Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

CHANGING HOW MEDICARE PAYS FOR CLINICAL DIAGNOSTIC LABORATORY TESTS: AN UPDATE ON CMS'S PROGRESS

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RESULTS IN BRIEF

This report provides a progress update on the Centers for Medicare & Medicaid Services' (CMS) implementation of Medicare's new congressionally mandated payment system for laboratory (lab) tests. CMS has made significant progress toward implementing this new payment system. CMS has completed significant parts of several key implementation tasks, and has plans in place to complete the remaining tasks before January 2018, when the new payment rates are scheduled to go into effect. Nonetheless, two aspects of CMS's plans are particularly concerning. First, CMS does not plan to verify whether labs that are required to do so submit the payment data that will serve as the basis for Medicare's new payment rates. Second, CMS does not plan to independently verify the data's completeness or accuracy. These aspects create risks for the new payment system's accuracy and could thus threaten the system's effectiveness in achieving its expected savings.

TASK 1. ISSUE THE FINAL RULE AND RELATED GUIDANCE DOCUMENTS

Largely completed. CMS issued a final rule in June 2016 detailing how it will implement the mandated changes to the payment system. CMS plans to issue key supplementary guidance to the lab industry, although it only has a short period of time to do so before reporting begins in January 2017.

TASK 2. ESTABLISH AND CONSULT WITH THE ADVISORY PANEL

Completed. CMS established the required advisory panel in 2015 and the panel continues to meet and provide recommendations to CMS. CMS will need to balance panelists' expertise with their financial interests when considering recommendations.

TASK 3. COLLECT PRIVATE PAYER DATA REPORTED BY APPLICABLE LABS

Significant progress. CMS has built the system that labs will use starting in early 2017 to submit their payment data from private payers (i.e., private health insurers, Medicaid managed care organizations, and Medicare Advantage plans). Before then, CMS must ensure that labs are aware of reporting requirements and able to collect their private payer data. Although CMS has tested parts of the data collection system, it has not completed testing the system's user capacity.

TASK 4. ENSURE THE COMPLETENESS AND ACCURACY OF REPORTED DATA

In progress. CMS has developed preliminary plans to conduct checks for data completeness and accuracy after labs submit the first round of data. CMS has some safeguards to prevent or mitigate incomplete and inaccurate reporting by labs, but it does not plan to independently verify the labs' data. Absent processes to verify whether applicable labs report their data or to verify the quality of the data that labs report, CMS may set inaccurate Medicare payment rates for lab tests.

TASK 5. DETERMINE AND PUBLISH NEW MEDICARE PAYMENT RATES

In progress. CMS has begun to plan how it will determine and publish Medicare's new payment rates once labs report their data in early 2017. CMS must follow a compressed timeframe for determining and publishing these new rates by CMS's target of November 2017.

TASK 6. IDENTIFY ADVANCED DIAGNOSTIC LABORATORY TESTS

In progress. The new payment system created a new category of tests: advanced diagnostic laboratory tests (ADLTs). CMS plans to issue supplementary guidance regarding these tests and to begin designating tests as ADLTs in late 2016.

BACKGROUND

Beginning January 1, 2018, the Centers for Medicare & Medicaid Services (CMS) will change the way it sets payment rates for clinical diagnostic laboratory (lab) tests. This is the first such reform in 3 decades, and is a result of the Protecting Access to Medicare Act of 2014 (PAMA). PAMA requires CMS to replace the current payment rates, which are based on historical lab charges adjusted for inflation, with new rates based on current charges in the private health care market.[1] CMS estimates that the new payment system will save Medicare $3.9 billion over 10 years.[2]

PAMA also mandated that the Office of Inspector General (OIG) conduct analyses that OIG determines appropriate regarding the implementation and effect of the new payment system for lab tests.[3] This progress report is one of a series that OIG will issue leading up to, and following, CMS's implementation of the new payment system. OIG is also issuing a companion report, *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data* (OEI-09-16-00040), a data brief with an analysis of Medicare payments for lab tests.

HOW PAMA CHANGES MEDICARE'S PAYMENT SYSTEM FOR LAB TESTS

Under PAMA, Medicare Part B *coverage* of lab tests will remain the same, but the system that Medicare uses to establish payment rates for these tests will change in 2018. Medicare Part B covers most lab tests ordered by physicians and pays 100 percent of allowable charges.[4] Medicare pays for these tests according to the Clinical Laboratory Fee Schedule (CLFS). Physicians use information from these tests to prevent, diagnose, and treat disease.

The first change under PAMA is to the data source that Medicare uses to set payment rates. Current rates are based on the amounts that labs charged Medicare in 1984 and 1985, and have been adjusted for inflation over the years.[5] PAMA applies a market-based approach in which Medicare's payment rates will be set based on rates from private payers and adjusted every 3 years using new data from private payers.[6, 7]

Another change that PAMA makes is to replace Medicare's current local fee schedules for lab tests with a single national fee schedule. Currently, Medicare pays for tests according to different fee schedules for 57 areas generally bounded by State lines. Rates for some of those tests are significantly lower than the national limitation amount, which is the maximum rate allowed.[8] Under the new system, each test will have a single Medicare payment rate nationwide without local variation.[9]

A third change that PAMA makes to Medicare's payment system is the creation of a new category of tests: ADLTs.[10] CMS will approve certain tests for ADLT designation based on statutory criteria. New tests designated as ADLTs will be subject to a distinct method of temporary pricing, and labs that perform ADLTs will need to report private payer data annually.

Medicare's Payment System Will Change in Three Primary Ways

CURRENT *Implemented in 1984*	FUTURE *To be implemented in 2018*
Payment rates for existing tests are based on **lab charges in 1984–1985**, adjusted annually for inflation	Payment rates for existing tests will be based on **current private payer rates**, and updated every 3 years using current data
57 local fee schedules	**Single** national fee schedule
Same pricing schedule for all categories of lab tests on the fee schedule	Creates a new category of lab tests—**advanced diagnostic laboratory tests**—with different pricing schedule

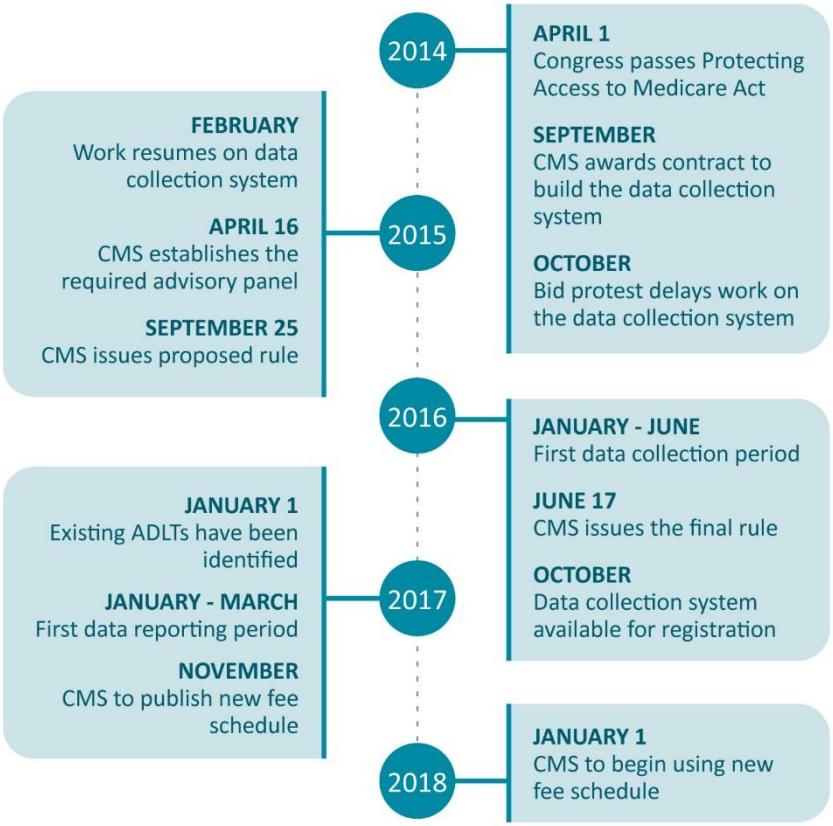
How CMS Is Implementing the New Payment System

Soon after the passage of PAMA in 2014, CMS began planning for implementation of Medicare's new payment system for lab tests. CMS assigned the implementation to the Division of Ambulatory Services within the Center for Medicare's Hospital and Ambulatory Policy Group (HAPG). This division manages five other Medicare payment systems, such as the payment system for Part B prescription drugs.

As shown in the following timeline, CMS's initial efforts focused on establishing the PAMA-required advisory panel, building a Web-based system for labs to report private payer data, and issuing a proposed rule—followed by a final rule—to describe how CMS will implement PAMA's statutory provisions for lab test payment rates.[11] CMS officials explained that the PAMA-established timeframe meant they needed to build the Web-based data collection system before publishing the final rule—otherwise, they would have published the rule first.

In the final rule, CMS postponed its implementation of the new payment system to 1 year beyond date specified by PAMA. CMS wanted to ensure that labs would have sufficient time to prepare their systems to collect the data they will be required to report. Therefore, in the final rule—published in June 2016—CMS postponed the beginning of the first reporting period from January 2016 to January 2017, setting a period of January to March 2017 for labs to report their data from the period of January to June 2016. The final rule postponed the effective date for new payment rates from January 2017 to January 2018.[12]

CMS's Timeline for Implementing the New Payment System for Lab Tests

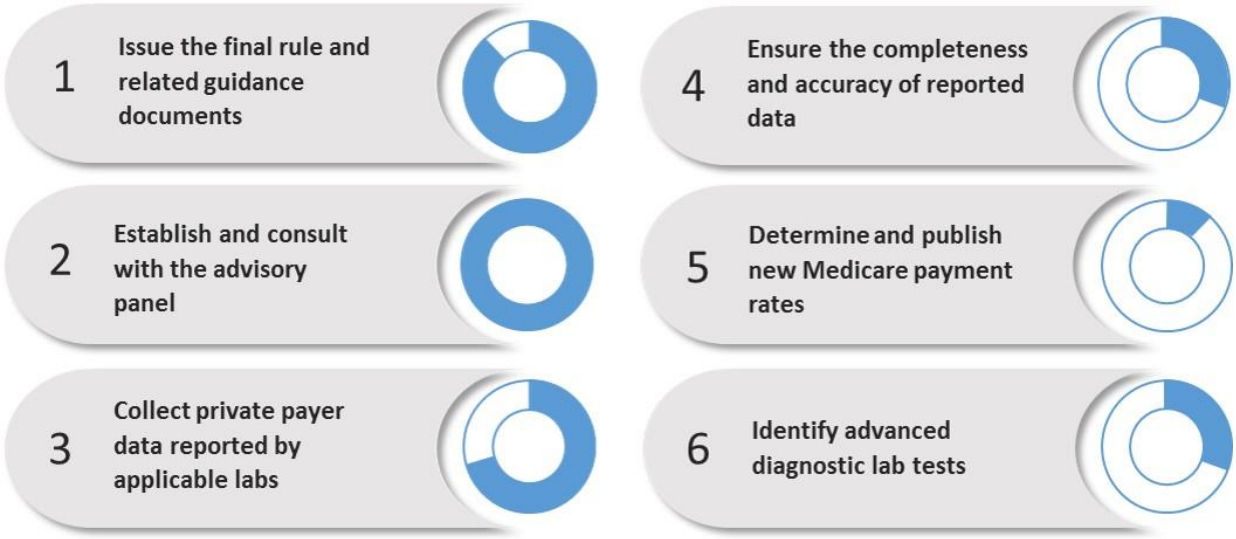


Source: OIG analysis of CMS's implementation of Medicare's new payment system for lab tests, 2016.
Note: Timeline was current as of August 15, 2016.

KEY IMPLEMENTATION TASKS

For purposes of our monitoring, we identified—from our review of PAMA—six key tasks that CMS needs to complete to implement the new payment system by January 2018. As shown in Figure 1, as of August 2016, CMS had completed all or parts of most tasks and had plans in place to complete the remaining parts of these tasks.

Figure 1. Status of CMS's Key Implementation Tasks as of August 2016



Source: OIG analysis of CMS's implementation of Medicare's new payment system for lab tests, 2016.

METHODOLOGY

To provide a progress update on CMS's implementation of the new payment system, we conducted interviews with CMS staff and contractors and reviewed documentation regarding the six key implementation tasks. For each task, we interviewed individuals responsible for implementing the task and collected documentation about the completed activities, current status, remaining activities, future plans, and challenges. This report describes CMS's progress as of August 2016.

Between April 2016 and August 2016, we conducted a series of interviews with CMS and the contractor responsible for building the Web-based system that labs will use to report private payer rates and that CMS will use to calculate new payment rates. We asked CMS staff about roles, responsibilities, resources, communication, and challenges regarding implementation activities.

We asked CMS to provide documentation supporting its implementation efforts. CMS provided us with a variety of documents such as recommendations from the advisory panel, deliverables from CMS's contractors, and reports about the functionality of the data collection system.

TASK 1. ISSUE THE FINAL RULE AND RELATED GUIDANCE DOCUMENTS

STATUS: Largely completed. CMS issued the final rule in June 2016 and plans to issue key supplementary guidance to the lab industry in the coming months.

WHAT'S BEEN DONE

- ✓ CMS issued the final rule on June 17, 2016
- ✓ CMS issued subregulatory guidance on data reporting procedures and requirements

WHAT'S STILL TO COME

Before January 2017, CMS must issue guidance on the process that labs will use to apply for a test to be designated as an ADLT

In the long term, CMS will determine whether additional regulations or subregulatory guidance is needed

WHAT TO WATCH

Because the data reporting period will begin on January 1, 2017, CMS has a short period of time to issue necessary subregulatory guidance to instruct labs on applying for ADLT designation for tests

WHAT'S BEEN DONE

In June 2016—a little more than 2 years after PAMA was enacted in April 2014—CMS issued the final rule detailing how it will implement Medicare's new payment system for lab tests,.[13] CMS staff initially spent time developing the expertise needed to write a regulation for an industry with a wide range of provider types and reporting capabilities. CMS issued the proposed rule in September 2015 and received about 1,300 comments from the lab industry and other interested parties. CMS considered and responded to these comments in the final rule.

In the final rule, CMS described several types of guidance that it plans to issue separately (i.e., subregulatory guidance) to facilitate the payment system's implementation. This guidance will provide details to the lab industry and other interested parties regarding (1) how labs should report private payer data to CMS, (2) which lab test procedure codes labs should include in data reporting, and (3) the process that labs will use to apply for a given test to be designated as an ADLT. As of August 2016, CMS had published the first two types of subregulatory guidance.[14]

WHAT'S STILL TO COME

CMS plans to publish guidance on its ADLT application process—and any other guidance documents—before January 2017. In the long term, CMS may adjust its regulatory and subregulatory guidance for implementing the new payment system. For example, CMS stated that it may revisit the "low-expenditure threshold" that determines whether a lab is required to report its data.

WHAT TO WATCH

Because the data reporting period will begin on January 1, 2017, CMS has a short period of time to issue necessary subregulatory guidance instructing labs on applying for tests to be designated as ADLTs. As of August 2016, CMS had fewer than 5 months to issue this guidance (described in the final rule) and any other guidance it deems necessary.

TASK 2. ESTABLISH AND CONSULT WITH THE ADVISORY PANEL

STATUS: Completed. CMS established the required advisory panel in 2015 and panel meetings are ongoing.

WHAT'S BEEN DONE

- ✓ CMS established the advisory panel in April 2015
- ✓ The panel has met four times and made recommendations to CMS

WHAT'S STILL TO COME

CMS will continue to receive and consider recommendations from the panel and its subcommittees

WHAT TO WATCH

CMS will need to balance panelists' expertise with their financial interests when considering their recommendations

WHAT'S BEEN DONE

In April 2015, CMS established a Federal advisory panel—as required by PAMA—to consult regarding payment rates and coverage for new lab tests and changes to Medicare's payment system.[15] PAMA required that panelists have expertise in issues related to lab tests—for example, panelists could be molecular pathologists or researchers. In addition, CMS required that panelists have experience with clinical lab tests and services by working at a lab or as an academic or researcher.[16] CMS received 64 nominations from the public and selected 15 panelists. CMS evaluated nominees based on factors that included geographical representation; female and minority representation; points of view; areas of expertise; and years of experience.[17]

The advisory panel has met four times: August 2015, October 2015, July 2016, and September 2016.[18] During these meetings, panelists made recommendations for setting Medicare payment rates for new tests. The panel also recommended a definition for ADLTs.

The advisory panel has formed two subcommittees. One subcommittee advises CMS on payments under the new system for automated "profile" tests. A profile is a set of blood tests that are commonly performed together; CMS has been paying for these sets of tests at a capped rate per set. The second subcommittee advises CMS on the ADLT application process. Each of these subcommittee first met in July 2016.

WHAT'S STILL TO COME

The advisory panel will meet to provide recommendations to CMS through April 2017, unless the charter is extended. If the charter is renewed, CMS will consult with the panel up to four times per year as it continues to implement the new payment system for lab tests.[19]

WHAT TO WATCH

CMS will need to balance panelists' expertise with any financial interests when considering recommendations. Although panelists provide expertise regarding the lab test industry, their ties to the lab industry could influence their recommendations to CMS. CMS has discretion over whether to implement the advisory panel's recommendations and has experience with other advisory panels in which members may have financial interests in the topic at hand.

TASK 3. COLLECT PRIVATE PAYER DATA REPORTED BY APPLICABLE LABS

STATUS: Significant progress. CMS has completed work on the system that labs will use to submit private payer data. CMS plans for labs to begin submitting data in early 2017.

WHAT'S BEEN DONE

- ✓ In December 2015, CMS and its contractor finished building the data collection system that labs will use to report private payer data
- ✓ CMS and its contractor have performed some testing of user experience, security, and capacity of the data collection system

WHAT'S STILL TO COME

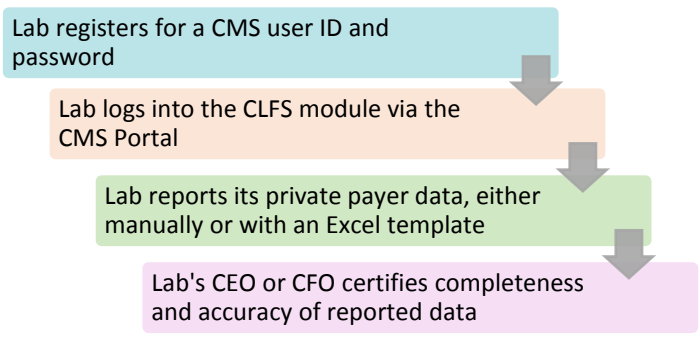
- CMS and its contractor plan to complete user experience testing of the data collection system
- A second CMS contractor is scheduled to complete independent validation of the data collection system in October 2016
- CMS plans to make the data collection system available for labs to begin registering in October 2016
- CMS plans to educate labs about the reporting requirements
- From January to March 2017, CMS will collect the first set of labs' private payer data

WHAT TO WATCH

- CMS must carry out its outreach plan to educate labs on reporting requirements before January 2017
- Some labs face challenges in preparing to report private payer data by the end of the reporting period
- CMS's stress testing of the data collection system's user capacity was hindered because of limitations of CMS's Presentation Zone

PAMA requires that labs report their private payer data to CMS every 3 years.[20] From January 1 to March 31, 2017, CMS is scheduled to collect the first set of private payer data from labs required to report their data, referred to as "applicable labs".[21] For each test conducted during the data collection period, applicable labs must report the rate paid by each private payer and the volume of tests paid at each rate. CMS projects that as many as 3,500 labs will report and certify data. These labs must report payments that they received from all private payers—including private health insurers, Medicaid managed care organizations, and Medicare Advantage plans—during the first 6 months of 2016.

HOW LABS WILL USE THE DATA COLLECTION SYSTEM



WHAT'S BEEN DONE

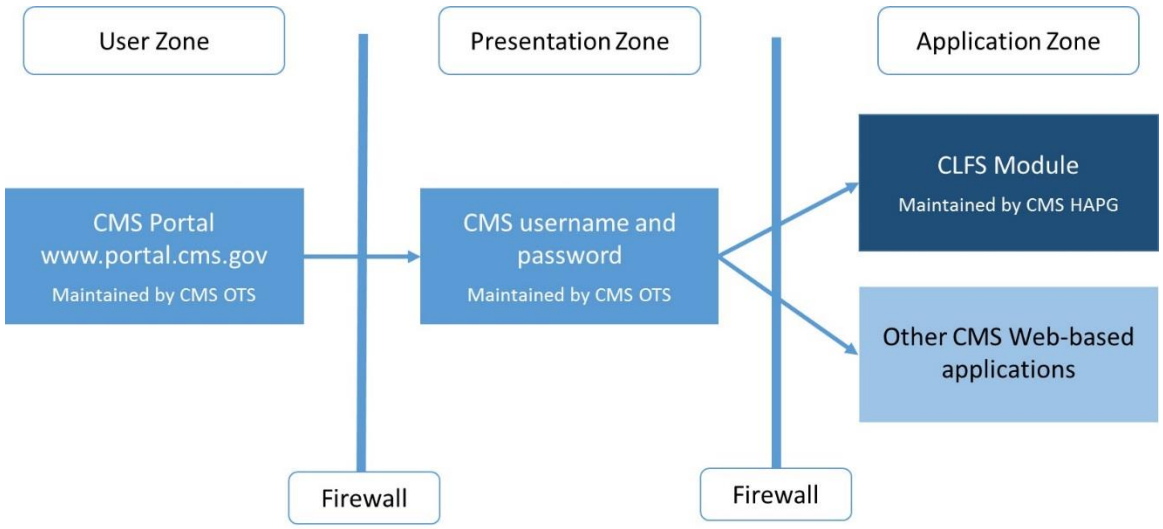
Building the data collection system. CMS built a Web-based application to collect private payer data from labs. In September 2014, CMS awarded a contract to Data Computer Corporation of America (DCCA) to build the data collection system. The system includes a new application, called the Clinical Laboratory Fee Schedule (CLFS) module. This module was an extension of an

existing DCCA project that built a similar application to collect average sales prices from drug manufacturers. A protest over the bidding process delayed work from October 2014 to February 2015. In December 2015, DCCA completed building the CLFS module.

The CLFS module is one of more than 50 Web-based applications that users access via the CMS Portal. The CMS Portal is a user-facing Web site that acts as the gateway to all component-specific applications. As shown in Figure 3, a lab will pass through three "zones" to access the CLFS module. In the first zone—the User Zone—the lab accesses the CMS Portal via a public Web site. In the second zone—the Presentation Zone— the lab will enter its unique username and password to gain access to the CLFS module through the CMS Portal.[22] The final zone—the Application Zone—houses the CLFS module and other CMS applications. Firewalls separate the zones and restrict access to the secure Presentation and Application Zones to only authorized users.

Two different CMS divisions are responsible for the data collection system's zones. The Office of Technology Solutions (OTS) maintains the Presentation Zone. HAPG maintains the Application Zone and coordinated with OTS to connect the CLFS module to the CMS Portal.

Figure 3: A Lab's Experience Using the Data Collection System



Source: OIG analysis of CMS's implementation of Medicare's new payment system for lab tests, 2016.

Testing the data collection system. HAPG and DCCA have tested labs' ability to access and use the data collection system. DCCA has addressed many of the defects identified by this user experience testing. In addition, DCCA has tested the user capacity of the Application Zone to ensure that it can support the maximum number of labs that CMS expects may use the CLFS module at the same time. Finally, HAPG contracted with National Government Services to conduct independent validation of the data collection system.

In addition to conducting user experience and capacity testing, CMS has tested the security of the data collection system. OTS performs tests to ensure that the Presentation Zone can be accessed only by authorized users. OTS officials reported that these tests, intended to protect connected applications from being hacked, have not identified any significant vulnerabilities. As part of its user experience testing within the CLFS module, DCCA has tested the system's ability to monitor the authorization of users accessing the Application Zone.

Educating labs about reporting requirements. Prior to issuing the final rule, CMS conducted one educational telephone seminar, met with industry associations, and provided information during its public meeting held annually about updating the CLFS. After issuing the final rule, CMS published guidance documents on its Web site and hosted a second educational telephone seminar

WHAT'S STILL TO COME

Further testing and maintaining the data collection system. As of the time of this report's publication, CMS and DCCA were still in the process of resolving defects identified by their user experience testing. National Government Services was scheduled to complete its independent validation in October 2016.

CMS plans to make the data collection system available to labs to begin registering in October 2016, and for the system to be ready for data collection by January 2017. From January to March 2017, CMS will collect labs' private payer data. During this period, CMS and DCCA will monitor the data collection system closely and DCCA will operate a help desk to handle technical issues.

Further educating labs about reporting requirements. CMS has created an outreach plan to educate labs about reporting requirements under PAMA. Before the end of the data reporting period in March 2017, CMS plans to host another telephone seminar, send three emails to each lab that is registered for CLFS updates, and offer one Web-based training.

WHAT TO WATCH

Successful data collection will depend upon three key conditions: (1) labs must know whether they are required to report private payer data and, if they are, (2) they must be able to collect the required data and (3) they must be able to access the data collection system to submit their data. If any of these three conditions are not met, the new payment system will not be as effective or efficient as it should be and the payment rates that CMS publishes may be based on incomplete data.

CMS must carry out its outreach plan to educate labs on reporting requirements before January 2017. Applicable labs must be aware of the new reporting requirements and be able to determine whether they qualify as applicable labs and are thus required to report. CMS has posted reporting guidance on its Web site and plans to carry out other forms of outreach through the initial reporting period.

Some labs face challenges in preparing to report private payer data by the end of the reporting period. Applicable labs will need to collect and report their private payer data from the first 6 months of 2016. Stakeholders have indicated to CMS that many labs, particularly small and mid-size community labs, will face challenges reporting. CMS did not finalize labs' reporting requirements until June 2016; by this time, the data collection period was nearly over, leaving labs with limited time to prepare IT systems and retroactively collect private payer data.

CMS's testing of the data collection system's user capacity was hindered by limitations of the Presentation Zone. As of August 2016, CMS had not completed user capacity testing. Specifically, HAPG and DCCA were unable to conduct testing designed to find breakage points in the system's user capacity without exceeding the capacity of the Presentation Zone. HAPG and DCCA's ability to conduct user capacity testing is contingent on OTS, which operates the Presentation Zone. HAPG and DCCA plan to conduct additional user capacity testing in collaboration with OTS in October 2016.

User capacity testing is needed to ensure that the maximum number of labs can access the data collection system. CMS has a contingency plan in the event of system capacity problems: labs will be required to submit their files directly to CMS through a secure server.

TASK 4. ENSURE THE COMPLETENESS AND ACCURACY OF REPORTED DATA

STATUS: In progress. CMS has developed preliminary plans to conduct checks for data completeness and accuracy in mid- to late 2017, after labs submit the first round of data.

WHAT'S BEEN DONE

- ✓ CMS included automated data verification and certification features in the CLFS module

WHAT'S STILL TO COME

CMS plans to publish pricing and volume data in September 2017 and to solicit public input on the accuracy of preliminary Medicare payment rates

WHAT TO WATCH

- CMS does not plan to independently verify whether all applicable labs report their private payer data as required
- For labs that report data, CMS does not plan to independently verify the completeness and accuracy of the data
- Absent processes to verify whether applicable labs report their data or to verify the quality of data that labs report, CMS may set inaccurate Medicare payment rates for lab tests

CMS must ensure that data used to establish new payment rates are complete and accurate. PAMA requires labs to certify the completeness and accuracy of their data upon submission.[23] Additionally, PAMA authorizes the Secretary of Health and Human Services to impose civil monetary penalties (CMPs) of up to $10,000 per day on labs for each failure to report data or each misrepresentation or omission in reported data.[24] CMS plans to coordinate with OIG to impose any needed CMPs.

WHAT'S BEEN DONE

DCCA built features into the data collection system that will verify the identity of the submit and certify private payer data. The data collection system will check against a provider individuals who enrollment database to ensure that the individuals submitting the data are from the labs they claim to be from. As the data are submitted, the data collection system will automatically ensure that all required fields are populated in the expected format. For example, users will see an error message if a payment rate is missing or reported in a non-numeric format.

The data collection system will require that each lab certify the completeness and accuracy of the data that it submits. The certifier must be the lab's CEO or CFO or a designated officer who works directly for the CEO/CFO.[25]

WHAT'S STILL TO COME

CMS plans to—as one way of ensuring data accuracy—publish preliminary new payment rates and supporting pricing and volume data in September 2017. CMS anticipates that publishing these data will allow labs and the public to identify potential discrepancies in the data. CMS may also publish—after deidentifying the data—the private payer data that labs reported.

CMS will work with OIG to determine what reporting failures would result in a CMP. In the final rule, CMS discussed its approach to imposing CMPs on labs that fail to report, or misreport, their private payer data.[26] CMS made clear that it does not intend to impose CMPs for minor errors. CMS officials

said they do not wish to penalize labs during the first data reporting period for omissions that stem from a lack of experience or knowledge about the new reporting requirements.

WHAT TO WATCH

Complete and accurate reporting by applicable labs is critical to setting new Medicare payment rates, which will be in place for 3 years.

CMS does not plan to independently verify whether all applicable labs report their private payer data as required. CMS does not plan to compile a list of applicable labs and, therefore, will not be able to discern whether all applicable labs report their data, as required. Because new payment rates are based on the volume-weighted median of private payer rates, minor errors are unlikely to affect new rates. However, if any labs that perform large volumes of tests fail to report their data, the missing data could affect the median and resulting payment rate.

For labs that report data, CMS does not plan to independently verify the completeness and accuracy of the data. CMS will rely on labs' certifications and public review of pricing data to ensure that labs have reported their data completely and accurately. CMS does not plan to audit the data that labs report to ensure it is accurate and complete. CMS stated that resource constraints prevent it from auditing the data. CMS plans to check for outlier values—prices or volumes that are extremely high or low compared with those reported by other labs. However, CMS staff did not yet have details about the process they would use or what the threshold amounts to determine outliers would be. CMS officials stated that they may use data from the first reporting period as a baseline for analyzing data from future reporting periods.

Absent processes to verify whether applicable labs report their data or to verify the quality of data that labs report, CMS may set inaccurate Medicare payment rates for lab tests. PAMA required CMS to set Medicare payments rates for lab tests by using a market-based approach—specifically, by using private payer data submitted by labs. If CMS does not have appropriate safeguards to ensure that all applicable labs report complete and accurate data, it may result in new Medicare payment rates that are inaccurate.

Further, CMS may be unable to identify instances of noncompliance that warrant CMPs. Absent processes to verify whether applicable labs report their data or to verify the quality of data that labs report, CMS may not be in a position to use its authority to pursue potential CMPs. In addition, CMS has not yet established a process for referring noncompliant labs to OIG.

TASK 5. DETERMINE AND PUBLISH NEW MEDICARE PAYMENT RATES

STATUS: In progress. CMS plans to determine and publish Medicare's new payment rates in late 2017, after labs report their data.

WHAT'S BEEN DONE

- ✓ CMS has begun to prepare for calculating and publishing the new payment rates but cannot move forward with much of the task until the labs report their data

WHAT'S STILL TO COME

- CMS plans for its contractor to build into the data collection system the capacity to calculate new Medicare payment rates using data reported by labs in early 2017
- CMS plans to publish in November 2017 the new rates based on private payer data

WHAT TO WATCH

CMS must follow a compressed timeframe for determining and publishing new Medicare payment rates for lab tests

Once it collects private payer data from labs, CMS must calculate and publish the new payment rates. PAMA requires CMS to calculate the new payment rate for each test as the weighted median, by volume, of the most recent private payer data reported by labs.[27, 28]

WHAT'S BEEN DONE

CMS plans to use the data collection system to determine the new payment rates. DCCA has begun to gather and clarify requirements for this aspect of the data collection system.

WHAT'S STILL TO COME

DCCA will build an algorithm into the data collection system to automatically calculate the volume-weighted median of private payer rates after the data reporting period ends on March 31, 2017. CMS expects to publish a draft of the new fee schedule for lab tests in September 2017. After receiving public input, CMS will publish the final fee schedule in November 2017. The new fee schedule will be effective January 1, 2018.

WHAT TO WATCH

CMS must follow a compressed timeframe for determining and publishing the new Medicare payment rates for lab tests. CMS will publish the first fee schedule based on labs' private payer data in November 2017. Before then, CMS has a limited amount of time to carry out a number of tasks. After the data reporting period ends in March 2017, CMS must (1) resolve any data quality problems that might arise from quality checks that it performs; (2) calculate and publish the preliminary new rates; and (3) resolve any data quality problems that might arise from public input on the preliminary new rates.

TASK 6. IDENTIFY ADVANCED DIAGNOSTIC LABORATORY TESTS

STATUS: In progress. CMS has defined the criteria for a test to qualify as an ADLT. It plans to issue guidance in late 2016 on the process of applying for the ADLT designation.

WHAT'S BEEN DONE

- ✓ CMS established the criteria for determining whether a test will be considered an ADLT
- ✓ CMS established the reporting requirements for labs that perform ADLTs

WHAT'S STILL TO COME

- Before January 2017, CMS must establish and publish the process for applying for ADLT designation
- CMS will review applications for ADLT designation to ensure the tests qualify as ADLTs

WHAT TO WATCH

CMS must establish and implement a process for determining whether tests qualify as ADLTs

PAMA requires that CMS implement a framework for designating a new class of tests—ADLTs.[29] Once CMS has designated a test as an ADLT, it must assign a unique procedure code to that ADLT and establish a unique payment rate for it.[30] ADLTs will be subject to a different reporting schedule and different temporary pricing than other lab tests. Labs must report private payer rates for ADLTs annually, rather than every 3 years.

WHAT'S BEEN DONE

CMS finalized the definition of ADLTs in the final rule. An advisory panel subcommittee met in July 2016 to develop a recommended process for a lab to apply for a test to receive the ADLT designation.

WHAT'S STILL TO COME

CMS must publish the ADLT application process through subregulatory guidance. HAPG staff will then review applications to determine whether tests meet the ADLT definition, in consultation with the advisory panel, CMS medical officers and staff from other CMS divisions.

WHAT TO WATCH

CMS must establish and implement a process for determining whether tests qualify as ADLTs. Although advanced diagnostic tests are a growing segment of the lab market, it is unclear how many labs will apply for the ADLT designation for their tests. A lab that performs tests that meet the ADLT definition but does not apply for ADLT designation for those tests will be required to report private payer data every 3 years, as long as it meets the definition of an applicable lab.

What is an ADLT?

To be considered an advanced diagnostic laboratory test, or ADLT, a test must be offered and furnished by a single lab, and either:

- be cleared or approved by the Food and Drug Administration, or
- be a test that
  - evaluates a patient's DNA, RNA, or proteins; and
  - provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
  - uses a unique algorithm that predicts the chance the patient will develop a condition or respond to a treatment.[32]

CMS officials expect the number of applications for ADLT status to be limited by the requirement that the test provide new and unique information, and by the enhanced reporting requirements that ADLTs have. Regardless of the number of applicants, CMS must determine—in consultation with the advisory panel—whether each application meets the multifaceted definition of this new category of test.

The ADLT application process was part of the agenda for the advisory panel's meeting on September 12, 2016. After considering the advisory panel's recommendations and deciding on the process, CMS will need to communicate the process and begin accepting applications by 2017.

CONCLUSION

Since PAMA's enactment in April 2014, CMS has been making progress toward implementing Medicare's new payment system for lab tests. CMS has completed significant parts of several key implementation tasks, and it has plans in place to complete the remaining tasks between now and January 2018, when the new rates are scheduled to go into effect.

Although CMS has made significant progress toward implementing the new payment system, we find two aspects of CMS's plans particularly concerning. These aspects create risks for the new payment system's accuracy and could thus threaten the system's effectiveness in achieving its expected savings. First, CMS does not plan to identify which labs must report private payer data. Instead, CMS will depend on labs to determine whether they are required to report private payer data. Second, once labs report their private payer data, CMS does not plan to independently verify the data's completeness or accuracy. Without these safeguards, CMS may be unable to determine whether labs complied with reporting requirements or to determine whether the data on which new Medicare lab payment rates will be based are complete and accurate.

We will continue to monitor CMS's reform of the payment system in the years leading up to, and after, its implementation. In addition, we are monitoring Medicare payments for lab tests. We are also issuing a companion report, *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data* (OEI-09-16-00040), a data brief with an analysis of these payments.

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ENDNOTES

[1] PAMA, P. L. No. 113-93, § 216(a) (adding Social Security Act, § 1834A, 42 U.S.C. §1395m-1).

[2] 81 Fed. Reg. 41036, 41097 (June 23, 2016) (final rule implementing PAMA, § 216(a)).

[3] PAMA § 216(c)(2)(B).

[4] The allowable charge for labs tests is the lowest of three rates: the billed rate, the local rate, or the national limitation amount. SSA § 1833(a)(1)(D)(i)(I), 42 U.S.C. § 1395l(a)(1)(D)(i)(I).

[5] Deficit Reduction Act of 1984, P.L. No. 98-369, § 2303(d).

[6] SSA § 1834A(a)(1) and (d), 42 U.S.C. § 1395m-1(a)(1) and (d).

[7] In the case of ADLTs, Medicare will update the payment rates annually. SSA § 1834A(a)(1), 42 U.S.C. § 1395m-1(a)(1).

[8] OIG, *Variation in the Clinical Laboratory Fee Schedule*, OEI-05-08-00400, July 2009.

[9] SSA § 1834A(b)(4)(B), 42 U.S.C. § 1395m-1(b)(4)(B).

[10] PAMA established advanced diagnostic lab tests as a new category of test. The category includes tests that are performed by a single lab and either (1) analyze multiple biomarkers combined with a unique algorithm to yield a single patient-specific result, (2) are cleared or approved by the Food and Drug Administration, or (3) meet other similar criteria established by the Secretary of Health and Human Services. SSA § 1834A(d)(5), 42 U.S.C. § 1395m-1(d)(5).

[11] The proposed rule appears at 80 Fed. Reg. 59386–59422 (Oct. 1, 2015). The final rule appears at 81 Fed. Reg. 41036–41101 (June 23, 2016).

[12] 81 Fed. Reg. 41066 (Table 3 listing the postponed data reporting period and effective date) and SSA § 1834A(a)(1) and (b)(1) (specifying the original statutory data reporting period and effective date).

[13] The final rule was released and on display in the Federal Register on June 17, 2016, and was published in the Federal Register on June 23, 2016. CMS, *PAMA Regulations*, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html. PAMA required the final rule to be published by June 30, 2015. SSA § 1834A(a)(12), 42 U.S.C. § 1395m-1(a)(12).

[14] CMS, *Medicare Part B Clinical Laboratory Fee Schedule: Guidance to Laboratories for Collecting and Reporting Data for the Private Payor Rate-Based Payment System* (*MLN Matters* Number SE1619), available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1619.pdf; and CMS, *PAMA Regulations* (see endnote 13 for URL).

[15] Secretary of Health and Human Services, *Charter—Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests*, filed April 16, 2015. Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/PAMA-Tab-F-1635-N.pdf. SSA § 1834A(f), 42 U.S.C. § 1395m-1(f) (requiring establishment of the advisory panel not later than July 1, 2015).

[16] 79 Fed. Reg. 63919–63920 (Oct. 27, 2014).

[17] Ibid.

[18] 80 Fed. Reg. 47491 (Aug. 7, 2015) (announcing August 26, 2015 meeting); 80 Fed. Reg. 59782 (Oct. 2, 2015) (announcing October 19, 2015 meeting); 81 Fed. Reg. 35772 (June 3, 2016) (announcing July 18, 2016 meeting); and 81 Fed. Reg. 55461 (Aug. 19, 2016) (announcing September 12, 2016 meeting).

[19] Secretary of Health and Human Services, *Charter—Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests*, supra endnote 15.

[20] SSA § 1834A(a)(1), 42 U.S.C. § 1395m-1(a)(1).

[21] Both PAMA and the final rule exempt certain labs from reporting their private payer data to CMS. Labs that do not receive the majority (i.e., more than 50 percent) of their Medicare revenue from the CLFS or the Physician Fee Schedule will not have to report, nor will labs that receive less than $12,500 in lab test revenues from the CLFS during a data collection period. The low-expenditure threshold does not apply to single labs with respect to ADLTs that they offer and furnish. SSA § 1834A(a)(2), 42 U.S.C. § 1395m-1(a)(2). 81 Fed. Reg. 41041–51 (June 23,

2016). See also 42 CFR § 414.502 (including the low-expenditure threshold in the definition of applicable laboratory).

[22] The CMS Portal checks with the Enterprise Identity Management System, through which the lab has already registered and created a username and password.

[23] SSA § 1834A(a)(7), 42 U.S.C. § 1395m-1(a)(7).

[24] SSA § 1834A(a)(9), 42 U.S.C. § 1395m-1(a)(9).

[25] 42 CFR § 414.504(d).

[26] 81 Fed. Reg. 41069.

[27] SSA § 1834A(b)(1)(A) and (b)(2), 42 U.S.C. § 1395m-1(b)(1)(A) and (b)(2). The new payment rates will be phased in over time, according to the schedule included in PAMA (as amended by a 1-year delay that CMS announced in the Final Rule). 81 Fed. Reg. 41080 (), revising the statutory phase-in of payment reduction timetable located at SSA § 1834A(b)(3), 42 U.S.C. § 1395m-1(b)(3). From 2018 through 2020, reductions resulting from the new payment rates cannot exceed 10 percent each year. From 2021 through 2023, reductions cannot exceed 15 percent each year. 42 CFR § 414.507(d).

[28] Newly developed tests that enter the market will be temporarily paid for using different methodologies until private payer data is collected. SSA § 1834A(c) and (d), 42 U.S.C. § 1395m-1(c) and (d).

[29] SSA § 1834A(d)(5), 42 U.S.C. § 1395m-1(d)(5).

[30] SSA § 1834A(e)(2), 42 U.S.C. § 1395m-1(e)(2).

[32] 42 nn § 414.502 (defining ADLT).