Biotechnology Industry Organization

November 24, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 22224-1850

BY ELECTRONIC DELIVERY

RE: CMS Proposed Rule CMS-1621-P: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule entitled *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System.*

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Specifically, many of BIO's members develop therapeutic products that are guided by molecular diagnostics tests. BIO companies also include those that develop and administer laboratory tests as well as those that develop and market in vitro diagnostic technologies for a variety of research, investigational, and clinical uses. Accordingly, BIO is pleased to offer the following comments on the Proposed Rule.

GENERAL COMMENTS:

BIO supports the provisions under section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) that reform the Medicare payment system for clinical diagnostic laboratory tests (CDLTs) to a market-based payment system that reflects the value these tests bring to patient care. We share CMS' objective to implement these PAMA requirements in a manner that is transparent, efficient, and fair. We believe that any new market-based payment system must allow for the reflection of not only the cost of performing these diagnostics tests but also the cost of development and clinical validation.

1201 Maryland Avenue SW
Suite 900
Washington DC 20024
202.962.9200 P
202.488.6306 F
bio.org

Successful implementation will help enhance patient access to high-quality, innovative diagnostic tests that can help guide clinical decision making.

In these comments, BIO will address concerns with specific provisions of the Proposed Rule such as the definition of "applicable laboratory", the definition of Advanced Diagnostic Laboratory Tests (ADLTs), and the rate establishment process for new ADLTs. BIO will also provide recommendations on the local coverage determination process and designation of Medicare Administrative Contractors for CDLTs. We appreciate the opportunity to provide these comments.

I. The definition of "applicable laboratory" omits key categories of laboratories from the reporting requirement which may impact the new Medicare payment rates for tests.

A. Hospital laboratories must be included in the definition of "applicable laboratory."

BIO believes that CMS' interpretation that PAMA intended to limit reporting primarily to independent laboratories and physician offices and not include other entities (such as hospitals or other health care providers) that do not receive the majority of their revenues from Physician Fee Schedule (PFS) or Clinical Laboratory Fee Schedule (CLFS) services is misguided. Hospital laboratories are a critical component of the laboratory market that bill Medicare on a fee-for-service basis under both the CLFS and PFS. To capture the true market value of the products under each code, CMS must require reporting by ***all*** of the various types of laboratories that bill Medicare for these services, including hospital laboratories.

On the floor of the U.S. Senate, Sen. Richard Burr (R-NC) 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 laboratory 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. Orrin Hatch (R-UT) agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."[1] Therefore, excluding hospitals from the PAMA reporting requirement undermines the clear intent of Congress that the laboratory market be fully represented.

BIO urges CMS to not, by default, exclude all hospital laboratories from meeting the definition of "applicable laboratory." Hospital laboratories are a significant part of the laboratory market. In 2014, 24% of all lab tests paid under Medicare Part B occurred in hospital laboratories.[2] We believe the exclusion of hospital laboratory data would materially affect the quality and sufficiency of the data needed to set rates and, at a minimum, skew

[1] See 160 Cong. Rec. S2860 (daily ed. May 8, 2014).
[2] HHS OIG. *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data* (OEI-09-15-00210), pg. 3. September 2015.

the rates unnecessarily low by failure to account for a distinct sector of the market that bills Medicare under the CLFS and PFS.

Further, BIO recommends the "majority of Medicare revenue" determination be calculated at the laboratory level, and not at the parent entity level as is proposed. This would eliminate the default exclusion of hospital labs from reporting private payor data and ensure the full laboratory market is represented in the new rates.

B. CMS should refine the definition of an "applicable laboratory" to only include those laboratories that meet the CLIA definition.

PAMA defines an "applicable laboratory" as a laboratory that receives more than 50 percent of its Medicare revenues from services that are paid on a fee-for-service basis under the CLFS and PFS in a data collection period. An "applicable laboratory" is required to report applicable information for a data collection period for each CDLT that the laboratory furnishes during the period for which payment is made under Medicare Part B. However, as CMS acknowledges in the proposed rule, "laboratory business models vary throughout the industry." Some laboratories operate as large national networks with multiple laboratories under one parent entity. Some are single, independent laboratories that operate individually. And others, such as hospitals or large practices, include laboratories as well as other types of providers and suppliers.

BIO disagrees with CMS' proposal to define an "applicable laboratory" as a Tax Identification Number (TIN)-level entity that derives more than 50 percent of its entire Medicare revenues from the CLFS or PFS. For large entities, the "majority of Medicare revenues" determination would be based on all of its Medicare revenues received including all *non-laboratory* components. To define "applicable laboratory" at the TIN level would exclude many laboratories from the reporting requirement because the "majority of Medicare revenues" threshold would be nearly impossible to meet within an entity that is a large health care system. The proposed definition, coupled with the proposed low-revenue threshold, would remove the overwhelming majority of hospital laboratories and physician office laboratories from the entities reporting private payor rates. This will narrow the overall dataset that CMS will use to determine market-based reimbursement rates for CDLTs and would be inconsistent with the underlying purpose of PAMA to establish rates that are reflective of the entire laboratory market. BIO recommends that CMS use an alternate identifier, such as the National Provider Identifier (NPI) or CLIA number, that offers greater accuracy in identifying those laboratories that should report pricing data to CMS for the purpose of calculating the true market value.

C. CMS should allow entities that do not meet the definition of an "applicable laboratory" to voluntarily report "applicable information".

CMS proposes to prohibit any entity that does not meet the definition of an "applicable laboratory" from reporting applicable information. This prohibition does not appear in the statute and could be counterproductive to achieving the goal of capturing applicable information that reflects the entire laboratory market. An entity that is not itself

an applicable laboratory, whether due to the 50% of Medicare revenue threshold or low-volume threshold, should be permitted to voluntarily report applicable information on any of the tests that it performs. BIO asks CMS to amend this language in the proposed regulatory text.

II. CMS should extend the data collection deadline for the initial data collection period from March 31, 2016 through at least September 30, 2016.

Under PAMA, a Final Rule implementing section 216 was due by June 30, 2015. Instead, the Proposed Rule was released for review on October 1, 2015 followed by a comment deadline of November 24, 2015. BIO asks CMS to extend the initial data collection deadline from March 31, 2016 through at least September 30, 2016. With a final rule expected no sooner than December 2015, laboratories will only have a few short months to determine whether they meet the criteria of an "applicable laboratory," determine what data is considered "applicable information", set up a system to consolidate, organize, format, and verify all the required applicable information (including determinations of how to report data for claims that are under appeal, re-appealed, extended, etc.), and formally submit a validated data package to CMS by the deadline. Furthermore, many laboratories will not know whether they will be required to report until the final rule is released. The dramatically abbreviated timeframe for compliance will place a tremendous, perhaps insurmountable, burden on laboratories, and could undermine the integrity or completeness of the dataset CMS is seeking.

Additionally, laboratories face severe civil monetary penalties of up to $10,000 per day for each misrepresented or missing data point. Given the potentially crippling size of the penalty, reporting entities must be provided adequate time to collect, format, verify, and submit the data, which many laboratory stakeholder groups have estimated could take at least 6 months. A deadline extension will give applicable laboratories the time necessary to provide the most complete and accurate dataset for CMS review. An accurate reflection of market rates is necessary as the rates established in this initial period will be active for three years beginning on January 1, 2017. Because of the potential impact these new rates may have on CDLT developers and providers, it is critical rates are established using the most robust and accurate data available.

III. PAMA, by establishing a separate designation for Advanced Diagnostic Laboratory Tests (ADLTs), intended for CMS to recognize the sophisticated bioinformatics associated with algorithmic-based biomarker tests and to establish special reporting and payment requirements accordingly.

A. <u>The definition of ADLTs should not be restricted to only those that analyze DNA and RNA, but should also include those tests that analyze protein biomarkers combined with a unique algorithm as the PAMA statute originally intended.</u>

Under PAMA, the term "advanced diagnostic laboratory test" is defined as a "clinical diagnostic 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 (or a successor owner) and meets one of the following criteria:

(A) 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.
(B) The test is cleared or approved by the Food and Drug Administration.
(C) The test meets other similar criteria established by the Secretary."

CMS has proposed to re-interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA. This re-interpretation of the plain text of the statute excludes tests that solely analyze proteins as qualifying for ADLT status. BIO believes that the statutory language of criteria (A), by using the word "or", is intended to mean that biomarkers being analyzed in the test can be any one of the three categories stated (DNA, RNA, or proteins). Therefore, DNA and/or RNA analysis is <u>not</u> a prerequisite to meet the requirements of criteria (A). BIO interprets that whether a test is an analysis of multiple biomarkers of DNA combined with a unique algorithm or an analysis of multiple biomarkers of proteins combined with a unique algorithm that both would qualify for ADLT status under the plain meaning of the statute.

BIO believes CMS' interpretation of this statute, one that was intended to distinguish innovative technologies, is impermissible and flawed. BIO strongly urges CMS to clarify that the legislated definition of an ADLT does include analyses of protein biomarkers combined with a unique algorithm to yield a single patient-specific result.

B. <u>The start of the "new ADLT initial period" should be based on the date when the test receives ADLT designation and is covered by Medicare, and not when the test is first performed.</u>

PAMA provides that, in the case of an ADLT for which payment has not been made under the CLFS prior to April 1, 2014 (the date of enactment of PAMA), during an initial three quarters, the payment amount for the test shall be based on the actual list charge for the test. After the new ADLT initial period, CMS will reset the rate to the market price through reporting and recover any overpayments if the list price was greater than 130% of market price.

CMS has proposed that the new ALDT initial period start "on the first day of the first full calendar quarter following first day on which a new ADLT is *performed*". BIO recommends that CMS start the new ADLT initial period based on the date when the test receives ADLT designation status <u>and</u> is paid under the Medicare program. For new ALDTs, the process of ramping up sales and establishing CMS coverage could take 6-12 months or even longer in some cases. As proposed, the initial list price period for new ADLTs will likely have expired before a payment is ever received.

IV. CMS should establish a local coverage determination process that provides the opportunity for maximum stakeholder engagement.

Under PAMA, CMS is granted the discretion to move to a system that would include one to four Medicare Administrative Contractors (MACs). In addition, PAMA mandates that coverage decisions made by contractors must be made pursuant to the process for developing local coverage determinations (LCDs). The potential consolidation of contractor activity moves the LCD process more closely to what is essentially a *de facto* national coverage decision (NCD). Because the protections, transparency and opportunity for stakeholder input are different for a LCD versus a NCD, this consolidation could create a system that mirrors the scope of NCD, but lacks a commensurate process to ensure transparency, accountability, and stakeholder input.

While BIO is not opposed to the consolidation of contractors for the purpose of administering coverage and payment for diagnostic laboratory tests, we are concerned that the process for local coverage determinations lacks adequate opportunity for stakeholder input in its current form. If CMS were to consolidate MAC functions for administering coverage and payment for laboratory tests under the CLFS, BIO recommends that CMS move to a system with four contractors. This approach would result in a less abrupt move towards a NCD-like system, and retain the benefit of recognizing some regional variations in standards of care.

Conclusion

BIO appreciates this opportunity to comment on the Proposed Rule to significantly revise the Medicare clinical diagnostic laboratory test payment system and other changes as required by section 216 of the Protecting Access to Medicare Act of 2014. We would be pleased to provide further input or clarification of our comments, as needed. We look forward to continuing a positive dialogue with CMS throughout the rulemaking process to advance innovation in the diagnostic field and to bring high-level healthcare to Medicare beneficiaries.

Respectfully submitted,

/s/

Phi D. Vu, J.D.
Director, Diagnostics and Personalized Medicine Policy
Biotechnology Industry Organization