period. Throughout the late summer and early fall of 2016, CMS did some outreach to stakeholders and issued guidance on how an entity would determine whether it was an applicable laboratory, but it appears that a number of physician offices were unaware until fairly recently that they had a duty to report their private payor rates to the agency, which payments they are required to report, and what it takes to prepare all of the data for reporting. CMS reported receiving questions from physician offices and others as late as mid-March about whether they had an obligation to report data to CMS under the law. The continuing uncertainty among physician offices is reflected in the last update to the Frequently Asked Questions document on CMS's website, which was updated most recently on March 9, 2017 and which includes clarifying statements that are aimed at POLs.

While some physician offices are considered applicable laboratories, the regulatory definition has the effect of excluding almost all hospital laboratories from reporting applicable information to CMS. That is because very few hospital laboratories bill Medicare Part B under their own NPI numbers; generally, those charges are billed using the same NPI number as the hospital as a whole. While hospitals do receive Medicare revenue under the CLFS, especially those with robust outreach programs that serve non-patients and that compete with independent laboratories, the overwhelming majority of most hospitals' Medicare revenue comes from Part A.

The new CLFS rates that are to take effect on January 1, 2018 will be based on private payor rates reported by a narrow sliver of the laboratory market as a whole. Furthermore, the definition of ''applicable laboratory'' that CMS set forth in the final rule removes almost an entire class of laboratories – hospital laboratories – from private payor rate reporting altogether. This has been a cause of great concern to some stakeholders who worry that, because the universe of ''applicable laboratories'' is not a true representation of the laboratory industry, the Medicare rates that CMS develops for laboratory tests going forward will not reflect rates paid in the entire market.

Online Data Reporting System

Even before CMS released the final rule to implement Sec. 216 of PAMA, the agency hired a contractor to build an internet-based system for laboratories to use to report applicable information. (It is similar in several respects to the system that pharmaceutical manufacturers use to report their Average Sales Prices to CMS.) The CLFS Data Collection System is accessed through the CMS Portal, which allows users to get to one or more of about 50 different CMS applications.

On November 2, 2016, about two months before the start of the first data reporting period, CMS held a webinar to explain how a laboratory would submit data to the agency. Because of the number of steps involved and the complexity of the system – especially to someone who is new to the CMS Portal—the agency urged laboratories not to wait until the last minute to prepare for data submission. A laboratory reporting data first has to be enrolled in the Provider Enrollment, Chain, and Ownership System (PECOS) at the taxpayer identification number (TIN) level, and the person submitting the data for that TIN-level laboratory must register for a CMS Enterprise Identity Management user name and password, answer security questions, and submit to a ''soft credit check'' for identity verification purposes. The data submitter and the data certifier cannot be the same person, and the data certifier must be the laboratory's President, CEO, or CFO, or someone who reports directly to one of those individuals. After the users have registered, it may take up to 72 hours to receive an email notification that he or she may access the CLFS Data Collection System. To assist laboratories, CMS released a comprehensive user manual, available on the CMS website, with step-by-step instructions for registration, data submission, and data certification.

Applicable information is to be collected and reported in a spreadsheet with specified fields. Each line

 COPYRIGHT © 2017 BY THE BUREAU OF NATIONAL AFFAIRS, INC. MELR ISSN 1935-7230

includes a test's HCPCS code, payment rate, volume, and the NPI of the laboratory submitting the data; a laboratory that had more than one private payor rate for the same test will report each payment rate and the associated volume on separate lines of the spreadsheet. Each spreadsheet field is limited to a certain format and number of characters (for example, the payment rate must include only numerals and have two decimal places). When all applicable information is entered into the spreadsheet, it can be uploaded.

During the fall of 2016, the agency invited a small number of laboratories to test the CLFS Data Collection System so that the agency could gather information about what problems might remain with the system and to identify the ''bugs''. While some laboratories were able to submit ''dummy data'' successfully during the testing phase, a number of laboratories could not submit their data at all, despite repeated efforts. Large data files were particularly problematic, and the data upload timed out before completion. Another problem that the testing revealed was that the system could not provide a laboratory with the location of a formatting error in a file submission, and a file with even one formatting error cannot be uploaded. For example, a laboratory mistakenly may have included a payment rate with three decimal points, but the system could not point the laboratory to the exact line with the error. This problem reportedly was not fixed until late in March, soon before the data reporting period was scheduled to close.

''Enforcement Discretion'' for Not Reporting by March 31, 2017

While CMS urged laboratories not to wait until the last minute to register to use the CLFS Data Collection System and submit applicable information to the agency, remaining glitches in the system and the sheer magnitude of the work involved conspired to prevent many laboratories from being ready to report their applicable information to CMS by March 31, 2017.

On March 30, 2017, CMS announced that it would ''exercise enforcement discretion'' until May 30, 2017 with respect to an applicable laboratory that did not report applicable information and the possible imposition of civil monetary penalties for failure to report. CMS chose to exercise ''enforcement discretion,'' rather than simply extend the reporting deadline by two months, because the specific start and end dates for the data reporting period are included in the regulations implementing Sec. 216 of PAMA, and the agency did not believe it could change either of those dates without engaging in further rulemaking. The statement that CMS released on March 30, 2017 said that industry feedback indicated that many applicable laboratories would not be able to submit complete applicable information to CMS by the end of the data reporting period. It also said that sixty days was the maximum amount of extra time that CMS could allow and still be in a position to develop new CLFS rates for the planned January 1, 2018 effective date. Laboratories that are prepared to report applicable information to CMS may do so at any time before May 30, 2017.

What's next?

CMS has said that it plans to release preliminary Calendar Year 2018 CLFS rates in early September 2017 and that it will provide the public with 30 days to submit comments on the preliminary rates. Final rates would be made available to the public in early November 2017, for implementation on January 1, 2018.

As much as CMS would like to see applicable laboratories submit data through the CLFS Data Collection System as soon as possible, it is likely that much of the data will not be reported until close to the end of the period of ''enforcement discretion.'' The timeline that CMS set for itself to collect and organize applicable information submitted by thousands of laboratories and to develop weighted medians was seen by some as aggressive, even with a data reporting period that would have ended on March 31, 2017. Now, with a data reporting period that effectively ends on May 30, 2017, and with much of the information not coming into the system until late in the period, it may be difficult for the agency to calculate preliminary CY 2018 CLFS rates by early fall so that it can provide stakeholders an opportunity to review and comment on them.

Publicly, CMS still claims that it will have sufficient time to complete its work. But the agency will have only about three months to calculate weighted medians before sharing the new rates with the public, and the logistical challenges may make an early September release of preliminary rates challenging. Whenever that data is released, it is certain that stakeholders will scrutinize the preliminary rates very carefully. Entities that receive Medicare reimbursement under the CLFS have a lot at stake and will want to be sure that CMS has done its math correctly, given that the new rates are to stay in effect for three years, until after the next data collection and data reporting periods. Thus, the delay in the reporting deadline is likely to create additional pressures both for CMS and for laboratories.