

April 13, 2016

The Honorable Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: Medicare Program; Medicare Clinical Diagnostic Laboratory Test Payment System (CMS-1621-P)**

Acting Administrator Slavitt:

As the Centers for Medicare & Medicaid Services (CMS) moves forward with final rulemaking to implement Section 216 of the Protecting Access to Medicare Act (PAMA), we are writing to express our concerns with the proposed definition of the term “applicable laboratory” included in the proposed rule published on October 1, 2015.<sup>1</sup> Under the proposed rule, the overwhelming majority of hospital laboratories would not be considered “applicable laboratories” and would be prohibited from providing data to CMS about private payor rates for clinical laboratory tests they have furnished. CMS’s failure to include such a large portion of the laboratory market in rate reporting would result in reimbursement rates for laboratory services that do not reflect the market and may threaten access to laboratory testing services for Medicare beneficiaries. We believe applicable laboratory should be defined as a facility identified by a CLIA number that derives the majority of its Medicare revenue from the Clinical Laboratory Fee Schedule (CLFS) and the Physician Fee Schedule (“PFS”), and request a meeting with you at your earliest convenience to discuss this important issue.

Congress enacted Section 216 of PAMA with the goal of establishing Medicare Clinical Laboratory Fee Schedule (CLFS) reimbursement rates that reflect market rates. According to a September 2015 report by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), 57 percent of CLFS payments are made to independent laboratories, 24 percent of payments are made to hospital laboratories, and 19 percent are made to physician office laboratories.<sup>2</sup> Thus, hospital laboratories comprise a significant portion of the laboratory sector in the United States.

Section 216 of PAMA overhauls the method CMS will use to establish CLFS rates, the first major reform of the CLFS in three decades. It requires “applicable laboratories” to report “applicable information” to CMS every three years, which includes the rates paid during a data collection period by all private payors for the more than 1,200 clinical laboratory tests on the CLFS, along with the volume of tests reimbursed at each rate. The new rate for a test paid for under the CLFS will be the weighted median of all private payor rates reported to CMS. An

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<sup>1</sup> Medicare Program; Medicare Clinical Diagnostic Laboratory Test Payment System, 80 Fed. Reg. 59386, 59391 (Oct. 1, 2015), available at <https://www.gpo.gov/fdsys/pkg/FR-2015-10-01/pdf/2015-24770.pdf>.

<sup>2</sup> Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data (Sept. 2015), available at <http://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf>.

“applicable laboratory” is defined in the statute as a laboratory that receives a majority of its Medicare revenues under the CLFS and/or Medicare Physician Fee Schedule (“PFS”).

Despite the make-up of the laboratory market, CMS’s proposed definition of “applicable laboratory” would apply the “majority of Medicare revenues” test to a Taxpayer Identification Number (TIN)-level entity, which CMS acknowledges would result in private payor rate reporting by virtually no hospital laboratories and only four percent of physician office laboratories. Furthermore, as proposed, an entity that does not meet the regulatory definition of “applicable laboratory” would be prohibited from reporting private payor data.

We are deeply troubled that, as proposed, the majority of the laboratory market would be prohibited from supplying private payor data to CMS to calculate new CLFS reimbursement rates. Since all components of the laboratory market will be reimbursed using the newly created reimbursement rates, all components of the laboratory market should be part of data reporting.

We recommend that CMS define the term “laboratory” as a facility identified by a Clinical Laboratory Improvement Amendments (CLIA) number, rather than a TIN. Each laboratory facility, including each hospital laboratory, has a CLIA number. This approach would ensure that a hospital laboratory’s status as an “applicable laboratory” is based on whether the part of a hospital furnishing laboratory services receives a majority of Medicare revenue from the CLFS and PFS, rather than applying that test to an entire hospital, even those parts of the hospital furnishing services that are reimbursed under the inpatient and outpatient prospective payment systems. Use of CLIA number would be the most accurate reflection of Congress’ intent and would ensure that the resulting CLFS rates are reflective of all sectors of the laboratory market. The statute allows CMS to implement a low Medicare revenue threshold to exclude some laboratories from reporting. We support the use of a reasonable Medicare revenue threshold, used in conjunction with CLIA number, in order to exclude those laboratories whose private payor data would have little or no impact on the weighted median. While exclusions are calculated and “applicable laboratory” is defined at the CLIA level, data certification and submission will occur at either the individual CLIA level or, in aggregate at the TIN level, with a listing of all CLIA numbers under the TIN to afford flexibility and reduce administrative burden for reporting laboratories.

Section 216 of PAMA dramatically changes how clinical laboratory testing services are reimbursed by the Medicare program. The success of CLFS payment reform hinges on accurate, market based payment rates calculated in a manner consistent with the statute. We urge CMS to define applicable laboratory as a facility identified by a CLIA number that derives the majority of its Medicare revenue from the CLFS and PFS, with appropriate low Medicare revenue thresholds to reduce the reporting burden for small laboratories.

We look forward to discussing this issue with you in greater detail. Thank you.

Sincerely,

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