AdvaMedDx
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AdvaMed
Advanced Medical Technology Association

November 24, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Mr. Slavitt:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed) and AdvaMedDx, we are writing to provide comments on the proposed rule implementing the new Clinical Diagnostic Laboratory Tests Payment System that was established by Section 216 of the Protecting Access to Medicare Act (PAMA) of 2014.[1]

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

AdvaMedDx operates as a division within AdvaMed and represents the world's leading diagnostics manufacturers by advocating for the power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs. Throughout this letter, AdvaMed refers to both AdvaMed and AdvaMedDx.

Timing and Transparency - CMS Should Delay Implementation of PAMA §216

AdvaMed, along with other stakeholders, supported the development of the legislative initiative to revise the way clinical diagnostic laboratory tests are paid by Medicare that ultimately resulted in the passage of PAMA §216. The revisions to Medicare's clinical diagnostic laboratory payment system represent the first major reforms to the way payment amounts are established and updated on the Medicare Clinical Laboratory Fee Schedule (CLFS) in more than 30 years. The new payment system will link Medicare payment rates under the CLFS to the rates paid for

[1] Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Proposed Rule (CMS-1621-P), 80 Fed Reg 59386 (October 1, 2015).

laboratory tests in the private sector. This is a significant change to the current model and one that stakeholders, including AdvaMed, want to ensure is implemented in a workable manner. For the reasons discussed below, we urge the Centers for Medicare & Medicaid Services (CMS) to delay implementation of the new payment system while the Agency provides more detail regarding the significant new requirements of the law, including data collection and data reporting by laboratories, coding and other requirements.

Although AdvaMed supported the revisions to the CLFS, the proposed rule sets forth a very aggressive implementation timeline, and does not provide adequate detail to enable laboratories to comply with onerous new requirements. The proposed rule was issued on September 25, and comments from the public are due to CMS by November 24. However, the proposal would require laboratories to collect and submit to CMS private payer data, including payer rates and volume data, potentially even before a final rule is issued. The proposed rule refers to guidance that is under development that will further describe the form and manner of data reporting. This guidance has not been released. Therefore, laboratories would be required to begin reporting extensive amounts of private payer data very soon without the benefit of a complete understanding of the rules.

Further, CMS must ensure that there is sufficient transparency in the rate-setting process. CMS should allow stakeholders to review the preliminary payment rates prior to their effective date, and to request that CMS reexamine and correct rates that are potentially inaccurate – a practice that occurs in other Medicare payments systems, such the Physician Fee Schedule.

In the proposed rule, CMS describes very limited opportunity for review of the payment rates that will result from the private payer data reporting before issuing final rates in November of 2016. Again, we believe this is a very aggressive timeline that will be difficult if not impossible to meet, and it leaves very little time and no process for stakeholders to address inconsistencies or errors that are likely to occur between the reported payment rates and the payment rates CMS will establish as a result.

We recognize that, given the delayed publication of this proposed rule, and the statutory deadline for establishing a new payment system by January 1, 2017, the inclusion of a time period for stakeholders to review preliminary payment rates will be challenging. However, given the large amount of private payer data that CMS must collect from laboratories in a very short time, and the potential for error or miscalculation in a brand new payment system, a "review" step will be critical and could avoid potential problems in the long term, should challenges arise regarding the new payment rates for specific tests.

AdvaMed has strong concerns about the timelines established in the proposed rule for the collection and reporting of private payer data, as well as the lack of transparency and opportunity to review and potentially correct errors in the process. Laboratories need time to not just understand the parameters of the data collection and reporting, but also to institute the necessary systems and processes to carry out these new requirements. Further, we believe CMS requires more time to process the information it will collect from laboratories and to translate massive

amounts of data into payment rates that will be effective for the next three years. Finally, CMS must incorporate a process under which the new rates can be reviewed and any errors in the calculations can be corrected. The importance of ensuring accuracy and review of the data and rates is amplified by the fact that rates established in this process will be in effect for three years. **Because more time is needed by all stakeholders, including CMS, and because of the delay by CMS in issuing a proposed rule, AdvaMed supports a delay in the effective date of the payment rates of at least one year, to January 1, 2018.**

AdvaMed's comments on the proposed rule will focus on the following areas:

I. Applicable Laboratories
II. Physician Office Laboratories and Low Revenue Threshold
III. Cost Sharing
IV. Definition of an Advanced Diagnostic Laboratory Test (ADLT)
V. Data Collection and Reporting and Public Release of Limited Data (Transparency)
VI. Coding for Certain Clinical Diagnostic Laboratory Tests (CDLTs) on the CLFS
    a. Coding Under PAMA
VII. Medicare Payment for Tests Where No Applicable Information is Reported
VIII. Local Coverage Determination Process and Designation of Medicare Administrative Contractors for Clinical Diagnostic Laboratory Tests
IX. Advisory Panel on Clinical Diagnostic Tests

I. Applicable Laboratories – *Applicable Laboratories Should Represent the Private Market*

The payment reforms contained in PAMA §216 require CMS to establish payment amounts for tests paid under the CLFS by calculating a weighted median of the private payer rates that are reported to CMS by "applicable laboratories." In general, the intent of the legislation was to associate Medicare payment rates with those payment rates made by payers in the private sector. In order to ensure the payment rates established under this new payment system accurately reflect those in the private sector, the laboratories that report private sector data should also represent the laboratory market, including independent laboratories, hospital laboratories when they perform outreach testing (i.e., when payments for laboratory testing are not bundled into the inpatient or outpatient payments for a beneficiary's hospital services, but rather are paid separately under Part B of Medicare), and physician office laboratories.

A recent HHS OIG report entitled *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data*¸ indicates that while 57% of CLFS payments (Medicare Part B) are made to independent laboratories, 24% of CLFS payments are made to hospital laboratories and 19% to physician office laboratories.[2] As drafted, the proposed rule

[2] Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data, HHS Office of Inspector General Data Brief, OEI-09-15-00210 (September 2015).

would exclude significant portions of the market, particularly physician office laboratories and hospital outreach laboratories, whose inclusion would establish a more accurate representation of the private market. CMS should evaluate the laboratory tests that are offered and furnished in different settings by different types of laboratories and consider ways to improve the data reporting for those tests to ensure more accurate market representation.

AdvaMed recognizes the need to balance the need for sufficient private sector data with the burden of data collection and reporting on certain laboratories, and we offer several specific recommendations throughout this comment letter; however we highlight the need to reflect the laboratory market as accurately as possible in order to establish accurate payment rates that are representative of that market.

II. Low Revenue Threshold – Impact on Physician Office Laboratories

A wide range of private payer rates are available in the private market. As previously noted, clinical diagnostic laboratory tests (CDLTs) are furnished by a variety of entities, including not only independent clinical laboratories (not affiliated with hospitals or physician offices) but also laboratories that function within hospitals and in physicians' offices. In-office laboratories perform a significant number of point-of-care tests for patients, and may also perform moderate-complexity and high-complexity tests, as well as tests for other physicians. Because a substantial number of point-of-care tests are performed in physicians' offices, and because we believe physician offices contract differently with private payers for many of these tests, which are performed in the physician office laboratory using special point-of-care technologies, it is especially important for CMS to consider these data in establishing payment rates that reflect the private market.

CMS has proposed to establish a low revenue threshold for excluding an entity from the definition of "applicable laboratory" that will have the effect of excluding the majority of physician-office laboratories from the private payer data reporting requirement. We do agree with CMS that there should be a balance between collecting sufficient data to calculate an appropriate weighted median and the resulting burden on entities that receive only a small amount of revenues under the CLFS, relative to other providers, and that may have limited resources to comply with the reporting requirement. However, CMS estimates that the proposed $50,000 revenue threshold (entities whose Medicare revenues from laboratory tests billed under the CLFS are less than $50,000) will exclude 94 percent of physician office laboratories and 52 percent of independent laboratories, while retaining a high percentage of Medicare utilization. CMS further estimates that of the tests currently paid on the CLFS, the utilization of about 17 tests would be completely attributed to laboratories that would be excluded under the low revenue threshold. CMS did not identify which tests are included in this category.

AdvaMed is concerned that the exclusion of the majority of physician office laboratories from reporting private payer data will result in inaccurate pricing for many tests that are currently furnished at the point of care in the physicians' office. Further, dramatic reductions in payment amounts for such tests could have a negative impact on patient access if physicians are no longer able to furnish them at the point of care.

We are aware of other organizations that are discussing proposals for enriching the data relevant to tests furnished in physicians' offices. One such proposal, for example, suggests that CMS could identify test codes for which the majority (50 percent or more) of the utilization of the particular tests is performed in Place of Service 11 (physician office). For laboratories that do not meet CMS' current definition of an applicable laboratory, because those laboratories do not meet the $50,000 criterion for CLFS revenue, CMS could identify those laboratories that are substantial performers of those tests that are furnished primarily in physician office labs. Where the laboratory meets some threshold for CLFS revenues (e.g., more than $2,500 in CLFS revenue in the most recent year of claims data), CMS could contact those laboratories and request that they report the applicable information for those tests only.

This reporting could be subject to a limited data collection period, and CMS could request the data no more frequently than the Agency would otherwise collect data for clinical diagnostic laboratory tests (CDLTs) under PAMA (i.e., no more than once every three years). A laboratory could decline to report the information if, for example, the laboratory did not perform the test during the data collection period.

We believe that such a proposal, designed solely to enrich the private payer database for tests codes that are billed primarily by physician office laboratories, would not substantially increase the reporting burden for most physician office laboratories. Further, the additional data would serve to provide CMS with a broader range of private payer rates than otherwise would be reported under the currently proposed methodology, and would be more reflective of the full laboratory market.

This example represents one potential solution to the issue of insufficient data reporting by physician office laboratories. There may be other proposals that would result in better data representing the whole laboratory market that do not substantially increase the burden on certain types of laboratories. AdvaMed looks forward to working with CMS and with other stakeholders to find solutions resulting in the best data and most accurate pricing, with minimal burden, under the statute.

Recommendation:

- CMS should consider requesting private payer data from certain physician office laboratories that bill for some threshold level of tests that are performed primarily in those settings.

- CMS could do this in a way that balances the need for more complete market data with any associated reporting burden on physician office laboratories. As noted, the example discussed above is one potential solution. AdvaMed will work with CMS and other stakeholders to identify workable solutions that achieve the best outcomes under the statute.

III. Cost Sharing

AdvaMed supports CMS' proposal that applicable laboratories report private payer rates inclusive of all patient cost-sharing amounts, including all patient deductibles and coinsurance amounts. We agree with CMS' rationale that it is important for private payer rates that are reported by laboratories to be analogous to how they will be used by CMS to determine the new Medicare payment amounts for tests under the revised payment system. Because Medicare does not require beneficiaries to pay deductibles or coinsurance on laboratory tests on the CLFS, and to ensure consistency, we agree that reported private payer rates should be comparable to how they will be used by CMS to determine Medicare payment amounts under the new payment system.

IV. Definition of an Advanced Diagnostic Laboratory Test (ADLT)

Per the statute, an advanced diagnostic laboratory test (ADLT) is defined as a CDLT 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 that meets one of the following criteria:

(1) 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;
(2) The test is cleared or approved by the FDA;
(3) The test meets other similar criteria established by the Secretary.

However in the proposed regulation, CMS incorrectly interpreted this provision to require that an ADLT must analyze, at a minimum, biomarkers of DNA or RNA, and proposes that under the first criterion, such a test must be a molecular pathology analysis of DNA or RNA, eliminating the statutory reference to proteins. CMS does discuss in the preamble that an ADLT could include other assays, such as a component that analyzes proteins.

CMS further proposes that, in order to qualify as an ADLT, a test must provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests. There is no basis in the statute for this "novelty" requirement. The language in §216 of the PAMA statute was intended to instruct CMS on coding and establishing payment for new tests on the CLFS, and did require ADLTs to provide new clinical diagnostic information that cannot be obtained from tests currently on the market.

The statutory language defining an ADLT was specific and was intended to be self-executing. We believe that CMS has gone beyond the legislative intent by interpreting the first criterion in the ADLT definition more narrowly than the law intended. Additionally, the law did not require an ADLT to provide new clinical diagnostic information that cannot be obtained from any other existing tests. In fact, such a requirement seems to imply a judgment regarding coverage of a test, and not coding and payment as intended by the law. Furthermore, such a coverage determination regarding only new or novel tests would confer a "first-to-market" benefit that was not contemplated in the law.

The Advisory Panel on Clinical Diagnostic Tests, which was established by PAMA §216, discussed these issues at its public meeting on October 19, 2015, and agreed with stakeholders that CMS did not correctly interpret the first ADLT criterion when it eliminated the reference to analysis of proteins from the definition. The Advisory Panel also agreed with stakeholders regarding the proposal that an ADLT provide new or novel information that cannot be obtained from a test or tests currently on the market. The panel recommended that CMS follow the statutory language and define an ADLT as a test (offered and furnished by a single laboratory) that is an analysis of multiple biomarkers of DNA, RNA or proteins, combined with a unique algorithm to yield a single, patient-specific result. The Panel further recommended that CMS strike the proposed "novelty" requirement from the proposed rule, as it does not conform to the language in the law.

Recommendations:

- CMS should follow the language in the law to define an ADLT as a test (offered and furnished by a single laboratory) that is an **analysis of multiple biomarkers of DNA, RNA <u>or</u> proteins**, combined with a unique algorithm to yield a single, patient-specific result.
- CMS should not finalize the proposed requirement that an ADLT provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests.

V. Data Collection and Reporting and Public Release of Limited Data (Transparency)

a. Data Collection and Reporting

CMS has proposed an initial data collection period of July 1 – December 31, 2015, with subsequent data collection periods running a full calendar year. We understand that for many laboratories, a retrospective data collection period will be difficult, if not impossible, to accomplish. CMS has not issued any specific guidance for laboratories to follow in terms of what specific data to collect and report to CMS, yet the proposed rule describes a data collection period that is currently ongoing. The proposed rule references a forthcoming guidance document that will describe the

"form and manner" of data collection, but without this document in advance, labs are left with no direction as to what information to collect, in what format, or how to prepare it for reporting to CMS.

CMS has proposed that the first data reporting period run from January 1 – March 31, 2016. Again, this is a very aggressive timeline that will be difficult for laboratories to meet.

b. Public Release of Limited Data (Transparency)

We were pleased that CMS suggested it would make the payment rates resulting from the public reporting available (tentatively) in September, prior to the final rates being made available in November (under CMS' currently proposed timeline) and we strongly urge CMS to follow through on this suggestion. AdvaMed has long-supported transparency in coding and payment processes, and we encourage CMS to ensure transparency in this new process. However, we are concerned that the enormity of data to be collected, processed and calculated under this new payment system may present challenges in making the rate data available in a timely fashion.

We understand that CMS is establishing a web-based portal for laboratories to report their private payer data, and that more information about this process is forthcoming. We commented more than a year ago that CMS should provide an opportunity for laboratories to test their rate-reporting capabilities in advance. This would also allow CMS to test the infrastructure it is building for this purpose. AdvaMed continues to be concerned that the very tight timelines established in the proposed rule are not adequate to allow such testing to occur.

With respect to the data itself, we request that CMS make available more comprehensive data, in addition to the median values used to establish proposed payment rates. In this way, stakeholders will be able to identify any issues, such as calculation errors, that may result in inaccurate payment rates that, without opportunity to correct, will be in place for three years. Such data could include data on test volumes reported for each code, total number of distinct rates reported for each code, median payment rates by type of provider and/or place of service code, and other additional data. The public release of this type of data would be consistent with what CMS currently does in other payment systems, such as the Physician Fee Schedule or Hospital Outpatient Prospective Payment System. CMS could redact any confidential information that could potentially lead to identification of a specific laboratory or private payer.

Recommendations:

- Again, we urge CMS to delay implementation of these data collection and reporting requirements and to issue guidance as soon as possible so that laboratories can begin to develop the appropriate systems to ensure compliance.

- CMS must provide adequate opportunity for test manufacturers, laboratories and other interested stakeholders to review the new payment rates before they become effective. Under the revised payment system, the new payment rates are effective for three years, underscoring the importance of ensuring rates are accurate and representative of the reported market data.
- With respect to transparency of the data itself, we urge CMS to release additional data, including volume and other data described above. Such data could be instrumental in allowing stakeholders to identify reporting or calculation errors, or other issues, prior to rates going into effect.

VI. Coding for Certain Clinical Diagnostic Laboratory Tests (CDLTs) on the CLFS

a. Coding Under PAMA

The statute required CMS to address coding for new and existing tests. Per the statute, CMS must:

- Adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests and new laboratory tests that are cleared or approved by the FDA; and
- Assign unique HCPCS codes to existing advanced diagnostic laboratory tests and laboratory tests that are cleared or approved by the FDA "if such test has not already been assigned a unique HCPCS code."
- The statute further allowed for the establishment of unique identifiers for certain tests (ADLTs or laboratory tests that are cleared or approved by the FDA) if a laboratory or a manufacturer requests such an identifier for purposes of tracking or monitoring its test. The unique identifier provision gives CMS discretion to determine a mechanism for identifying such tests, at the request of a laboratory or manufacturer.

i. Temporary codes

In public comments to date, AdvaMed has not expressed a preference for HCPCS codes (G-codes) or other methods (AMA-CPT codes, McKesson Z-code, e.g.). Our primary concerns continue to relate to issues of timeliness, predictability and consistency with respect to any method that is used to assign codes to new laboratory tests billed on the CLFS.

CMS proposes to assign a temporary G-code to a new ADLT or CDLT that is FDA-cleared or approved if it has not already been assigned a HCPCS code. The temporary G-code would be effective for up to two years until a permanent HCPCS code is established (with an opportunity for the Secretary to extend the length of time, if appropriate). CMS proposes that if, at the end of two years, the American Medical Association (AMA)-CPT Editorial Panel has not created a CPT code to describe the test and CMS continues to have a need to pay for the test, the Agency will continue to use the G-code.

AdvaMed has concerns regarding the assignment of G-codes and the potential for coverage and payment delays created by use of these codes (or failure to use these codes) by private payers. We are aware of proposals that have been submitted by other stakeholders relative to CMS' G-code proposal that would address our concerns through the creation of a system similar to that currently used to develop codes for diagnostic tests. These proposals would represent a one-code solution that would not require discontinuance of a code at any point during the lifecycle of a test.

AdvaMed has significant concerns regarding potential issues relating to test pricing and Medicare coverage that could arise when a temporary code is replaced by a permanent code after two years (or longer, as needed). Because the new clinical laboratory payment system established by PAMA is ultimately based on the reporting of private payer data by applicable laboratories, a transition from a temporary to a permanent code after only two years could result in confusion, both for laboratories and for payers. Such a change could also cloud the data being collected and reported to CMS.

As an alternative, CMS could consider developing a mechanism for assigning permanent codes to new tests that would be sufficiently unique to describe the new test and would be effective throughout the lifecycle of the test. CMS could assign such codes on its own, or could consider contracting with an entity, such as the American Medical Association, to establish a permanent coding mechanism under PAMA §216 that would satisfy the need for unique coding, timely issuance (e.g., quarterly), consistency in use across various payers, and would eliminate transition delays at the end of two years. Such as mechanism would establish a more predictable coding system, with continuity of coding, that would also be flexible over time.

Recommendations:

- Any coding mechanism for new tests should be timely, predictable and consistent over time.
- CMS should assign codes to new tests on a quarterly basis.
- CMS should consider assigning permanent codes to new tests that will be effective for the lifecycle of the test. Such a mechanism would result in greater predictability and consistency, and would avoid stakeholders potentially having to revisit pricing and coverage issues as the result of transitioning to a permanent code after two years. This solution would create consistency and would negate the need to transition to a permanent code after two years.

ii. Existing Codes

The statutory language regarding the assignment of unique HCPCS codes to existing ADLTs and FDA-cleared or –approved laboratory tests that have not already been assigned a unique HCPCS code raises the question of what constitutes "unique." Existing tests that are already assigned an AMA-CPT code, even where the test is one of multiple tests assigned to a particular CPT code, may already be covered and paid

by CMS and/or commercial payers. Laboratories or manufacturers that do not feel an existing CPT code adequately describes or differentiates their tests are allowed, per the statute, to request a unique identifier. While AdvaMed is a strong proponent of granularity in the coding system, we do not believe there is a need, or a statutory requirement, that CMS assign individual, unique HCPCS codes to multiple tests within the CPT "bucket" wherein they currently reside.

There are more than 1200 CPT codes currently listed on the Clinical Laboratory Fee Schedule (CLFS). The number of tests associated with those codes could be very high. AdvaMed is concerned that the CMS proposal goes beyond the statutory intent, will be unduly burdensome for CMS and for stakeholders, and could create issues downstream with coverage and payment.

AdvaMed interprets the statute as requiring CMS to assign a unique HCPCS code to an existing test only where the test is not currently described by a unique CPT or HCPCS code (e.g., a test that is currently being paid under a miscellaneous or unlisted code). In all other cases laboratories or manufacturers should request a unique identifier.

Recommendations:

- CMS should clarify its intent regarding this proposal. If it was not CMS' intent to assign individual, unique HCPCS codes to each test that is described by an existing CPT code, but rather to rely on the current CPT code as the unique HCPCS code for purposes of this statutory provision, then CMS should clarify this in the final rule.
- CMS should assign a unique HCPCS code (or other unique code, using an alternative mechanism as described above under the section on "temporary codes") to an existing test in circumstances where the test is not currently described by a unique CPT or HCPCS code (e.g., a test that is currently being paid under a miscellaneous or unlisted code).

iii. Unique Identifier

The statute requires CMS to develop a way to track or monitor a test through a mechanism such as a HCPCS code or modifier, if such a tracking code is requested by a laboratory or manufacturer. This statutory provision was intended to address the circumstance where multiple tests may be described by an existing code (e.g., an AMA-CPT code), but where a laboratory or manufacturer is interested in tracking or monitoring the utilization of a specific test within that bucket. For example, ten tests may be described by a given code, but the manufacturer of an FDA-cleared or -approved test that is described by that code may desire to track or monitor the utilization of its tests in various care settings (physician office, hospital outpatient department, etc.). A unique identifier would allow the manufacturer to gather this data over time. Likewise, a laboratory could request a unique identifier to gather data on a test it has developed, but that is billed under a CPT code with other similar tests.

In the proposed rule, CMS states it believes the requirements of this section can be met by the existing HCPCS coding process, and that it will assign a unique HCPCS code to a test if it does not already have one. This proposed process makes it unclear when or if a unique HCPCS code will be assigned and raises a number of other questions (e.g., does a test that currently resides in a CPT "bucket" "already have" a unique HCPCS code? Will the unique HCPCS code replace the current CPT code for that specific test? How will pricing be determined? Will it crosswalk back to the original CPT code?)

We believe that CMS has misinterpreted the intent of the statute and that the proposed rule does not address the circumstances described above. The statutory language requires CMS to establish a mechanism under which a code can be tracked separately, even though it is currently described by a code that encompasses multiple other tests.

As discussed above, CMS could consider developing a mechanism, either on its own or using a process developed by the AMA, for assigning unique identifiers by creating and assigning codes to those tests (at the request of a manufacturer or laboratory) that would be sufficiently unique to describe the test and would be effective throughout the lifecycle of the test. Such a mechanism would satisfy the requirements of PAMA §216, as well as the need for unique coding, timely issuance, continuity, and other issues.

Recommendation:

- CMS should establish an appropriate mechanism for tracking a specific test, at the request of a laboratory or manufacturer, so that the interested party may gather data over time regarding utilization of a unique test within an existing code. Such coding mechanism for assigning unique identifiers that could serve as permanent codes that would be sufficiently unique to describe the test and would be effective throughout the lifecycle of the test.

VII. Medicare Payment for Tests Where No Applicable Information is Reported

When no applicable information is reported by an applicable laboratory(ies), CMS proposes to use gapfilling or crosswalking to establish payment rates on or after January 1, 2017. CMS correctly notes that the statute did not address this situation. CMS provides a number of potential reasons why no applicable information would be reported for a laboratory test (e.g., the test is not performed for any privately insured patients during the collection period, or the test is not performed by any applicable laboratories, etc.).

CMS states in the proposed rule that it considered proposing that the current payment amount for a test under the current CLFS be carried over, if no private payer data are

reported during a reported period, but did not recommend this because the previous payment rate would not reflect changes in costs or pricing for the test over time.

We agree that CMS must have a process in place for establishing payment amounts for CDLTs that are paid on the CLFS and for which no data are reported during a data reporting period. It would seem that carrying over, or crosswalking to, a previously established rate would be a more logical approach than reevaluating the payment basis (crosswalk versus gapfill) for a test for which payment had once been established.

AdvaMed intends to monitor situations where this occurs to gain a better understanding about the impact, and will consider providing additional comments in future rulemaking cycles.

VIII. Local Coverage Determination Process and Designation of Medicare Administrative Contractors for Clinical Diagnostic Laboratory Tests

AdvaMed supports the CMS decision to not designate one or more MACs to either establish LCDs for CDLTs, or to establish LCDs and process claims for CDLT payments. We agree with CMS that reducing the number of MACs processing claims for CDLTs could be complex, difficult to operationalize, and result in inefficiencies.

IX. Advisory Panel on Clinical Diagnostic Tests

We were pleased that Congress created the Advisory Panel on Clinical Laboratory Tests in the statute. However, we anticipated that the panel would be used to provide information, clinical and technical expertise and experience with a wide range of clinical laboratory tests to CMS. To date the panel has met twice, August 26th and October 19th, with much of the discussion focusing on specific codes that are being considered for payment on the CLFS in CY 2016. The panelists have been able to offer insight into the manner in which certain tests are performed and to highlight specific characteristics of certain tests, in ways that should be very helpful for CMS in its deliberations. Some panelists were able to briefly discuss differences between, for example, multi-analyte tests with unique algorithms and other types of tests, such as next-generation sequencing procedures or whole genome sequencing procedures.

AdvaMed believes the panel should be given more opportunity to fully discuss the various types of tests. For example, in considering whether certain tests should be priced using the gapfill methodology or via crosswalking, it is important to understand the characteristics of the tests and whether existing codes could in fact be adequately crosswalked. Knowing this information is beneficial to CMS.

AdvaMed would further appreciate and support opportunities in the future to provide input to CMS regarding the Advisory Panel agendas and topics to be considered by

the panel in advance of scheduled meetings. Such opportunities would allow stakeholders the ability to raise relevant issues for the panel to consider. CMS should also consider allowing clinical, scientific or other subject matter experts to testify before the panel when specific issues will be included on the agenda.

We look forward to working with CMS going forward to think about ways to maximize the Advisory Panel to the benefit of the Agency and stakeholders in the laboratory industry.

We reiterate that AdvaMed was an early supporter of many of the payment reforms that were included in the PAMA legislation in 2014. We hope that CMS is able to develop and implement a data collection and reporting system that works smoothly. However, given the many components of this new system, and the very short timeframe for implementation, we urge CMS to work with stakeholders should issues arise so that we can solve them together.

AdvaMed greatly appreciates the opportunity to provide these comments. Please contact me or Chandra Branham, JD, at cbranham@advamed.org if you have additional questions or need any additional information.

Sincerely,

/s/

Donald May
Executive Vice President
Payment and Health Care Delivery Policy