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Changing Times for Clinical Laboratories

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As Bob Dylan wrote, ''The times, they are a-changin' ''[1] While Dylan certainly had larger issues in mind than the state of the clinical laboratory industry, it still is a fair description of what is happening for laboratories right now.

For many years, clinical laboratory testing involved relatively simple blood and urine tests. The U.S. Food and Drug Administration (FDA) took a relatively ''hands off'' approach toward laboratory-developed tests (LDTs), exercising what the agency termed ''enforcement discretion'' for these tests, which are developed and used in-house by laboratories. But, in recent years, there has been a dramatic change in the nature of the clinical laboratory industry. The mapping of the human genome and more advanced analytic techniques have led to great advances in laboratory testing, most of which is more sophisticated and costly than the simple blood and urine tests that were laboratories' bread and butter in the past. The FDA has become more concerned about the complexity of LDTs that laboratories oftentimes develop and market today. The FDA announced in 2014 that it is ready to bring regulation of LDTs under its enforcement umbrella for the first time, possibly affecting thousands of tests.

Meanwhile, Medicare payment for laboratory tests is in a state of flux, as well. For more than thirty years, Medicare has paid for tests furnished to beneficiaries based on a fee schedule that was developed in 1984. Increased competition has reduced prices paid by private payors, and the Centers for Medicare and Medicaid Services (CMS) long has complained that it has not shared in these price concessions. Sometime in the next several months, CMS is expected to release a final rule implementing Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which will detail the process the agency will use going forward to establish prices for laboratory services furnished to Medicare beneficiaries, the first major reform of the Medicare laboratory test rate setting system in three decades. A host of coding reforms for clinical laboratory tests are part of the overhaul of the fee schedule, bringing more confusion to an already complicated process.

The confluence of an entirely new Medicare rate setting system and FDA regulation of a substantial sector of the clinical laboratory market has caused great uncertainty in the industry, and it is likely that the result

[1] B. Dylan, ''The Times They Are A-Changing'' (1963)

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will be a vastly different laboratory landscape. The best approach for laboratories is to stick with Bob Dylan and ''have a strong foundation when the winds of change shift.'' [2] Understanding the forces at work will assist laboratories as they prepare for what's ahead and adjust to a new clinical laboratory market in the U.S.

Protecting Access to Medicare Act

In late September 2015, CMS released a proposed rule to implement Section 216 of the Protecting Access to Medicare Act, or PAMA, as it is known.[3] That section of the law fundamentally changes the way that CMS establishes prices for clinical laboratory tests furnished to Medicare beneficiaries, introduces new coding requirements for new tests and for tests that are cleared or approved by the FDA, and establishes separate rate-setting and reporting requirements for so-called ''advanced diagnostic laboratory tests'' (ADLTs). The widespread interest in the proposed rule among various stakeholders is evidenced by the fact that the agency received more than 1,300 comments in response to its proposals. Although Congress directed that major portions of the law are to be implemented starting January 1, 2016, there is great uncertainty around when these changes will become effective, given the fact that CMS has yet to issue a Final Rule.

Payment Rates

The Clinical Laboratory Fee Schedule (CLFS), which currently has about 1,200 tests on it, was established in 1984. In reality, there have been 56 state- and territory-based fee schedules, with negligible price differences between them. Initially, laboratories were reimbursed at a rate equal to the lower of submitted charges or the relevant fee schedule rate. Eventually, Congress directed the Medicare agency to establish a National Limitation Amount, which gradually has decreased to 74 percent of the median of all local fee schedule amounts for most tests.

In Section 216 of PAMA, Congress directed CMS to develop a new way to establish prices for clinical laboratory tests on the CLFS that is based on the rates that private payors pay for the services. PAMA Section 216 added a new section 1834A to the Social Security Act, which outlines a process for CMS to use to collect data from ''applicable laboratories'' on private payor rates paid to them for individual laboratory tests and to develop new market-based prices from the weighted median of those rates. Every three years, an ''applicable laboratory'' will have to report ''applicable information'' to CMS about each rate paid by each private payor during a data collection period, along with the volume of such tests for each payor for the reporting period. An ''applicable laboratory'' is one that derives a majority of its Medicare revenue from the CLFS and/or the Physician Fee Schedule. In the statute, ''applicable information'' is defined as the payment rate paid by each private payor for a test during the data collection period, and the volume of each test for each payor during that period. In the proposed rule, CMS said that a clinical laboratory that is not an ''applicable laboratory,'' as defined in the statute and the proposed rule, would be prohibited from reporting ''applicable information,'' although it declined to say how it would enforce such a prohibition. The statute specifies that applicable laboratories are to begin reporting private payor rates to CMS on January 1, 2016 and that the weighted medians derived from the data are to take effect on January 1, 2017. Current methods for pricing tests for Medicare beneficiaries are to be used through December 31, 2016.

There are numerous questions about how laboratories will report their rates to CMS.

As a threshold matter, without a final rule, clinical laboratories have very little to go on to determine whether or not they will be considered ''applicable laboratories'' that are required to report private payor rates to CMS. It is not at all clear, for example, whether or not hospitals with robust outreach programs will be considered ''applicable laboratories''; in the proposed rule, CMS said it did not think Congress intended for hospital laboratories to have to report their rate information, but since publication of the final rule, some members of Congress have pushed back on that notion. The data collection period–the three or six or 12 month period of time for which applicable laboratories will have to report their private payor rates–also remains unsettled. And, perhaps most importantly, there are numerous questions about how laboratories will report their rates. The statute requires that a laboratory report every payor rate for every test, even if the rates change during the reporting period. This is a colossal task, requiring each applicable laboratory to analyze tens of thousands of data points. The vast number of questions left open by the proposed rule, and the many areas in the proposed rule about which CMS did not make a proposal but instead only asked for stakeholder advice, make planning for many major aspects of PAMA's implementation an impossibility for clinical laboratories.

Congress included a deadline of June 30, 2015 for CMS to issue a final rule to implement the law; however, the agency did not issue even a proposed rule until almost three months after the date set by Congress for a final rule, and it has raised numerous questions about the actual timeline for implementing the law. Even though the comment period stretched through November 25, 2015, in the proposed rule, CMS laid out a virtually unachievable schedule for the first data reporting period, suggesting that it would begin on January 1, 2016. Clearly, the date on which laboratories are supposed to start reporting data to CMS has come and gone, and CMS is nowhere near issuing a final rule. The huge number of comments that the agency received – and to which it must respond – undoubtedly will delay publication of a final rule.

ADLTs

In Section 216 of PAMA, Congress defined an ''advanced diagnostic laboratory test,'' or ''ADLT'', as a laboratory test that is marketed and performed only by a single laboratory and not sold for use by another laboratory and that meets one of the following criteria: (1) the test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to

[2] B. Dylan, ''Forever Young'' (1973).
[3] 80 Fed. Reg. 59386 (Oct. 1, 2015).

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yield a single patient-specific result, (2) the test is cleared or approved by the FDA, or (3) the test meets other similar criteria established by the Secretary of Health and Human Services. The significance of designation as an ADLT is that initially, Medicare payment will be based on the laboratory's list price, and private payor rate reporting will be done annually, rather than every three years, providing an opportunity for more favorable Medicare reimbursement as more private payors recognize and pay for a test.

Based on the statutory definition, many laboratories offering multianalyte assays with algorithmic analysis – so-called ''MAAA'' tests – expected to be included among ADLTs and to benefit from their relatively favorable treatment. CMS added certain glosses to the statutory definition that could limit the number and kind of tests that would get the benefit of designation as ADLTs. For example, CMS proposed that an entity that holds more than one Clinical Laboratory Improvement Amendments (CLIA) certificate would not be considered a ''single laboratory'' and therefore could not have an ADLT, even if only one laboratory operated by that entity has any involvement in the development, performance, and marketing of a test. Inexplicably, CMS also determined that a MAAA test whose biomarkers are proteins, rather than DNA or RNA, would not qualify as an ADLT, even though Congress explicitly included protein biomarker tests among those that could be ADLTs. This is another area where Congress has weighed in with CMS since publication of the proposed rule.

In addition, the great advantage of being an ADLT is to be paid at the list price for the three quarters of the year after the test is introduced. (If the established list price exceeds the weighted median ultimately established by CMS by more than 130 percent, then CMS can recoup the difference in the amount paid.) Congress did not specify at what point the ''three quarters'' starts to run; under CMS's formulation in the proposed rule, it would begin as soon as the test is offered for the first time, regardless of whether or not it is covered and paid for by Medicare at that time. Usually there is significant lag time between when a test is offered initially and when Medicare pays for it. CMS's interpretation means that the ''three quarters'' would begin to run even before the test is paid for by Medicare. Under the statute, reporting about rates paid by private payors for an ADLT would have to begin by the end of the second quarter, even if the test is not yet paid for by Medicare. Thus, it is likely in many cases that the ''three quarters'' would pass before Medicare even pays for the test, which makes the statute's elaborate payment formulation irrelevant.

At the same time that CMS is working on finalizing the proposed rule, laboratories that currently offer or that are planning to offer MAAA tests and FDA-cleared or –approved tests are grappling with decisions that could affect how, and how often, they report private payor rates to CMS. While businesses oftentimes have to make consequential decisions with incomplete information, the proposed rule's open questions complicate choices such as whether to enter into a marketing agreement with another laboratory, when to pursue FDA-clearance or approval for a test or to introduce the test to the market, and how to set the list price that would serve as an ADLT's initial reimbursement rate.

Coding

PAMA's coding provisions are not extensive, but they too are having an impact on laboratories' decision-making. The statute requires CMS to adopt temporary Healthcare Common Procedure Coding System (HCPCS) codes to identify new ADLTs and new laboratory tests that are FDA-cleared or -approved and to do so by January 1, 2016, a deadline the agency obviously no longer can meet. For an existing ADLT or FDA-cleared or –approved test without a unique HCPCS code, the Secretary is to assign a unique HCPCS code and publicly report the payment rate for the test.

CMS proposed to assign a HCPCS G-code to a test that does not already have a unique CPT or HCPCS code. (CPT codes—the American Medical Association's ''Current Procedural Terminology'' codes—are the primary codes that are used to identify and bill most medical services today.) The unique CMS-assigned code would be effective up to two years, but CMS could extend its application for longer than that. The statute is silent on whether the HCPCS code that CMS assigns to a test must be a Level I HCPCS code (a CPT code) or a Level II HCPCS code (a G-code). Many stakeholders are cool to the idea of automatically-assigned G-codes, since they generally cannot be used outside of the Medicare program. The American Medical Association (AMA) CPT Editorial Panel is considering the development of a distinct set of CPT codes that could be used for new ADLTs and for FDA-cleared and -approved tests, along with a procedure for assigning the codes in response to requests from test developers.

This issue is important for laboratories with tests that do not have specific CPT codes. A laboratory will need a specific code to be able to report the private payor rates for a test. Once the code assignment process is established, it will take time for laboratories to obtain a unique code—either from CMS or the AMA. This is also an issue that must be resolved quickly, before PAMA rate reporting begins.

FDA Regulation of Laboratory-Developed Tests

While laboratories are awaiting a final rule from CMS, many also are keeping a watchful eye out for final guidance from the FDA on regulation of laboratory-developed tests (LDTs). The FDA issued draft guidance in October of 2014 that set forth its plans to begin regulating LDTs as medical devices.[4] In Congressional testimony late in 2015, the agency stated its intention to release final guidance in 2016, and more recently agency officials have said that the guidance would be released before the end of the Obama Administration. But several members of Congress are working with industry stakeholders on an alternative to FDA's medical device-based approach, and other members of Congress want the FDA to work with CMS to develop a regulatory framework that dovetails more comfortably with regulatory requirements under the CLIA. In short, it is anybody's guess whether and when the agency will release final guidance to implement its plans, whether any

[4] Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories; Framework for Oversight of Laboratory Developed Tests (LDTs) (Oct. 3, 2014), *available at* http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm416685.pdf.

guidance issued by the FDA will depart significantly from its draft guidance, and whether Congress will step in before the FDA begins to implement any final guidance.

For many years, the FDA had taken the position that it had the authority to regulate LDTs but that it would exercise ''enforcement discretion'' and not require them to go through a pre-market approval or clearance process, nor would it impose other device regulations on LDT developers. In more recent years, the agency has said that it has grown concerned about changes in the way that LDTs are used, noting that the tests more often are used to assess high-risk diseases and oftentimes are performed in a laboratory far away from a patient's treating physician. While the FDA's release of draft guidance toward the end of 2014 was not a complete surprise to the laboratory industry – for a few years, the agency had been hinting that it may not continue its hands-off approach to LDTs – the breadth of the draft guidance has made concrete what previously had been theoretical.

The main elements of the FDA's approach include notification to the FDA or registration and listing of each LDT offered by a laboratory, medical device reporting (also known as ''adverse event reporting''), ongoing enforcement discretion for certain classes of LDTs, phased-in premarket review requirements for ''high-risk'' and ''moderate-risk'' LDTs, and quality systems regulation.

Risk-Based, Phased-In Approach

The FDA plans to rely on the existing medical device classification system to stratify the risk profile of each category of LDTs. Medical devices are classified as Class I, II, or III, depending on the controls necessary to assure the safety and effectiveness of a device, and this is based on the intended use, technological characteristics, and the risk to patients if a device were to fail. In classifying LDTs, the FDA is most interested in whether a test is intended for use in patients with high-risk diseases, whether it is for screening or diagnosis, the potential consequences of erroneous results, and other factors. While the agency intends to issue guidance to describe what it considers to be Class I, II, and III LDTs, it has said that it considers the highest-risk LDTs to be those that have the same intended uses as cleared or approved companion diagnostics, LDTs for determining the safety and efficacy of blood products, and LDTs with the same intended use as existing Class III medical devices.

FDA said that its regulation of LDTs would happen gradually, over a span of nine years or so after a final guidance document is released. But as soon as just one year after publication of final guidance, laboratories offering what the FDA considers Class III LDTs would have to submit documents to the FDA in service of either premarket approval or premarket clearance. The FDA would continue to exercise ''enforcement discretion'' with respect to those LDTs while such applications are pending.

(As an aside, at the same time as the FDA is planning its risk-based classification of LDTs, the New York State Department of Health's Clinical Laboratory Evaluation Program has proposed its own policy for risk-based evaluation, review, and approval of LDTs.[5] It would apply to laboratories holding New York State clinical laboratory permits. The FDA's proposed criteria for risk classification differ from what New York State has proposed, which may create some confusion and complications for those laboratories that hold New York State laboratory permits and offer LDTs.)

Notification or Registration and Listing

Under the draft guidance, within six months of publication of the final guidance, each laboratory offering an LDT would be required to ''notify'' the FDA about its LDTs and submit certain information to the FDA. Not only would the agency use this information to classify LDTs, but it also would make much of the information publicly-available, including the monthly test volume, intended use, what the test measures or detects, the target patient population, sample type, and whether the test is a modification of an existing FDA-cleared or –approved test. A laboratory that opted not to notify the FDA about its LDTs would be subject to the FDA's onerous registration and listing requirements for medical devices.

Because of the significant additional costs associated with registration and listing – costs that many laboratories currently do not incur – most laboratories probably will choose to notify the FDA about their tests. However, laboratories will have to weigh the monetary costs of registration and listing against the competitive costs of having a host of information about each and every LDT made public. Another concern is the application of the 2.3 percent medical device tax, which was included in a provision of the Affordable Care Act and applies to medical devices that are listed with the FDA, but not to those about which a developer merely notifies the FDA (Congress has suspended the medical device tax through the end of 2017).

Quality System Regulation

If the FDA were to finalize its draft guidance, one of the most burdensome aspects of it for laboratories would be compliance with FDA's quality system regulation (QSR) requirements. While the FDA said it intends to assist laboratories with understanding and implementing the QSR requirements, many laboratories will be required to invest a tremendous amount of organizational resources and money to revamp their LDT-development processes to comply with existing QSR requirements. The FDA's QSR requirements outline the systems that medical device manufacturers must implement to ensure that their devices are safe and effective. All clinical laboratories already are regulated under the CLIA and implementing regulations, and that framework is designed to ensure that all tests are accurate, reproducible, and reliable. Laboratories offering LDTs still will be regulated under CLIA, and it still is unclear how the FDA's QSR requirements and CMS's CLIA requirements will overlap. QSR requirements include management, organizational, and personnel requirements; development and maintenance of a quality plan; written quality system policies and procedures; quality

[5] NYSDOH Proposed Policy for Risk-based Evaluation of Laboratory Developed Tests (LDTs) (Mar. 1, 2016), *available at* http://www.wadsworth.org/sites/default/files/WebDoc/308752912/Risk-based_LDT_Proposed%20Policy_3-10-16_final.pdf.

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audits; design control procedures; establishment and maintenance of a design history file; and many other elements. The FDA has acknowledged that most laboratories do not have any of these elements in place, and for an LDT developed many years ago, it may not be possible to recreate the ''design control'' documents it was never required to have in the first place.

Conclusion

Clinical laboratories have reason to be concerned about what is on the horizon. Many believe that there will be significant cuts in Medicare reimbursement for a number of tests on the CLFS after PAMA is implemented, and even though any cuts will be phased on over a number of years. Reductions in Medicare reimbursement may, in turn, exert downward pressure on rates paid by private payors, resulting in a slow downward spiral in reimbursement, which could affect access to certain laboratory tests and threaten the viability of some laboratory companies altogether.

The onerous private payor rate reporting process mandated by PAMA could get underway just as independent clinical laboratories and hospital laboratories also are wrestling with understanding a new FDA regulatory framework for LDTs. If and when the FDA releases final guidance on regulation of LDTs, a major first step will be gaining a clear understanding what the FDA requires a laboratory to do, with respect to which LDTs, and by when. This will be no small task, especially for laboratories that do not have large legal and compliance departments. Laboratories offering LDTs then will have to implement whatever new requirements the FDA finalizes by training staff, developing new policies and procedures, implementing ''adverse event reporting'' systems, and squaring the FDA's quality system regulation requirements with CLIA's test performance standards.

While it is not possible to anticipate every detail of either CMS's final rule to implement Section 216 of PAMA or of the FDA's final guidance on regulation of LDTs, laboratory leadership should take the time now to learn what they can about each of the agency's proposals and consider what additional personnel and consultants they may need to add in the near future. For most laboratories, it will not be possible to avoid the turmoil altogether, but thoughtful planning may help mitigate the disruption to laboratory operations and innovation as the new reality for laboratories takes hold.