Submitted Electronically

November 23, 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 over 200 member hospitals and health systems, the Florida Hospital Association (FHA) 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). As proposed, "applicable laboratories" would be required to report private payer laboratory test payment rates and volume data every three years. CMS would then base the new Medicare CLFS payment amounts on the weighted median of the private payer rates.

We believe that hospital participation in this rate reporting will be critical in determining whether the rates that CMS calculates accurately reflect the market and whether hospitals and independent clinical laboratories will be paid fairly going forward. As proposed, however, most hospital-based laboratories would not be considered applicable laboratories and would be prohibited from reporting. The weighted median CLFS payment rates would be dominated, actually driven down, by payment data submitted primarily by the large independent laboratories – and not actually market based. Unlike hospital-based laboratories, large independent laboratories are able to charge much lower rates due to the huge volume of testing they conduct. Hospital outreach laboratories generally are reimbursed at higher rates than independent clinical laboratories when furnishing the same test. If hospital laboratories do not report their private payer rates to CMS, then the Medicare rates that CMS eventually develops will be derived only from the typically lower rates paid to independent clinical laboratories. Yet these rates would still apply to hospital laboratory outreach services that are paid separately under the CLFS. For some hospital laboratories, outreach testing represents a significant portion of their overall Medicare business.

The FHA urges the agency to modify its proposals to increase the number of hospital 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.

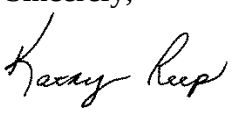
We recommend that CMS define an applicable laboratory at the National Provider Identifier (NPI) level. Doing so would increase the number of hospital-based laboratories that would report as applicable laboratories, without imposing unreasonable reporting burden on hospitals. We understand that some hospitals 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.

As recommended by the American Hospital Association, 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 toward rates that more closely reflect the market. In order to increase the amount of hospital-based data submitted to CMS, we recommend 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 would make the new weighted median CLFS payments more representative of the overall laboratory market.

We believe that this interpretation of applicable laboratories is supported by a colloquy on the Senate floor between Sen. Richard Burr (R-NC) and Sen. Orrin Hatch (R-UT) in which Sen. Burr noted that it was his understanding that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule." Sen. Hatch agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."

Thank you again for the opportunity to comment. If you have any questions, please contact me at kathyr@fha.org or by phone at (407) 841-6230.

Sincerely,



Kathy Reep
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