American Hospital Association

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November 24, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1621-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS–1621–P, Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule; (Vol. 80, No.190), October 1, 2015.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare Clinical Diagnostic Laboratory Tests Payment System proposed rule.

The proposed rule, which implements Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), would make extensive changes to reimbursement under the Clinical Laboratory Fee Schedule (CLFS). Specifically, certain "applicable laboratories" would be required to report private payer laboratory test payment rate and volume data ("applicable information") every three years. CMS would base the new Medicare CLFS payment amounts on the weighted median of the private payer rates. As proposed, most hospital-based and physician office laboratories would not be considered applicable laboratories and, therefore, would be prohibited from the requirement to report. Subsequently, laboratory test payment rates would be based primarily on rate data provided by large independent laboratories; this is expected to substantially decrease reimbursement under the CLFS.

We are concerned that the new CLFS rates would not be representative of overall market rates. This would cause hospitals to see precipitous declines in Medicare payments for laboratory services, which could harm patient access to laboratory testing in many communities. Specifically, while payments for most hospital laboratory tests furnished to Medicare beneficiaries are packaged into their inpatient and outpatient prospective payment systems (PPS) rates, reimbursement for community outreach testing services is made under the CLFS. Many hospitals and health care systems engage in outreach testing as a service to their

communities and to improve access to care for beneficiaries. For some hospital laboratories, outreach testing represents a significant portion of their overall Medicare services provided. **The AHA urges the agency to modify its proposals, as discussed below, to increase the number of hospital and physician laboratories that qualify as applicable laboratories and, therefore, must report their private payer data.** We believe that this will generally increase the weighted median CLFS rates and make them more representative of overall market rates.

Further, we are concerned that the compressed timeframe CMS proposes for collecting and reporting private payer data from applicable laboratories, which began even before this proposed rule was issued, is unrealistic. We believe it could result in widespread confusion and, ultimately, errors in the calculation of the final market-based CLFS rates. **Because PAMA authorizes civil monetary penalties of up to $10,000 per day for each failure to report or each misrepresentation or omission, such confusion also could expose hospitals to compliance risk and enforcement penalties. The AHA urges CMS to delay the effective date of the rule by at least one year, to calendar year 2018, in order to allow adequate time for laboratories to review the final rule and clarifying guidance; to make changes to laboratory finance information systems so as to permit correct and complete data collection and reporting; and to engage in end-to-end testing of CMS's data reporting system.**

DEFINITION OF AN APPLICABLE LABORATORY

In enacting Section 216 of PAMA, Congress intended that the new laboratory payment rates be market-based, that is, based on the rates paid by private insurers to certain applicable laboratories. The law defines an applicable laboratory as one that receives the majority of its overall Medicare revenue from the CLFS and the physician fee schedule (PFS). CMS proposes to identify applicable laboratories at the Tax Identification Number (TIN) level, inclusive of all the individual provider/supplier National Provider Identifiers (NPIs). CMS states that it chose the TIN level because it believes that this is the level at which a provider/supplier negotiates payment rates with private insurers and also because it believes that this will reduce the administrative burden of reporting.

However, the AHA is concerned that, under CMS's proposed TIN-level definition, virtually no hospital-based laboratories and only 4 percent of physician office laboratories would qualify as applicable laboratories. This is because most hospital laboratories do not have their own TIN and, instead, fall under the hospital's overall TIN. As a result, very few hospitals would meet the PAMA definition of an applicable laboratory, which requires that the majority of the entity's Medicare revenue derives from the physician fee schedule and the clinical lab fee schedule. By contrast, according to a September 2015 report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG), *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data*, 24 percent of CLFS payments are made to hospital laboratories and 19 percent are made to physician office laboratories. **Therefore, the weighted median CLFS payment rates would be dominated and driven by payment data submitted primarily by the large independent laboratories – and not actually market based.** Unlike hospital-based and physician office laboratories, large independent laboratories are able to charge much lower rates due to the huge volume of testing they conduct. But because all laboratories would be subject to these new CLFS rates, we are concerned that many hospital and

health system-based outreach laboratories will be forced to shut their doors, to the detriment of patient access to laboratory testing.

The AHA recommends that CMS revise its proposed definition of an applicable laboratory, within the scope of PAMA's provisions, in order to increase the number of hospital-based and physician office laboratories that meet the definition. Doing so will result in more hospital and physician office-based laboratories being required to report their private insurer payment data to CMS and, consequently, lead to weighted median CLFS rates that are more representative of the entire laboratory sector. This would be consistent with Congress's intent to establish market-based reimbursement for clinical laboratories that is broadly representative of the universe of testing that occurs.

Therefore, we recommend that CMS define an applicable laboratory at the NPI level; doing so would increase the number of hospital-based laboratories that would report as applicable laboratories, without imposing unreasonable reporting burden on hospitals. We understand that some hospitals and health systems have obtained separate NPIs for one or more of their clinical laboratories. This is particularly the case where hospitals operate reference laboratories or have large outreach laboratories that serve community physicians and other providers. If applicable laboratory is defined at the NPI level, more hospital and health system-based laboratories would be required to report their private payer data. We believe that this would help to make the private sector data at least somewhat more representative of the national laboratory market. Further, for health systems, which may have physician office laboratories, independent laboratories and hospital-based laboratories, obtaining data and reporting by the unique NPI number of the particular laboratory would ensure that the data is easily identifiable and complete for each laboratory. The NPI is included on claims submitted by applicable laboratories and can be easily used to determine whether the laboratory meets the "majority of revenue" criterion for being an applicable laboratory.

Further, in the proposed rule, CMS discusses an option it considered to separate the mechanics of reporting from the definition of an applicable laboratory**. The AHA recommends that CMS adopt such an approach for reporting private payer data. That is, CMS should permit, but not require, hospitals and health systems (and other entities) that have multiple "applicable laboratory" NPIs under the same TIN to aggregate their NPI-level data and report at the TIN level.** We believe that this option could reduce the burden of reporting for hospitals and health systems that have multiple outreach laboratories.

Finally, while defining applicable laboratories at the NPI level would result in a greater number of hospital-based laboratories reporting their data, we believe that still more hospital-based laboratories must be included in CMS's calculations in order to move towards rates that more closely reflect the market. **Therefore, in order to increase the amount of hospital-based data submitted to CMS, the AHA recommends that CMS allow hospital and health systems that have outreach or reference laboratories that would not qualify as applicable laboratories, even under an expanded definition, to voluntarily submit their private insurer data to CMS.** We believe that this also would make the new weighted median CLFS payments more representative of the overall laboratory market.

TIMELINE FOR DATA COLLECTION AND REPORTING

The AHA is deeply concerned that the proposed rule fails to give sufficient guidance to laboratories on data collection and reporting, leaving many critical questions unanswered and, at the same time, proposes a timeline for laboratories to submit data to CMS that is unworkable. The proposed rule sets the initial data collection period as July 1, 2015 to Dec. 31, 2015, with data reported to CMS between Jan. 1, 2016 and March 31, 2016. CMS would then publish the updated proposed CLFS in early September 2016 with a 30-day public comment period before the final rates for calendar year 2017 are published on Nov. 1, 2016.

The agency has created this unworkable timeline. Specifically, PAMA required that the agency issue the final laboratory payment rule by June 30, 2015 and implement the new payment system on Jan. 1, 2017. However, CMS did not issue a proposed rule until Sept. 25, yet the agency seems to still plan to implement the system on Jan. 1, 2017 – and patients will pay the price for this compression. Specifically, the resulting timeline would require hospitals to either begin data reporting before the final rule is even issued, when critical information needed by laboratories will not yet be available, or wait until a final rule is issued and face the burden of submitting a tremendous amount of data through a new system in a very short amount of time. Until the final rule is issued, laboratories will not know if they are going to be required to report, what exactly they must report, while key questions about how information should be collected and submitted will be unanswered. And no information about the method of submission of information will be available. They will not have had any time to alter their financial information systems so as to make the capture of the "applicable information" for reporting purposes less cumbersome. **Reporting data in the absence of a final rule and comprehensive guidance based on the policies described in the final rule exposes laboratories to compliance risks and enforcement penalties, including civil monetary penalties of up to $10,000 per day for each failure to report or each misrepresentation or omission. Requiring hospitals and health systems to take on this burden is inappropriate.**

Instead, the AHA strongly urges CMS to delay implementation of the new payment system until at least CY 2018. We also urge CMS to provide laboratories with at least six months after the final rule is released, and comprehensive subregulatory guidance is issued, to build the necessary information systems to begin to collect and report data. We recommend that the duration of the data collection period should be six months, but that CMS should provide a six-month gap between the close of the data collection period and the beginning of the three-month data reporting period. This period will allow laboratories, which have no experience with collecting and reporting private payer data to CMS, the necessary time to comply with PAMA reporting requirements. During this six-month period, CMS should offer training and education to applicable laboratories, as well as comprehensive end-to-end testing of the reporting system to ensure that applicable information can be transmitted and received by CMS in a way that does not compromise the data's accuracy, completeness, confidentiality or integrity. This six-month gap between the close of the data collection period and the beginning of the data reporting period also will allow laboratories time to fully adjudicate the majority of private insurer claims that will be required to be reported as applicable information to CMS. This timeframe is consistent with PAMA**,** which provided CMS with an 18-month period from the

date that the final rule was to be issued (June 30, 2015) to the effective date of the new payment system (Jan. 1, 2017).

DEFINITION OF AN ADVANCED DIAGNOSTIC LABORATORY TEST

PAMA defines an "advanced diagnostic laboratory test" (ADLT) as a laboratory test that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory. Under the law, applicable laboratories would be required to report applicable information regarding their ADLTs every year, rather than every three years. Further, new ADLTs would be paid using their actual list charge during an initial period of three quarters. PAMA also requires that an ADLT meet one of three criteria[3] outlined in the law.

The AHA is concerned that CMS's proposed policies for defining ADLTs would exclude most hospital-based and health system-based laboratories from being able to identify any of their tests as ADLTs. Specifically, CMS proposes to define a "single laboratory" as a laboratory that has a single CLIA certificate. Under this proposal, an entity with multiple CLIA certificates, such as is the case in many hospitals and health systems, would not be a single laboratory and none of its tests would be eligible for ADLT status, even if all the other ADLT criteria were met.

Many hospitals and health systems have laboratory-developed tests (LDTs), which are diagnostic tests that are not commercially distributed to other laboratories but, instead, are developed, validated and performed in-house by individual laboratories. The ability of hospital-based and health system-based laboratories to qualify their LDTs as ADLTs, where appropriate, and to have new ADLTs initially reimbursed at their list price as PAMA requires, is critical to ensuring continued innovation in laboratory testing. These LDTs provide timely patient access to accurate and high-quality testing for many conditions for which no commercial test exists, or where an existing test does not meet current clinical needs. They provide physicians with important clinical information to diagnose and treat patients and are critical in the practice of all areas of medicine. **The AHA recommends that, for the purposes of hospitals and health systems, CMS waive its proposed definition of a single laboratory as one that has a single CLIA certificate, as long as the test is developed, validated and performed in-house by an individual hospital or health system laboratory, is not commercially distributed to other laboratories and meets one of the three criteria outlined in PAMA.**

As noted above, PAMA requires that ADLTs meet one of three criteria. The first statutory criterion states, "The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result." However, when discussing the ADLT definition, CMS states, "we interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA," and further proposes that an ADLT is "a molecular pathology analysis of DNA or RNA." The agency erroneously omits tests that are solely comprised of protein biomarker analysis from the ADLT definition, despite the fact that

[3] *1. The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins combined with a unique algorithm to yield a single patient-specific result. 2. The test is cleared or approved by the FDA. 3. The test meets other similar criteria established by the Secretary.*

they are explicitly included in the PAMA statute**. Therefore, the AHA recommends that CMS define ADLTs to include tests that are solely comprised of protein analysis. This revised definition would reflect the statute and Congressional intent.**

CODING FOR CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS ON THE CLFS

PAMA mandates the creation of specific Healthcare Common Procedure Coding System (HCPCS) codes for ADLTs and other clinical diagnostic laboratory tests that are cleared or approved by the Food and Drug Administration. CMS proposes to implement the PAMA coding requirement through the creation of HCPCS level II G-codes if a specific HCPCS code does not already exist. However, the AHA believes that G-codes should be kept at a minimum as they are intended to be temporary codes and are often not recognized by private payers.

Instead, the AHA supports the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel decision to create a new clinical laboratory test section to support the PAMA mandate. The new section will provide an infrastructure whereby a clinical laboratory or manufacturer that meets certain criteria may request a code to more specifically identify their test. It is envisioned that the codes in this new section will be issued on a quarterly basis and made effective the following quarter to allow payers time to load them into their systems. We believe that the CPT Editorial Panel is well positioned to create these codes as its Molecular Pathology Coding Workgroup has hosted public meetings with stakeholders to discuss potential CPT coding solutions that could meet the statutory coding requirements in PAMA. The CPT Editorial Panel has a long-standing established, transparent process that will ensure consistent national coding across Medicare and other public and private payers.

Further, with regard to the data reporting requirements, CMS proposes that applicable laboratories would report a specific HCPCS code for each test that identifies the test being reported. As such, CMS would define a specific HCPCS code as a code that does not include an unlisted CPT code, as established by the AMA, or a HCPCS level II miscellaneous/not otherwise classified (NOC) code, as established by the CMS HCPCS Workgroup. **The AHA supports CMS's proposal to expressly prohibit the use of unlisted and NOC codes, as use of these codes will make it extremely difficult to track payment data from private payers.**

ADDITIONAL QUESTIONS

The AHA urges CMS to clearly and comprehensively address the following questions that have been posed by hospitals and health systems in the final rule and in subsequent guidance:

- Bundled payments: How should laboratories report the payment rates of individual laboratory tests that, when ordered with other specific laboratory tests, have bundled payments?
- Denials: How should laboratories account for insurance denials that result in no payment for the laboratory test?

- Incompletely adjudicated claims: How should laboratories report payments when the claim for a service that falls within the data collection period is not resolved before the end of the data reporting period, such as if there are pending appeals?
- Date of service or date of payment: Is the applicable information that must be collected and reported based on the date of service, the date the claim was submitted or the date of payment?
- Out-of-network claims: How should payment rates for out-of-network tests be reported?
- Secondary payer claims: How should laboratories report payment rates for tests that are covered by both a primary and a secondary payer?
- CLFS/PFS: Would applicable laboratories only have to report applicable information for laboratory tests paid under the CLFS or would they also have to report applicable information for those laboratory tests that are paid under the PFS, for example, molecular pathology services are paid under the PFS, but not the CLFS?
- G-codes: Laboratories will not be reporting data for laboratory tests assigned G-codes, as private insurers do not use these codes. However, G-codes are assigned to some high-volume tests furnished to Medicare beneficiaries, such as drug screening tests. How will CMS determine the payment rate for laboratory tests that are currently assigned G-codes?
- Transparency: How can laboratories be assured that the weighted medians that CMS calculates for each test is correct? The final rule should describe how CMS will validate the data it receives and the accuracy of its calculations.
- Data submission process: The proposed rule does not address the data submission process. What is the expectation for data submission? In what format must data be submitted and how will transmission be secured? What is the site registration process?

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President