November 24, 2015

SUBMITTED ELECTRONICALLY TO REGULATIONS.GOV

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System [CMS-1621-P].

Dear Acting Administrator Slavitt:

On behalf of the Coalition for 21st Century Medicine (C21), please accept these comments on the Proposed Rule entitled, "Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System."

C21 represents the world's most innovative diagnostic technology companies, clinical laboratories, researchers, physicians, venture capitalists and patient advocacy groups – all linked by a common mission: To develop and commercialize state-of-the-art diagnostics that improve patient health.

C21 strongly supported the enactment of the Clinical Laboratory Fee Schedule (CLFS) reform provisions in Section 216 of the *Protecting Access to Medicare Act* (PAMA). These reforms, the first major reforms to the CLFS since 1984, establish a transparent market-based payment model, and ensure the Medicare program benefits from the dynamics of the private market place. This new system will ensure continued advancements in diagnostic innovation by providing a pathway to consistent coding and pricing decisions for all diagnostics.

We applaud the Centers for Medicare & Medicaid Services' (CMS) efforts in drafting the Proposed Rule and believe that the Proposed Rule represents an important first step to implementing the reforms contemplated in the PAMA legislation.

Following is a summary of our comments:

I. The definition of an "applicable laboratory" – CMS should include within the definition of "applicable laboratory" laboratories that offer and furnish new ADLTs, even if the

laboratory has not achieved the $50,000 CLFS revenue threshold during the data collection period.

II. The definition of "applicable information"
   A. "Applicable information" should be defined as the amount paid by a private payor for a Clinical Diagnostic Laboratory Test (CDLT) after all price concessions were applied, and include any patient cost sharing amounts, if applicable.
   B. We endorse CMS's proposed definition of "Specific HCPCS code" as a HCPCS code that does not include an unlisted CPT code or a "Not Otherwise Classified" code. We further encourage CMS to publish a list of specific HCPCS codes for which it expects applicable laboratories to report information.

III. The definition of an "Advanced Diagnostic Laboratory Test" (ADLT)
   A. CMS should establish an objective standard that a laboratory seeking ADLT status for a test need only demonstrate or certify that its ADLT algorithm is empirically derived and unique in order for the test to be considered an ADLT.
   B. CMS must allow an analysis of proteins that does not also include an analysis of DNA or RNA to qualify as an ADLT.
   C. CMS should identify a sponsor of an ADLT as being the single laboratory that offers and furnishes an ADLT notwithstanding that the laboratory may have multiple CLIA certificates.
   D. CMS should interpret "offered and furnished" as requiring that the ADLT be developed and performed only by a single laboratory.

IV. The process for classifying a test as an ADLT
   A. CMS should adopt an application for ADLT status that consists of an objective checklist of the statutory criteria. CMS should accept such applications on a quarterly basis.
   B. CMS should allow the Medicare Administrative Contractors (MACs) to recommend ADLT status for new tests based on criteria established by CMS and the MACs' own assessment of clinical, technological, and resource similarities to other tests that have already been assigned ADLT status.
   C. The ADLT application should permit applicants to satisfy the ADLT requirements by submitting non-proprietary, publicly-available information sufficient to describe the algorithm and assay.

V. The data collection and reporting process
   A. CMS should start the data collection period in 2016 and data reporting beginning in January 1, 2017; CMS should implement the payment rates based on data collection on January 1, 2018. Nonetheless, CMS should implement the new ADLT payment methodology on January 1, 2017, and assign of specific codes as soon as possible.
   B. CMS should finalize its proposal to establish a 12-month data collection period.

C. CMS should incorporate into its data collection portal a field or other mechanism that will allow laboratories to include their assumptions or any explanations when collecting and reporting applicable information.

D. CMS should allow laboratories that offer and furnish ADLTs to submit private payor rates paid under an NOC code for the initial data collection and data reporting period for new ADLTs to ensure that adequate and representative data is available to set market based rates for these tests.

VI. Test specific permanent codes for ADLTs – CMS should pursue the creation of a permanent HCPCS test-specific code set that would allow for a singular code set to be used by private payors and Medicare to avoid disruption on switching from a temporary to a permanent code.

VII. Payment for new ADLTs

A. CMS should clarify that the "New ADLT initial period" means "a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the first day on which a new ADLT is performed *following the date on which Medicare confers ADLT status upon the test and Medicare payment is first made.*"

B. The amount of payments that CMS should recoup, in the event that a test's Average List Charge (ALC) exceeds its weighted median payment rate, should be equal to the ALC minus 130 percent of the weighted median payment as determined by CMS.

VIII. Contractor reform

A. CMS should consider consolidating the responsibility for coverage development into a small number of specialized contractors.

B. CMS should not consolidate claims processing responsibilities.

IX. Additional considerations for CMS's implementation of this regulation – CMS should establish a process to publicly report the existing MAC payment of any test determined to be an existing ADLT particularly in light of any delays in implementation of this regulation.

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I. DEFINITION OF "APPLICABLE LABORATORY"

C21 appreciates the challenge of balancing the need for adequate information with the burden that data collection requirements could place on certain laboratories, particularly those with relatively low Medicare revenues from laboratory testing. Nonetheless, C21 has strong concerns about the consequences of the thresholds CMS has selected on laboratories

offering Advanced Diagnostic Laboratory Tests, particularly laboratories just starting out offering new ADLTs.

CMS's proposal would prohibit any laboratory that receives less than $50,000 in Medicare revenues under Sections 1834A and 1833(h) of the Social Security Act for laboratory tests furnished during a data collection period from reporting private payor rates and volumes to CMS in the subsequent data reporting period. For most existing Clinical Diagnostic Laboratory Tests that are performed by many clinical laboratories this exclusion may strike the right balance between adequate data collection and reporting burden, and will have little effect on CMS's ability to calculate a credible median rate.

However, for a laboratory offering a new single source laboratory test, this bar may prohibit that laboratory from reporting private payor information, and effectively prohibit CMS from establishing market-based payment rates for that test. Unlike most reference labs that offer a wide array of tests, most developers of ADLTs offer a single test or a very limited menu of tests, especially initially when they are just starting out. In the early years of a company, sales volumes, particularly Medicare sales volumes may be low or zero. Only after obtaining Medicare coverage will these new ADLTs begin to experience physician adoption and reimbursement (especially if the test has a relatively limited Medicare population). It may take a laboratory offering an ADLT substantial time – weeks, months or even years – before it realizes $50,000 in Medicare CLFS revenues. Unlike a multiple source CDLT, where exclusion of information from a single laboratory, or even a large number of small labs, may have little to no effect on the median payment rate, ADLTs are by definition performed by a single laboratory, and as such, prohibiting that laboratory from reporting payment rates for the test eliminates the only source of private payor information about that test available to CMS. In that case, CMS would not receive any private payor payment information from the laboratory, and has proposed to resort to cross-walking or gap-filling methodologies to establish a payment amount for the test.[1]

The intent of PAMA is clear: Congress unequivocally intended for new ADLTs to be reimbursed at their actual list charge for three quarters, and then to be reimbursed at the private payer weighted median rate. The limitation of $50,000 in Medicare revenues for the data collection period may exclude some new ADLTs from meeting the threshold and push these tests into the CMS annual crosswalking or gapfilling pricing process. As CMS itself acknowledges, Congress provided the Secretary with the authority to establish low volume or low expenditure thresholds for the purpose of relieving the burden of reporting on certain labs.[2] Congress did not intend for this flexibility to result in establishing payment amounts for new emerging ADLTs using crosswalking and gapfilling pricing methodologies.

[1] *See,* 80 *Fed. Reg.* at 59,412, *et seq.*
[2] "We believe it is important to achieve a balance between collecting sufficient data…and *minimizing the reporting burden* for entities that receive a relative small amount of revenues under the CLFS." 80 *Fed. Reg.* 59,393 (emphasis added).

For this reason, C21 believes that where a laboratory offers a new laboratory test designated by CMS as an ADLT, CMS should regard that laboratory as an "applicable laboratory" notwithstanding the amount of Medicare revenues that laboratory derives from furnishing services under the CLFS. CMS should continue to utilize other criterion as it sees appropriate for designating a laboratory as an "applicable laboratory."

Recommendation: Include within the definition of "applicable laboratory" laboratories that offer and furnish new ADLTs that are covered by Medicare, even if the laboratory has not achieved the $50,000 CLFS revenue threshold during the data collection period. Specifically, we recommend that CMS add new a paragraph (6) to the § 414.502 definition of "Applicable Laboratory" as follows: "(6) Paragraphs (4) and (5) shall not apply in the instance of a laboratory that furnishes a new Advanced Diagnostic Laboratory Test." CMS also should amend paragraphs (4) and (5) by adding "…subject to paragraph (6)."

II. DEFINITION OF "APPLICABLE INFORMATION"

A. PATIENT COST SHARING

C21 agrees with CMS's proposal to define applicable information in § 414.502 as, with respect to each CDLT for the data collection period, each private payor rate, the associated volume of tests performed corresponding to each private payor rate and the specific HCPCS code associated with the test, and to exclude information about tests for which payment is made on a capitated basis. C21 agrees with CMS that the private payor rate for a CDLT should be reported inclusive of patient coinsurance and copayment amounts. For that reason we encourage CMS to adopt in the Final Rule its proposal that applicable laboratories report private payor rates inclusive of all patient cost sharing amounts.

Recommendation: C21 recommends that CMS finalize the definition of private payor rate in § 414.502 that "applicable information" is the amount that was paid by a private payor for a CDLT after all price concessions were applied, and includes any patient cost sharing amounts, if applicable.

B. INCLUSION OF SPECIFIC HCPCS CODES AS APPLICABLE INFORMATION

C21 agrees with CMS that applicable laboratories will need to report a HCPCS code for each test that specifically identifies the test for which applicable information is being reported. We further agree with CMS's proposal to define "Specific HCPCS code" in § 414.502 as a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a Not Otherwise Classified (NOC) code established by the CMS HCPCS Workgroup. C21 recommends that in advance of each data reporting period the

agency publish a list of specific HCPCS codes for which it expects applicable laboratories to report information.

Recommendation: C21 supports the definition of "Specific HCPCS code" as a HCPCS code that does not include an unlisted CPT code or a NOC code. Further C21 recommends that the agency publish in advance of each data reporting period a list of specific HCPCS codes for which it expects applicable laboratories to report information.

III. DEFINITION OF AN "ADVANCED DIAGNOSTIC LABORATORY TEST"

A. DEFINITION OF "UNIQUE ALGORITHM"

Section 1834A(d)(5)(A) requires that to be classified as an ADLT, a test must combine an analysis of multiple DNA, RNA, or protein biomarkers with "a unique algorithm." In the Proposed Rule, however, CMS proposes an additional requirement that the test must "provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests."[3] Such a requirement is not supported by statute, and is unnecessary for the agency to appropriately identify ADLTs for payment purposes based upon the statutory definition.

We understand that CMS has proposed this "newness" criterion because the Agency believes the criterion is necessary to determine that a test for which a laboratory is applying for ADLT designation has a "unique algorithm." However, the newness criterion is neither necessary nor legally permissible to determine that a test comprises a unique algorithm. The statutory reference to a unique algorithm means that one ADLT must be *different* from other ADLTs. Insofar as a test (1) comprises multiple biomarkers of DNA, RNA, or proteins, (2) incorporates an algorithm to provide a patient-specific result, and (3) was developed by a single laboratory, there should be a presumption that the test comprises a unique algorithm because the test is the product of the development activities of the single laboratory. CMS can readily determine that a test comprises a unique algorithm by reviewing information, such as the Methods section of a peer-reviewed publication presenting the validation of the test, to confirm that the algorithm is unique and not a simple replicate of another test.

CMS appears to have concerns about two or more tests having ADLT status when the tests are similar—*e.g.,* have overlapping biomarkers and/or involve similar methods for translating the biomarkers into an individual patient result. It is possible that two laboratories could develop similar ADLTs, but it is highly unlikely that the algorithms would be the same since the weighting of variables included in an algorithm is dependent upon the patient population utilized in the validation of the assay. In effect, two ADLT developers would need to use the exact same patient population in their validation trial to reach the exact same variable

[3] 80 *Fed. Reg.* at 59,398.

weighting, which is unlikely to occur.

Insofar as two or more tests are similar, it is likely that there will be healthy competition between the laboratories offering the tests. This is more likely to result in savings to CMS if rates are adjusted based upon annual reporting than when rates are adjusted only every three years.

In addition, the newness criterion is not legally permissible because by requiring that the algorithm be unique, Congress was in no way saying the information provided also must be unique. Congress simply required that the algorithms – *i.e.,* the weighting of specific variables in the algorithm – be different from other ADLTs. CMS takes this a step too far by also requiring that the information produced – *i.e.,* the result of the algorithm – must be unique. Under the statutory language, two tests can qualify for ADLT status even if they provide substantially similar clinical information, so long as their algorithms are distinct.

For these reasons, CMS's Advisory Panel on Clinical Diagnostic Laboratory Tests unanimously recommended at its October 19, 2015, meeting that CMS *not* require, as part of the unique algorithm criterion, that the test provide new clinical diagnostic information that cannot be obtained from any other test or combination of tests.[4] Some Panel members articulated that this proposal would hinder innovation of new tests and competition among algorithms to see which tests can produce the most accurate and reliable results.

Additionally, it is important to note that the ADLT designation is used only for purposes of determining whether the test is eligible for annual reporting and eligible for initial payment using the Average List Charge methodology. Nothing in the designation of the ADLT payment category has bearing on Medicare coverage. Any determination regarding clinical utility among tests producing similar diagnostic or predictive information is within the purview of coverage review by CMS and its MACs.

Recommendation: CMS should establish an objective standard under subparagraph (A) that a laboratory seeking ADLT status need only demonstrate or certify that its algorithm is unique. The regulations § 414.502 should remove the language that the test "provides new clinical diagnostic information that

[4] "The Panel recommends that CMS revise its definition of a "unique algorithm" under criterion A to reflect the statutory language and modify the numbering to be consistent with the changes. (Unanimous approval) Panel Recommendation (1) The test— (i) Must be a molecular pathology analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; (ii) combined with a unique algorithm to yield a single patient-specific result; and (iii) May include other assays." From, "*Advisory Panel on Clinical Diagnostic Laboratory Tests (CDLT) Voting Results and Recommendations as recorded from written ballots";* October 19, 2015; https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2015-10-19-Lab-Panel-Results.pdf

cannot be obtained from any other test or combination of tests."

B. INCLUSION OF PROTEIN BASED TESTS AS ADLTs

Congress stated unambiguously in Section 1834A(d)(5)(A) that a CDLT that meets certain other requirements pertaining to its laboratory shall be an ADLT if 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."[5] CMS's proposed regulation implementing this statute (§ 414.502) impermissibly excludes tests based on proteins not including DNA or RNA from the ADLT definition.[6] CMS explains, "we interpret this provision to require that the test analyze, at a minimum, biomarkers of DNA or RNA,"[7] and proposes that an ADLT under subparagraph (A) be "a molecular pathology analysis of DNA or RNA."[8] Notably, protein-based tests that do not also include analysis of DNA or RNA— which are included expressly in the statutory definition — are omitted from the proposed regulatory definition.

Congress recognized that multianalyte protein tests with algorithms play a critical role in precision medicine. A number of C21 member laboratories have development programs for innovative new protein based assays that meet the statutory definition of an ADLT, but would not qualify under CMS's proposed definition because they do not also include analysis of DNA or RNA. The statutory language for the definition of an ADLT also closely tracks the AMA CPT definition for "Multianalyte Assays with Algorithmic Analyses" (MAAA) test codes, which expressly include multianalyte protein-based assays without requiring analysis of DNA or RNA as well.[9] The MAAA tests are unique laboratory tests that analyze many biomarkers including DNA, RNA or proteins through algorithms.

During the October 19, 2015, meeting of the Advisory Panel on Clinical Diagnostic Laboratory Tests, CMS stated its position that the definition of an ADLT was meant to describe an "advanced" test, and that tests of proteins are not "advanced." The Advisory Panel disagreed with CMS's position and recommended that the definition of ADLT should track the statutory language that describes ADLTs as including "analysis of multiple biomarkers of DNA, RNA, or proteins...."[10] The Advisory Panel members publicly stated that there is no scientific justification for excluding tests that analyze proteins without also

[5] Soc. Sec. Act § 1834A(d)(5)(A) (emphasis supplied).
[6] 80 *Fed. Reg.* at 59,420.
[7] 80 *Fed. Reg.* at 59,397.
[8] 80 *Fed. Reg.* at 58,398.
[9] The AMA CPT Editorial Panel defines MAAAs as procedures that utilize multiple results derived from panels of analyses of various types, **including molecular pathology assays**, fluorescent in situ hybridization assays and non-nucleic acid based assays (e.g., **proteins**, polypeptides, lipids, carbohydrates). Algorithmic analysis, using the results of these assays as well as other patient information (if used), is then performed and reported typically as a numeric score(s) or as a probability. (Emphasis added).
[10] "*Recommendations from the Clinical Diagnostic Laboratory Test Panel Meeting (October 19, 2015)*"; p.7; available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2015-10-19-Lab-Panel-Results.pdf; last accessed November 16, 2015.

analyzing DNA or RNA from the definition of an ADLT. Some Panel members noted that in many instances the analysis of proteins may even provide improved information about current status of a disease state that may not be captured through analysis of DNA or RNA**.**

Where Congress has stated that a test shall be an ADLT if it is "an analysis of multiple biomarkers of DNA, RNA, or proteins," CMS does not have the discretionary interpretive authority to contend otherwise. Congress was not providing CMS with a range of options from which to choose; instead, Congress was articulating the scope of biomarkers that qualify as ADLTs, and plainly intended for protein-based tests meeting the other specified requirements to be treated as ADLTs for reporting and rate-setting purposes.

Recommendation: The regulatory definition of an ADLT at § 414.502(1)(i) must be revised as follows: "Must be an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;"

C. DEFINITION OF A "*SINGLE LABORATORY*"

The PAMA statute provides that ADLTs are laboratory tests that have been developed and are offered and furnished by a single laboratory, and that are not for sale for use in other laboratories.[11] CMS proposes to implement this requirement by defining a "single laboratory" as a "facility with a single CLIA certificate," and excluding from ADLT status any test that is offered by entities with "multiple CLIA certificates associated with multiple testing locations."[12]

This proposal fails to recognize that a corporate "entity" that has developed and furnishes an ADLT may have multiple CLIA certificates for legitimate reasons, which should not disqualify the lab from being considered a "single laboratory." We are aware of laboratories that operate on a single campus, yet have multiple CLIA certificates. A corporate entity that chooses to expand its facility to meet increased testing demand may be forced to open an additional laboratory space, which may be disconnected from the original laboratory. The second location could be directly across the street or next door, but because it is disconnected from the original laboratory, it must obtain a distinct CLIA certificate. In this instance, under CMS's proposed definition of "single laboratory," this laboratory's test could not qualify as an ADLT despite the fact that the test continues to meet the statutory definition of having been offered and furnished by a single entity and is not for sale for use by another lab.

CMS's proposal would also prohibit a laboratory with multiple CLIA certificates from performing different ADLTs at each of its locations. In this scenario, each location would perform a single ADLT, and that ADLT would be performed at only a single location, yet none of the tests could be classified as an ADLT because the corporate entity holds multiple

[11] Soc. Sec. Act § 1834A(d)(5).
[12] 80 *Fed. Reg.* at 59,396.

distinct CLIA certificates notwithstanding the fact that the tests meet the statutory definition of an ADLT.

By requiring that to qualify as an ADLT the sponsoring entity be a single laboratory, Congress was not suggesting that the entity be in a single location, but rather that the test be offered by only one laboratory or entity. CMS can comply with the statute in ways that do not constrain laboratory operations.

Recommendation: CMS should identify a sponsor of an ADLT as being a single entity that offers and furnishes the test notwithstanding that the laboratory may have multiple CLIA certificates.

D. DEFINITION OF "OFFERED AND FURNISHED"

C21 agrees with CMS that in defining a single laboratory that "offers and furnishes" the ADLT, that laboratory must be the only one to develop and perform the test. However, there are two problems with CMS's proposed interpretations of markets and sells. By further defining this to include the activities of "marketing and selling" the test, CMS has gone beyond the intent of Congress and has placed undue restrictions on normal, typical business practices of ADLT laboratories that are neither contemplated by the statute, nor necessary to define a single laboratory.

For example, there are circumstances where a referring laboratory receives a specimen to be tested, and refers it to another laboratory, the reference laboratory, to perform the test. We agree with CMS that in these situations, because the reference laboratory performed the test, it would be the laboratory that offered and furnished the test for the purposes of the ADLT definition. However, which laboratory "marketed and sold" the test in that scenario may be unclear and defeat the reference laboratory from qualifying its test as an ADLT. Small ADLT laboratories may partner with larger laboratories to co-market or co-promote an ADLT test. In such a scenario, a test would be an ADLT consistent with the statutory intent because it is offered and furnished only by a single laboratory, but the test may not qualify for ADLT status under CMS's proposed interpretation.

Moreover, CMS's interpretation of the term "sell" as requiring that the ADLT sponsoring laboratory "receive remuneration" also is unclear and potentially unhelpful.[13] As CMS is well aware, under Medicare's billing rules, any test furnished within 14 days after a patient's discharge from a hospital is deemed to have been performed on the day of collection, when the patient was in or at the hospital.[14] When read in the context of other Medicare regulations (42 C.F.R. §§ 411.15(m) and 410.42), a laboratory test that is deemed to coincide with the date on which the patient was a hospital patient becomes a service

[13] *See,* 80 *Fed. Reg.* at 59,397.
[14] 42 C.F.R. § 414.510.

furnished by the hospital, and the hospital must bill Medicare for the test. In these instances, the hospital would pay the laboratory for the test, so the laboratory "receives remuneration," but the hospital also "receives remuneration," and does so directly from Medicare. CMS cannot expect this billing rule to thwart a laboratory test from qualifying as an ADLT.

For these reasons, we encourage CMS to clarify that a laboratory seeking ADLT status must offer and furnish the test, and that this means that only one laboratory may design and perform the ADLT test. Consistent with CMS's goal, if finalized in this manner, CMS would not expect to see more than one applicable laboratory report applicable information for an ADLT.

Recommendation: CMS should revise its proposed § 414.502 to state that:

> "*Advanced Diagnostic Laboratory Test (ADLT)* means a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the laboratory that designed the test or a successor owner of that laboratory, and meets one of the following criteria:"

IV. PROCESS FOR CLASSIFICATION OF AN ADLT

A. APPLICATION PROCESS FOR CLASSIFYING A LABORATORY TEST AS AN ADLT.

The Proposed Rule contemplates implementing Section 1834A(d)(5) — which declares that a test is an ADLT so long as it meets the requirements established therein — by requiring laboratories to submit applications for ADLT status. C21 agrees that an application process would be beneficial for the orderly implementation of the statute, but also believes that such applications should be essentially a checklist, limited to requiring laboratories to demonstrate that the applicant test meets objective and easily-validated factors contained in the statutory definition of an ADLT. Most of the terms under each criterion can be validated easily through publicly-available information. We have attached for your consideration a proposed model form of an ADLT application that CMS could use for this purpose.

Classification as an ADLT under Section 1834A(d) — in and of itself — does not determine whether an ADLT will be covered by Medicare. Every test classified as an ADLT will still be required to demonstrate to its MAC both its analytical and clinical validity in order to establish coverage. As such, it is reasonable and appropriate that the mere designation as an ADLT be ministerial in nature.

Finally, C21 notes that neither the Proposed Rule nor the statute specifies a timeframe within which a laboratory should request classification as an ADLT, or a timeframe in which laboratories should expect to receive a determination in this regard. CMS says that it plans to

release sub-regulatory guidance on the ADLT application process. Specific guidance as to both the timing of any application submission and the receipt of a determination is critical to laboratories. Such guidance should be clearly established by CMS well in advance of the start of the new payment methodology for ADLTs. Laboratories will need to be able to apply for ADLT designation, and receive a unique code in advance of data reporting obligations in order to start to establish private payor payment rates associated with the code.

Because switching codes can cause delays in claims processing and payments, it is critical that the ADLT and code assignments be made in as timely a manner as possible. Frequently, payers delay payment for new codes until claims pricing systems can be updated and these delays will impact a laboratory's ability to report information timely. The application process should be on a quarterly basis to allow laboratories the flexibility to launch a test and develop commercial payor contracts.

Recommendation: Any application process by which laboratories would apply for ADLT status should consist of an objective checklist of the statutory criteria, and should be submitted and reviewed on a quarterly basis. We recommend that CMS adopt an application form akin to the model attached to these comments.

B. IMPLEMENTATION OF CRITERION 1834A(d)(5)(C) FOR DEFINING AN ADLT

Section 1834A(d)(5)(C) grants the Secretary the discretion to establish "other similar criteria" by which a test could demonstrate that a test qualifies as an ADLT. While the statute provides discretion to CMS with respect to *this* subparagraph, the Proposed Rule proposes that if CMS were to exercise the authority granted by subparagraph (C) in the future, "it would be through notice and comment rulemaking."[15]

We believe that subparagraph (C) was included by Congress specifically and affirmatively to provide the Secretary with the statutory flexibility necessary to enable CMS policy to keep pace with the rapidly-changing technological innovation that characterizes advanced diagnostic laboratory testing. As has become increasingly evident, the annual rulemaking notice and comment process is often an inadequate tool for allowing CMS to maintain pace with the rate of technological development in the advanced diagnostic testing industry. Based on recent innovations in next generation sequencing and other technologies, it is clear that the agency should retain the flexibility under subparagraph (C) to classify new categories of ADLTs.

CMS should develop flexible criteria to allow MACs to make a recommendation to CMS in favor of ADLT status based on an assessment of clinical, technological, and resource

[15] 80 *Fed. Reg.* at 59,399.

similarities to other tests that have already been assigned ADLT status. Each clinical laboratory test undergoes an extensive clinical assessment by MACs prior to Medicare coverage and payment. This would provide both CMS and the MACs with the flexibility to assess innovative new diagnostic laboratory tests that may not meet the criteria in subparagraphs (A) or (B).

Recommendation**:** We recommend that the agency retain flexibility outside of annual rulemaking process to implement subparagraph (C), and consider developing criteria for MACs to recommend to CMS ADLT status under subparagraph (C) authority based on the MACs' assessment of clinical, technological, and resource similarities to other tests that have already been assigned ADLT status.

C. NON-PROPRIETARY, NON-CONFIDENTIALITY PROTECTIONS FOR ADLT APPLICATION

In the Proposed Rule, CMS suggests that while PAMA provides confidentiality for certain data submitted to CMS by laboratories, PAMA's express confidentiality provision "does not apply to subsection (d) of section 1834A of the Act, which relates to information provided to the Secretary to determine whether a test is an ADLT."[16] While CMS "do[es] not expect to make information in an ADLT application available to the public," CMS suggests "that information is not explicitly protected from disclosure under the confidentiality provisions of the statute, nor is it explicitly protected from [public] disclosure…."[17]

The specifications of an ADLT, particularly those details relating to a unique algorithm, are highly confidential and market sensitive. If CMS maintains its position that there was no congressional intent in PAMA to protect confidential and proprietary information submitted in support of an ADLT determination, the logical conclusion is that Congress did not intend to require that laboratories submit such information to CMS to be designated as ADLTs. CMS should therefore permit laboratories to seek designation as an ADLT through the submission of non-proprietary, non-confidential, publicly-available information. Such an approach would allow for CMS to maintain its interpretation of the statute without placing laboratories in the untenable position of being required to disclose nonpublic market sensitive information into the public domain.

To the extent that laboratories are required to provide proprietary or confidential information as part of their applications, CMS should affirmatively commit to invoking the provisions of 5 U.S.C. § 552(b)(4) that exempt trade secrets from disclosure under the Freedom of Information Act (FOIA) in response to any such public request. C21 believes that this FOIA exemption is unambiguously applicable in this context.

[16] 80 *Fed. Reg.* at 59,398.
[17] *Id.*

Recommendation: The ADLT application should permit applicants to satisfy the ADLT requirements by submitting non-proprietary publicly-available information sufficient to describe the algorithm and assay. Any proprietary information required by CMS as part of an ADLT application should be protected from public disclosure pursuant to 5 U.S.C. § 552(b)(4) as trade secret.

V. DATA COLLECTION AND REPORTING PROCESS

A. CMS SHOULD PROVIDE SUFFICIENT NOTICE FOR IMPLEMENTATION OF THE DATA COLLECTION AND REPORTING SYSTEM

While the Coalition appreciates the great effort CMS clearly put forward in developing this Proposed Rule, we are concerned that CMS has too little time to thoughtfully consider comments and meet the statutory implementation timetable. We also are concerned about CMS and laboratories' ability to implement the provisions of PAMA in the condensed timeframe. C21 believes that it will be exceptionally difficult for laboratories to begin collecting and reporting data in the absence of final direction, both regulatory and sub-regulatory, from CMS. Further, laboratories will find it exceedingly difficult to develop and test the systems necessary to collect accurate information by January 1, 2016.

C21 believes that applicable laboratories need additional information prior to beginning data collection, therefore, data collection should not commence prior to whatever time period in 2016 CMS publishes the Final Rule. However, we believe that other provisions of the Final Rule such as the new ADLT payment methodology in 2017 and the assignment of specific codes should proceed on time as intended by statute. Because data collection for new ADLTs would not proceed until 2017, delaying implementation of the new ADLT payment methodology is not necessary to accommodate the delay in reporting for existing ADLTs and CDLTs we are recommending.

Recommendation: The Coalition urges that CMS start the data collection period in 2016 and data reporting beginning in January 1, 2017, and implement the payment rates based on data collection on January 1, 2018. However, the Coalition also recommends that CMS implement the new ADLT payment methodology on January 1, 2017, as well as the assignment of specific codes as soon as possible, as specified in the statute.

B. 12-MONTH DATA COLLECTION PERIOD

CMS is proposing to define the "data collection period" as a full calendar year, that is, a period beginning January 1st and ending December 31st. We interpret this to mean that CMS is expecting laboratories to report applicable information for tests performed on dates of

service during any given data collection period. CMS states that it believes that a full calendar year of claims data will produce a "comprehensive set of data for calculating CLFS rates."[18] We appreciate that, throughout the Proposed Rule CMS considers the need to balance complete data collection with minimizing burden on laboratories that must report.

We believe that the data collection period must allow sufficient time for laboratories to submit claims to payors, and to allow those payors to process, review, price and ultimately make payment for the claim in order for the laboratories to collect and report applicable information. This is particularly critical for small labs and labs whose claims are most frequently "out-of-network." These labs often experience longer lags in claim response than other labs, particularly since those payors are under no obligation to make payment, much less timely payment, for tests from out-of-network providers. We believe that the 12-month "data collection period" allows for sufficient time for laboratory claims to be processed and paid by private payors so that CMS may collect a robust data array.

Recommendation: We encourage CMS to finalize its proposal to establish a 12-month data collection period.

C. LABORATORY ASSUMPTIONS UNDERLYING THEIR DATA REPORTS

PAMA is based on the underlying assumption that laboratories will be able to report complete, accurate and timely information that will be used by CMS to determine market based payment rates for laboratory tests. CMS's Proposed Rule makes strides toward providing laboratories with guidance needed to accurately collect data; however, as with any data collection of this magnitude, there are certain to be a number of issues where CMS's guidance is not perfectly clear, and that are left to the laboratories' good judgement.

As with the Part B Drug Average Sales Price reporting process, CMS should encourage laboratories to disclose the "reasonable assumptions" underlying their data reports.[19] The disclosure of such assumptions provides CMS with valuable information that can be used to better understand laboratories' reports and provides laboratories with a consistent process to follow when explaining to CMS the results of their reports. By allowing laboratories to provide assumptions, if CMS has questions about the assumptions, it can then discuss those assumptions further with the laboratory, rather than potentially accepting incomplete or inaccurate data.

Recommendation: CMS should incorporate into its data collection portal a field or other mechanism that will allow laboratories to include their assumptions or

[18] *Id*.
[19] In general, CMS encourages drug makers to report "reasonable assumptions" when face with the lack of specific guidance addressing a reporting issue. Such reasonable assumptions must be consistent with the general requirements of the Social Security Act, Federal Regulations, and customary business practices. *See 72 Fed. Reg. at 66,256*

any explanations when collecting and reporting their private payor data and volumes.

D. VOLUNTARY REPORTING OF PRIVATE PAYOR DATA FOR ADLTS WITHOUT A SPECIFIC CODE DURING THE "NEW ADLT INITIAL PERIOD"

The current CMS proposal prohibits applicable laboratories from reporting what would otherwise be applicable information on tests billed with a "not otherwise classified" code.[20] In the Proposed Rule, CMS takes the position that they cannot identify the specific test that corresponds to a private payor rate when it is billed with a NOC code.

The proposal fails to acknowledge that, in many cases, there are examples of existing tests that are billed using NOC codes that are covered and paid by Medicare Contractors that include information that is used to identify the specific test that is being billed. This is especially true for ADLT developers who typically offer a limited test menu. We know that Noridian's claims processing system, for example, is able to edit [analyze] the NOC code, ICD-10-CM code, and test descriptor code in box 19 and its equivalent segment in the electronic claim submission such that payment can be made or denied upon initial claim submission. This same approach is taken by some private payors. Thus, today, some private payors and Medicare Contractors are able to identify specific tests billed under NOC codes.

Specific to New ALDTs this proposal may have the unintended consequence of prohibiting tests which are assigned a specific code from reporting private payor information from payors who reimburse for the test under an NOC code prior to the adoption of a specific code. There are over a thousand health plans in the United States, and the process of switching codes to a new unique code does not happen overnight. If CMS were to not allow laboratories that are being paid under a NOC code during the initial reporting period to report that claim data, then it would not have a full picture of the market rate for that test.

Additionally, we are concerned that under the proposal a scenario may arise that once the laboratory applies for and receives a specific code for the tests, because the code may not be rapidly adopted and the initial data collection and reporting period for a new ADLT is very brief, the lab may be effectively prohibited from reporting an adequate volume of data upon which CMS can establish a market rate, even though under the NOC code they have a robust history of claims data upon which Medicare could rely to set its payment rates. Instead, in the absence of sufficient data CMS contemplates setting rates using crosswalking or gapfilling instead of using market based data. We do not believe this was the intention of the statue or CMS's proposal, and instead propose that CMS permit laboratories that are receiving reimbursement under a NOC code to report that data during the initial data collection and reporting periods for new ADLTs.

[20] 80 *Fed. Reg.* at 59,396

Recommendation: CMS should allow laboratories that offer and furnish ADLTs to voluntarily submit private payor rates paid under an NOC code for the initial data collection and data reporting period for new ADLTs to ensure that adequate and representative data is available to set market based rates for these tests.

VI. TEST SPECIFIC PERMANENT CODES FOR NEW ADLTS

In the Proposed Rule, CMS outlines its proposed approach to coding for certain new and existing tests:

1. **Existing tests** – CMS would assign a unique Healthcare Procedure Coding System (HCPCS) Level II G-code for existing Advanced Diagnostic Laboratory Tests (ADLTs) and existing Clinical Diagnostic Laboratory Tests (CDLTs) approved or cleared by the FDA that do not have a unique code.
2. **New tests** – For new ADLTs or new CDLTs cleared or approved by the FDA on or after January 1, 2017, CMS would assign a temporary HCPCS Level II G-code effective for up to 2 years until a permanent HCPCS code is assigned, unless CMS determines that the G-code should be extended.

We are concerned by CMS's proposal to use G-codes for new and existing ADLTs. Many private payors do not use G-codes established by CMS. Instead, those payers instruct providers to use permanent HCPCS codes. When this occurs, providers must report different codes for claims submitted to private payors versus Medicare. If labs are required to use different codes for Medicare versus private payors, labs will have a problem reporting data to CMS. If the database is limited to rates reported from private payors who accept G-codes, the database will be limited. If CMS allows laboratories to report data reported under CPT codes, CMS will need to establish a dictionary to crosstab G-codes with the applicable CPT code(s). This will be burdensome for CMS and clinical laboratories, and will likely introduce errors into the reporting database.

In addition, under a temporary G-code approach, at some point, permanent coding will be adopted. This too would create the need for a dictionary to crosstab G-codes to the new CPT codes. This may be straightforward if the descriptors are identical, but if the descriptors are not identical, as noted above, this would be burdensome for CMS and clinical laboratories and likely introduce error into the database.

Therefore, we believe a temporary coding approach utilizing G-codes is not desirable or consistent with the objectives of PAMA § 216. Instead, we recommend that CMS use permanent HCPCS codes to allow for a singular code set to be used by private payors and Medicare and that would avoid disruption on switching from a temporary to a permanent code.

We are aware of the recent announcement by the AMA that the CPT Editorial Panel has established a new section of permanent codes under CPT for clinical laboratory tests intended to meet the objectives and requirements of PAMA § 216.[21] This approach should meet the objectives and requirements of PAMA § 216 by creating a singular, permanent code set to report clinical laboratory test procedures. We support this approach, but only if private payors adopt and use the new code section. If private payors reject the new code section, or if codes from the new section are generally denied coverage, the objectives of PAMA § 216 will be thwarted. We strongly encourage CMS to reach out to private payors to obtain their input on the payors' willingness to accept and reimburse tests reported under the new specific HCPCS codes.

Recommendation: CMS should pursue the creation of a permanent HCPCS test-specific code set process that would allow for a singular code set to be used by private payors and Medicare and that would avoid disruption on switching from a temporary to a permanent code.

VII. PAYMENT FOR NEW ADLTS

A. THE DATE ON WHICH PAYMENT AT THE "ACTUAL LIST CHARGE" WILL BEGIN

PAMA provides that for new ADLTs "during an initial period of three quarters, the payment amount for the test for such period shall be based on the actual list charge for the laboratory test."[22] CMS's Proposed Rule defines the new ADLT initial period as beginning on the "first day of the first full calendar quarter following the first day on which a new ADLT is performed."[23]

Since the test must be an ADLT to receive payment at the ALC rate, CMS's proposed approach necessarily requires that the laboratory seek and be granted ADLT status for its laboratory test, and that Medicare reimbursement, in the form of an initial claim determination or a local coverage policy, be established before any ADLT can be paid at the ALC rate. As such, CMS should clarify that when the Agency says the initial period "starts on the first day of the next calendar quarter following the first day on which the *new ADLT* is performed," that CMS means that the Agency must first deem the test to be an ADLT, and Medicare coverage must be established before the initial period can begin. The date on which the test is first performed cannot itself, alone trigger the countdown to the initial period. To illustrate, if a test is first performed on February 4, 2017, but Medicare reimbursement is not established until March 4, 2018, and CMS does not confer ADLT status until March 14,

[21] Announcement by the CPT Editorial Panel regarding this new code set can be found at http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page.
[22] Soc. Sec. Act § 1834A(d)(5)(1).
[23] 80 *Fed.Reg.* at 59,401.

2018, March 14th, 2018 and not February 4th, 2017 would be the date that starts the clock to the first quarter on which the initial period can begin.

In order to facilitate reporting of private payor rate data for new ADLTs at the end of the second quarter following initial Medicare payment of the ADLT, CMS should allow a process whereby a laboratory can obtain designation of a test as an ADLT and obtain a code that private payors can use to pay claims for the test prior to the laboratory's starting to obtain Medicare payment for the test. With this sequencing of events, there will be private payor rate data available to report at the end of the second quarter after initial Medicare payment in order for CMS to calculate an ADLT payment rate to go into effect at the end of the three quarters of ALC payment. Without this sequencing of events, there may be no private payor data to report at the end of the second quarter of Medicare payment.

Recommendation: CMS should clarify the definition of "New ADLT initial period" in § 414.502 as follows: "*New ADLT initial period means a* period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the first day on which a new ADLT is performed *following the date on which Medicare confers ADLT status upon the test and Medicare payment is first made.*"

B. ALC RECOUPMENT

Section 1834A(d)(4) provides CMS with the authority to recoup payments if the Secretary determines that the ALC-based payment amount for a new ADLT is greater than 130 percent of the weighted median of the private payor rates, and instructs the Secretary to "recoup the difference between such payment amounts for tests furnished during such period."

In the Proposed Rule, CMS provides its interpretation of the phrase "*the difference between such payment amounts*" as being the difference between the ALC and the weighted median rate determined by CMS. We disagree with this interpretation and believe that the two payment amounts referenced in this section are (1) the ALC and (2) 130 percent of the weighted median rate as determined by CMS.

Congress intended to reimburse new ADLTs up to 130 percent of their weighted median private payer amount, and the recoupment should serve as a guardrail that prevents the laboratory from being abusive with respect to Medicare payments. Instead, sound public policy, as well as a natural reading of the statute, dictates that Medicare regard the recoupment provision as an outer boundary limiting the ALC. Consequently, CMS should in these cases recoup the difference between the ALC and 130 percent of the market-based rate.

Recommendation: The amount of payments that CMS should recoup should be equal to the ALC minus 130 percent of the weighted median payment as determined by CMS. As such, CMS should revise its proposed § 414.522(c) as

follows: "If, after the new ADLT initial period, the difference between the actual list charge of a new ADLT and the weighted median established under the payment methodology described in § 414.507 exceeds 130 percent, CMS will recoup the difference between the ADLT actual list charge and 130 percent of the weighted median."

VIII. CONTRACTOR REFORM

A. CMS SHOULD CONSIDER CONSOLIDATING RESPONSIBILITY FOR DEVELOPING LOCAL COVERAGE POLICY INTO SPECIALIZED CONTRACTORS

Consolidating the responsibility for coverage determinations and decisions into a smaller number of MACs with expertise in laboratory medicine may be appropriate. Establishing coverage policies for clinical laboratory testing requires an understanding of laboratory medicine, including methods for assessing analytical and clinical validity. Currently, this expertise resides with only a limited number of analysts and medical directors among the MACs. As it is neither realistic nor efficient to expect all MACs to have substantial expertise in laboratory medicine, assigning the responsibility for coverage decision making for laboratory tests to a smaller number of MACs with expertise in laboratory medicine could result in more informed policy setting decisions. In addition, if CMS decides to move forward with consolidation from a coverage perspective, we recommend that CMS instruct the designated contractors to establish reasonable and predictable criteria for coverage and interactive processes for laboratories and manufacturers to submit and discuss the evidence supporting coverage.

Recommendation: CMS should consider consolidating the responsibility for coverage development into a small number of specialized contractors.

B. CMS SHOULD NOT CONSOLIDATE CLAIMS PROCESSING OPERATIONS

As CMS notes, the PAMA statute provides CMS with the authority to consolidate the responsibility for developing local coverage determinations and for processing claims for diagnostic laboratory services into between one and four MACs.[24] In the Proposed Rule, CMS has elected to not exercise this authority at this time, citing the need to "conduct the necessary analyses to determine the feasibility and program desirability" of consolidating contractor operations. [25]

[24] Soc. Sec. Act §1834A(g)(2) allows the Secretary of HHS the authority to "designate one or more (not to exceed 4) Medicare Administrative Contractors to either establish coverage policies or establish coverage policies and process claims for payment for clinical diagnostic laboratory tests"
[25] 80 *Fed. Reg.* at 59,414.

We believe it would be inappropriate for CMS to consolidate the claims processing function for clinical laboratory tests. Assigning claims processing to different MACs for clinical laboratory tests from other items and services paid under Part B that the same providers may furnish for Medicare beneficiaries would create enormous administrative burdens for the providers—and likely for MACs as well. For laboratories also furnishing anatomic pathology services, claims would have to be submitted to different MACs for the same beneficiaries on the same dates of service.

Recommendation: CMS should not exercise its authority to consolidate claims processing operations into a small number of specialized MACs.

IX. ADDITIONAL CONSIDERATION FOR CMS'S IMPLEMENTATION OF THIS REGULATION

Under Section 1834A(e)(2), Congress established coding and payment rules for certain CDLTs that meet the new statutory definition of an "existing advanced diagnostic laboratory tests" (Existing ADLTs). Under this statutory definition, the Secretary is required to assign a unique HCPCS code for each Existing ADLT and publicly report the payment rate for each Existing ADLT no later than January 1, 2016. CMS has observed that Section 1834A(i) of the Act (the "Transitional Rule") separately requires that prior to December 31, 2016, CMS price certain ADLTs using the methodologies for pricing, coding, and coverage that were in effect on March 31, 2014, which may include cross-walking or gapfilling. C21 believes that the Agency can fulfill both of these statutory requirements in a fully transparent manner.

Eight MAAA tests that are currently covered by Medicare contractors with established payment rates recently underwent the annual CLFS rate setting process. These tests (and the laboratories that developed the tests) are Afirma (Veracyte), AlloMap (CareDx), CancerTypeID (Biotheranostics), ChemoFx (Helomics), Corus CAD (CardioDX), Onco*type*DX Colon Cancer Assay (Genomic Health), Vectra DA (Crescendo Bioscience), and VeriStrat (BioDesix). C21 has separately commented as part of the CLFS Preliminary Determinations that these tests should be priced in 2016 by MACs through the gapfilling process, and CMS concurred in nearly every instance with the Final Determinations posted on November 17, 2015.[26]

C21 believes that following publication of the final PAMA regulations, these tests will meet the requirement for designation as Existing ADLTs. As such, C21 strongly supports the publication of the existing MAC payment rates for any test determined to be an Existing ADLTs paid as of the date of enactment of PAMA. Publication of the existing payment rates for these Existing ADLTs should occur even though most of these tests are now also required

[26] "Calendar Year (CY) 2016 Clinical Laboratory Fee Schedule (CLFS) Final Determinations"; November 17, 2015; https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2016-CLFS-Codes-Final-Determinations.pdf

to commence the gapfilling process as a technical matter under the Transitional Rule. We read the Proposed Rule to support this interpretation. In relevant part CMS stated,

> "There may be other tests in the category of section 1834A(e)(2) existing laboratory tests that are currently being priced for January 1, 2016, and that are already being paid by the MACs.… As these tests are already being paid by MACs, we would be able to publicly report their payment amounts by January 1, 2016."[27]

C21 further observes that to the extent that there are any delays in the final implementation of the PAMA Final Rule, CMS should be cognizant of how those delays may impact the intersection of the statutory obligations to report the payment rates of Existing ADLTs and to price ADLTs under the Transitional Rule.

Recommendation: In the PAMA Final Rule, CMS should establish a process to publicly report the existing payment rates set by MACs currently making payment for any test determined to be an Existing ADLT.

* * * * *

Thank you for the opportunity to provide these comments. If you have any questions about C21's recommendations, please contact me directly at (650) 243-6363 or via email at john@veracyte.com.

Sincerely,

John W. Hanna
Chair, Reimbursement Workgroup
Coalition for 21st Century Medicine

Attachment (1)

[27] 80 *Fed. Reg.* at 59,404

PROPOSED ADLT Designation Request Form

Applicant must complete Section 1 and one of Criterion A, B, or C.

Section 1 i. Test is offered and furnished only by a single laboratory and not sold for use by a laboratory for use by a laboratory other than the original developing laboratory (or a successor owner)	☐
Applicant Comments:	
ii. Test is Covered by Medicare	☐
Applicant Comments:	
AND (Complete relevant Criterion)	
Criterion A i. Test includes biomarkers of DNA, RNA, or proteins	☐
ii. Test includes an algorithm that provides a single, patient-specific result	☐
Applicant Comments Regarding Criterion A:	
OR	
Criterion B iii. Test is cleared or approved by the FDA	☐
Applicant Comments Regarding Criterion B:	
OR	
Criterion C iv. Test has been proposed for ADLT designation by the regional MAC	☐
Applicant Comments Regarding Criterion C: