July 15, 2016

VIA ELECTRONIC MAIL: glenn.mcguirk@cms.hhs.gov

Mr. Glenn McGuirk
Centers for Medicare & Medicaid Services
Center for Medicare
7500 Security Boulevard
Baltimore, Maryland

Re: July 18, 2016 Advisory Panel on Clinical Diagnostic Laboratory Tests - ADLT Application and Designation Recommendations

Dear Mr. McGuirk:

On behalf of the Coalition for 21st Century Medicine (C21), we welcome the opportunity to provide input to the Advisory Panel on Clinical Diagnostic Laboratory Tests and the Centers for Medicare & Medicaid Services (CMS). In particular, we want to provide our recommendations on the application and designation process for Advanced Diagnostic Laboratory Tests (ADLTs). As CMS works to develop the sub-regulatory guidance for the ADLT application and designation process, the Advisory Panel has a critical role in providing input on implementation of the new ADLT payment category.

Additionally, we urge the Advisory Panel to review and comment on the 2016 Preliminary Gapfill Payment Determinations for the Multianalyte Assays with Algorithmic Analyses (MAAA) and Genomic Sequencing Procedure (GSP) Current Procedural Terminology (CPT®) codes as recently submitted by the Medicare Administrator Contractors. The Advisory Panel previously considered these codes at the August and October 2015 Panel meetings. The Preliminary National Limitation Amounts (Preliminary NLAs), if finalized, would represent drastic reductions in payment rates for these innovative tests in the magnitude of approximately 30% to 90%.

## I. ADLT Application and Designation Process

The release of the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule in June, 2016 provided much needed clarity on numerous provisions necessary to implement the new CLFS market-based payment system. We appreciate that in the Final Rule CMS addressed a number of the specific provisions on the statutory definition of an ADLT such as clarifying that an ADLT includes tests based only on an analysis of proteins and that single laboratory may include more than one CLIA certificate. The Final Rule, however, leaves many operational details to sub-regulatory guidance, including the designation of an ADLT under section

1834A(d)(5). It is critical for CMS to work with the Advisory Panel and other interested stakeholders on the implementation of the ADLT provisions of the Final Rule in order to provide a pathway to promote continued innovation in precision medicine.

A. ADLT Application Process

C21 agrees with CMS that the content of the application should be consistent with the definition of an ADLT in the statute and under 42 C.F.R. §414.502. **The application form should allow a laboratory to demonstrate that the elements of this definition have been met through publicly available information.** For example, CMS does not need extensive documentation to determine that a test is offered and furnished by a single laboratory. Also, CMS can determine that a test provides new clinical information from an empirically derived algorithm by reviewing public sources such as the Methods section of a peer-reviewed publication presenting the validation of the test, to confirm that the markers and algorithm are unique and not simple replicates of the another test. It is possible that two laboratories could develop the exact same "unique test" in parallel, but it is highly unlikely that this would occur because patent holders can and do closely monitor industry developments, and can identify patent infringement with relative ease.

The specifications of an ADLT, particularly those relating to a unique algorithm, are highly confidential. In light of CMS's position that PAMA's confidentiality provisions do not cover information provided to the Secretary for purposes of ADLT determination, the application should only require the submission of non-proprietary information. To the extent that a laboratory may provide proprietary information, such information should be exempt from disclosure under the Freedom of Information Act (FOIA) as trade secret.

The Final Rule does not establish a schedule for submitting an application for classification as an ADLT, or a timeframe for the determination of ADLT status. However, the agency notes that it would consider a quarterly application process. C21 agrees that ADLT application should be submitted and reviewed on a quarterly basis to facilitate the ability of a laboratory to launch a new test and negotiate private payor contracts. Additionally, a quarterly application process has proved to be very effective for transitional pass-through payment status in the hospital outpatient setting.

C21 respectfully requests that this guidance be published significantly in advance of the effective date of the data collection and reporting requirements in 2017 because laboratories will need to apply for ADLT designation and receive a unique code in advance of PAMA's data reporting obligations going into effect.

B. Designation of ADLTs Should Promote Innovation and Competition

The Panel is charged with offering advice and input to CMS on the "evaluation and designation of tests as advanced diagnostic laboratory tests." We agree with CMS that the agency should consider the recommendations of the Advisory Panel as part of the process for designating an ADLT.

In light of the fact that designation of an ADLT does not alone determine whether an ADLT will be covered by Medicare, it is appropriate under the statue and the regulations for designation of an ADLT to be focused on meeting the specific elements of the statute. Separate from ADLT designation, in order to obtain Medicare coverage, laboratories will still need to demonstrate to a Medicare contractor that the test is reasonable and necessary.

In particular, the Final Rule requires that an ADLT "*provide new clinical diagnostic information that cannot be obtained from any other test or any other test or combination of tests*." We understand that CMS has proposed this 'new information' requirement as a way to distinguish tests that are different from those already on the market, but we share the concerns echoed by the Advisory Panel at the October 2015 meeting that application of this provision could hinder innovation of new tests and competition among the labs to produce the most accurate and reliable results. There should be a presumption that a test provides 'new clinical diagnostic information' when a test (1) comprises multiple biomarkers of DNA, RNA, or proteins, (2) incorporates an algorithm to provide a patient-specific result, and (3) is offered and furnished by a single laboratory. CMS should need to overcome this presumption with specific data that another test provides the same diagnostic information. As CMS implements this standard, we believe that the agency should be informed by Advisory Panel on how to determine whether a test provides new clinical diagnostic information.

Additionally, we are concerned that in recent statements CMS indicated that ADLT status would be terminated if the agency determines that a subsequent test provides the same clinical diagnostic information. It would be operationally very challenging for laboratories and CMS to change data collection and reporting requirements once a test is established as an ADLT. CMS should not be concerned about designating similar - but different - tests as ADLTs because ADLT payment rates are based upon annual reporting rather than payment rates locked in for three years. New ADLT tests will compete with each other, decreasing prices, and creating savings for CMS on an annual basis. In contrast, the CMS approach could have the effect of re-categorizing a test from ADLT status to CDLT status, and therefore maintaining the current ADLT rate until the next three year CDLT reporting period.

Lastly, C21 believes that the designation process should provide the opportunity for a laboratory to respond to the agency's initial determination regarding whether a product qualifies as an ADLT prior to releasing any final determination. This will allow the laboratory to respond or to provide additional clinical information to the agency to ensure consistency in the application of the statute and implementing regulations. It is in the interests of transparency for the Advisory Panel to play a formal role in the designation of ADLT status as part of the designation process going forward. We recommend that any test which is initially determined not to be an ADLT should have the opportunity at the election of the laboratory to request a review by the Advisory Panel before a final decision is made by CMS.

## II. Preliminary Gapfill Payment Determinations

We are concerned that the significant variation in pricing among the MACs indicates an inconsistent application of the gapfill regulations at 42 C.F.R. § 414.500, that set forth how CMS is to determine payment rates for new tests based on (i) charges for the test and routine discounts

to charges; (ii) resources required to perform the test; (iii) payment amounts determined by other payers; and (iv) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. The NLAs must be adjusted in the 2016 Final Gapfill Payment Determinations to be released this Fall to comply with the regulatory criteria for gapfill, to avoid substantial fluctuations in payment prior to and with the implementation of Section 216 of the Protecting Access to Medicare Act of 2014, and to assure continued access to these advanced diagnostic tests.

A. MAAA Preliminary NLAs Are Inconsistent With Established Medicare and Private Payer Rates

In November 2015, CMS assigned these six test codes to be gapfilled in 2016 by the MACs. Each of these tests has been covered by the MAC in the jurisdiction where the test is performed and paid under a non-specific CPT code. The Medicare rates currently in effect for each of these tests under unlisted codes were established based by the local MACs considering the four gapfill criteria. These rates have been in effect for a number of years. During the gapfill pricing process earlier in the year, each of the six laboratories submitted to the MACs outside of their local jurisdictions clinical and cost information for each test. These data included the rates already established by their local MACs as well as rates paid by commercial payers.

As is clearly shown in Table 1, the Preliminary NLAs would, if finalized, represent drastic cuts for these tests from the rates currently paid by Medicare—rates which have been established through deliberative consideration of the tests by the local MACs who are covering the tests. As is also clearly shown, four of the MACs representing 28 of the 57 localities have established gapfill rates consistent with the current Medicare rates. By contrast four other MACs—MACs that generally have no familiarity with the tests involved—have established rates that are dramatically, and inexplicably, lower than the current Medicare rates. Because the four MACs representing these regions cover only 28 of the 57 localities and the other four MACs represent 29, the Preliminary NLAs are determined by those other MACs. Attached is a detailed comment letter submitted to CMS.

B. Wide Variations in Pricing Amongst the MACs for GSPs

In addition to the issues relating to the MAAA tests, there are also serious issues surrounding the gapfill process for the GSP codes. We are concerned that wide variable among the MACs for these GSP codes indicate that the gapfill criteria have not been appropriately applied. The differences in pricing both among the contractors are inconsistent with established payer rates and to the costs and resources required to perform these tests. The rates reported by many of the MACs do not reflect a fair assessment of the gapfill criteria.

For example, code 81342 is set to a NLA of $622.53 in the preliminary gapfill, and its sister code 81433 to describe the additional duplication/deletion analysis is set at $159.48. However, a code already on the CLFS describing a combination of the two procedures, 81162, has a NLA of $2485. An analysis of the other preliminary pricing amounts for GSP codes in Table 2 demonstrates no relationship between the length of genomic sequence or number of genes analyzed. We respectfully request that the Advisory Panel recommend that CMS work with the MACs and laboratory stakeholders to revisit the gapfill process to account for this variability in

reported prices due to an inconsistent application of the gapfill criteria for these genomic sequencing procedures. CMS and the MACs should review data submitted by laboratories and apply a consistent methodology to set prices for the GSP codes.

*** * * * * ***

Thank you for considering these comments. We look forward to working with the agency and the Advisory Panel to continue to provide input on the implementation of ADLTs in advance of implementation of these requirements.

Sincerely,

Coalition for 21st Century Medicine

**Table 1: Current Rates and 2016 Preliminary Gapfill Determinations**

| Code | Test/ *Laboratory* | Current Medicare Allowed Amount | Preliminary NLA | Change | ***28 Localities*** CGS--*2* Noridian--*14* Palmetto--*4* WPS--*8* | ***29 Localities*** Cahaba--*3* FCSO--*2* NGS--*12* Novitas--*12* |
|---|---|---|---|---|---|---|
| **81493** | Corus CAD *CardioDx* | $1,050.00 | $741.01 | -29% | $1,050.00<br>$1,050.00<br>$1,050.00<br>$1,050.00 | $741.01<br>$731.49<br>$741.01<br>$731.49 |
| **81525** | OncotypeDx Colon *Genomic Health* | $3,104.00 | $848.86 | -73% | $3,104.00<br>$3,104.00<br>$3,104.00<br>$3,104.00 | $848.86<br>$848.86<br>$780.13<br>$848.86 |
| **81538** | VeriStrat *Biodesix* | $2,112.00 | $283.00 | -87% | $2,112.00<br>$2,112.00<br>$2,112.00<br>$2,112.00 | $283.00<br>$283.00<br>$187.21<br>$283.00 |
| **81540** | CancerTypeID *Biotheranostics* | $2,900.00 | $1,522.17 | -48% | $2,900.00<br>$2,900.00<br>$2,900.00<br>$2,900.00 | $1,522.17<br>$1,522.17<br>$1,268.14<br>$1,522.17 |
| **81545** | Afirma *Veracyte* | $3,200.00 | $2,240.16 | -30% | $3,200.00<br>$3,200.00<br>$3,200.00<br>$3,200.00 | $2,240.16<br>$2,240.16<br>$1,746.80<br>$2,240.16 |

| Table 2: Next Generation Sequencing Multi-gene Panel Tests for Hereditary Conditions | | | |
|---|---|---|---|
| **Code** | **Description** | **# Genes** | **Proposed rate** |
| 81412 | (Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of **at least 9 genes**, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1) | 9+ | **$597.91** |
| 81432 | (**Hereditary breast cancer-related disorders** (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of **at least 14 genes**, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53) | 14+ | **$622.53** |
| 81433 | (**Hereditary breast cancer-related disorders** (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11) | 5 | **$159.48** |
| 81434 | (Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of **at least 15 genes**, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A) | 15+ | **$597.91** |
| 81437 | (Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma; genomic sequence analysis panel, must include sequencing of **at least 6 genes**, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL) | 6+ | **$597.91** |
| 81438 | (Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma; duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL) | 4 | **$597.31** |
| 81442 | (Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of **at least 12 genes**, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1) | 12+ | **$597.91** |

July 12, 2016

Mr. Glenn McGuirk
Division of Ambulatory Services
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

**RE: 2016 Preliminary Gapfill Payment Determinations for New MAAA CPT Codes: 81493, 81525, 81538, 81540, 81545, 81595**

Dear Mr. McGuirk**:**

On behalf of the Coalition for 21st Century Medicine (C21) and the six member laboratory providers listed below, we are pleased to submit comments in response to the 2016 Preliminary Gapfill Payment Determinations for six new Multianalyte Assays with Algorithmic Analyses (MAAA) Current Procedural Terminology (CPT®) codes for existing advanced diagnostic tests.

The Preliminary National Limitation Amounts (Preliminary NLAs), which appear to be based upon the median of rates submitted for these codes for each of the 57 Medicare localities, if finalized, would represent drastic reductions in payment rates for these innovative tests in the magnitude of approximately 30-percent to 90-percent. These Preliminary NLAs are determined by a 29 to 28 locality split among the Medicare Administrative Contractors (MACs) who reported rates for these six tests. Although we have transparency and a clear relationship to the four regulatory criteria for gapfill in 28 of the localities, there is neither transparency nor any apparent relationship to the gapfill criteria among the rates posted for the other 29 localities.

The NLAs must be adjusted in the 2016 Final Gapfill Payment Determinations to comply with the regulatory criteria for gapfill, to avoid substantial fluctuations in payment prior to and with the implementation of Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA 216), and to assure continued access to these advanced diagnostic tests, which the regional MACs where the laboratories are located have determined to be reasonable and necessary and valuable services for Medicare beneficiaries.

## Background on New MAAA CPT Codes

In 2015, the AMA CPT Editorial Panel developed test-specific codes to facilitate data collection and reporting for several existing advanced diagnostic tests. These existing advanced diagnostic tests, the laboratories that developed the tests, the CPT® codes adopted for 2016, and the uses of the tests are shown in Table 1, below:

**Table 1: Tests and Clinical Uses**

| Code | Test<br>*Laboratory* | Clinical Use |
|---|---|---|
| **81493** | Corus CAD<br>*CardioDx* | A non-invasive blood test that incorporates age, sex, and gene expression into a single score that can be used, in combination with clinical assessment, to help clinicians identify patients unlikely to have obstructive coronary artery disease as a cause of their symptoms and help determine appropriate next steps for patient management. |
| **81525** | OncotypeDx Colon<br>*Genomic Health* | A multi-gene test for predicting recurrence risk in patients with stage II and stage IIIA/B colon cancer to enable an individualized approach to treatment planning. |
| **81538** | VeriStrat<br>*Biodesix* | A blood-based predictive and prognostic proteomic test for patients with advanced non-small cell lung cancer who test negative for EGFR mutations (EGFR wild-type) or whose EGFR mutation status is unknown. Assesses disease aggressiveness, classifying patients as either Good or Poor. |
| **81540** | CancerTypeID<br>*Biotheranostics* | A molecular cancer classifier that helps identify the site of origin for cancers with indeterminate, uncertain, or differential diagnoses. The test uses real-time RT-PCR to measure the expression of 92 genes in the patient's tumor and classifies the tumor by matching the gene expression pattern of the patient's tumor to a database of known tumor types and subtypes, encompassing 50 tumor types. |
| **81545** | Afirma<br>*Veracyte* | The Gene Expression Classifier (GEC) measures the expression of 142 genes to determine if the FNA sample that was originally classified by cytopathology as indeterminate is benign or suspicious for cancer -- enabling patients with benign results to potentially avoid unnecessary surgery. |
| **81595** | Allomap<br>*CareDx* | A non-invasive blood test that uses genomic technologies to identify the absence of cardiac rejection. When used in conjunction with standard clinical assessments, may help identify patients with stable allograft function who have a low probability of moderate to severe acute cellular rejection at the time of testing. |

In November 2015, CMS assigned these test codes to be gapfilled in 2016 by the MACs. Each of these tests has been covered by the MAC in the jurisdiction where the test is performed and paid under a non-specific CPT code. Coverage and claims for five of these codes are governed by LCDs from Noridian (81493, 81525, 81540, 81545, and 81595). The other test code (81538) is currently covered and paid under a coverage policy from Novitas. The Medicare rates currently in effect for each of these tests under unlisted codes were established by the local MACs considering the four gapfill criteria. These rates have been in effect for a number of years.

**2016 Gapfill Pricing Process**

During the gapfill pricing process earlier in the year, each of the six laboratories submitted comments and information to the MACs for each test consistent with the gapfill criteria. These data included the Medicare testing volume, rates already established and paid by their local MACs, resources to perform the test, and rates established and paid by commercial payers including Medicare Advantage payers.

The current payment rates for five of the six tests (81493, 81525, 81540, 81545, and 81595) are established in the Noridian regions where the labs reside and all test claims are submitted. These current payment rates were submitted by CGS, Noridian, Palmetto, and WPS which comprise 28 of the 57 localities in the Preliminary Gapfill Determination spreadsheet posted by CMS. The rates posted by these four MACs for the 28 localities are the rates currently in effect and are consistent with the gapfill criteria as noted above and further explained more fully below.

In the case of the sixth test (81538), although its current rate was established by Novitas following the gapfill criteria, the rate posted by Novitas in the Preliminary Gapfill Determination is 87-percent less than the rate Novitas is actually paying for this test – this notwithstanding the fact that the laboratory provided Novitas with information, including Explanations of Medicare Benefits, showing the rate that has been established and paid by Novitas for this test. By contrast, in response to the information provided by that lab to CGS, Noridian, Palmetto, and WPS regions, these four regions did report the rate currently being paid by Novitas for the test.

The current Medicare rate, the Preliminary NLA, the percent reduction represented by the Preliminary NLA, and the rates reported by the MACs under the Preliminary Gapfill Determinations are shown in Table 2, below:

**Table 2: Current Rates and 2016 Preliminary Gapfill Determinations**

| Code | Test/ *Laboratory* | Current Medicare Allowed Amount | Preliminary NLA | Change | ***28 Localities*** CGS--*2* Noridian--*14* Palmetto--*4* WPS--*8* | ***29 Localities*** Cahaba--*3* FCSO--*2* NGS--*12* Novitas--*12* |
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| **81525** | OncotypeDx Colon *Genomic Health* | $3,104.00 | $848.86 | -73% | $3,104.00<br>$3,104.00<br>$3,104.00<br>$3,104.00 | $848.86<br>$848.86<br>$780.13<br>$848.86 |

| Code | Test/ *Laboratory* | Current Medicare Allowed Amount | Preliminary NLA | Change | ***28 Localities*** CGS--*2* Noridian--*14* Palmetto--*4* WPS--*8* | ***29 Localities*** Cahaba--*3* FCSO--*2* NGS--*12* Novitas--*12* |
|---|---|---|---|---|---|---|
| **81538** | VeriStrat *Biodesix* | $2,112.00 | $283.00 | -87% | $2,112.00<br>$2,112.00<br>$2,112.00<br>$2,112.00 | $283.00<br>$283.00<br>$187.21<br>$283.00 |
| **81540** | CancerTypeID *Biotheranostics* | $2,900.00 | $1,522.17 | -48% | $2,900.00<br>$2,900.00<br>$2,900.00<br>$2,900.00 | $1,522.17<br>$1,522.17<br>$1,268.14<br>$1,522.17 |
| **81545** | Afirma *Veracyte* | $3,200.00 | $2,240.16 | -30% | $3,200.00<br>$3,200.00<br>$3,200.00<br>$3,200.00 | $2,240.16<br>$2,240.16<br>$1,746.80<br>$2,240.16 |
| **81595** | Allomap *CareDx* | $2,821.00 | $732.12 | -74% | $2,821.00<br>$2,821.00<br>$2,821.00<br>$2,821.00* | $597.31<br>$732.12<br>$705.24<br>$732.12 |

*WPS reported $2,821-$2,827 across its 8 localities.

As is clearly shown, the Preliminary NLAs would, if finalized, represent drastic cuts for these tests from the rates currently paid by Medicare—rates which have been established through deliberative consideration of the tests by the local MACs who are covering the tests. As is also clearly shown, four of the MACs representing 28 of the 57 localities have established gapfill rates consistent with the current Medicare rates. By contrast four other MACs—MACs that generally have no familiarity with the tests involved—have established rates that are dramatically, and inexplicably, lower than the current Medicare rates. Because the other four MACs represent 29 localities, the Preliminary NLAs are determined by those other MACs.

Applying the Four Gap-fill Criteria Leads to Assignment of the Rates Consistent with the Currently Established MAC Rates

Under Medicare regulations, the MACs are required to consider the following criteria when establishing gapfill rates:

*(b) **Gapfilling**. Gapfilling is used when no comparable existing test is available. (1) In the first year, carrier-specific amounts are established for the new test code using the following sources of information to determine gapfill amounts, if available:*

*(i) Charges for the test and routine discounts to charges;*

*(ii) Resources required to perform the test;*

*(iii) Payment amounts determined by other payers; and*

*(iv) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.*

(42 C.F.R. 414.508(b)(1).)

Our members furnished information consistent with these criteria to the contractors that process their claims to support the establishment of the current Medicare rates for these tests. In addition, as noted above, our members furnished similar information generally to all MACs in support of the 2016 gapfill exercise. We have no transparency into how Cahaba, First Coast, NGS and Novitas may have used the data submitted to calculate the rates shown, but these cannot be based upon the gapfill criteria listed above.

Two of the four criteria relate to rates allowed by other payers. Criterion (i), in referring to charges and discounts, is referring to rates paid for the test by other payers. Criterion (iii) expressly refers to amounts determined by other payers. The current Medicare rates for these six tests are consistent with rates paid by commercial payers and Medicare Advantage payers. These private payer rates and current Medicare rates should be given substantial weight in the gapfill process under these defined criteria.

In terms of resources (criterion [ii]), many of our members submitted detailed information to their MAC comprising financial accounting data on resources expended to develop and run the tests involved and the numbers of tests over which such expenditures are applied. These data reflect the cost of research and development as well as laboratory operations. CMS has repeatedly acknowledged that research and development expenditures are valid and appropriate resources to consider to support rate-setting for clinical diagnostic laboratory tests. These data supported the current Medicare rates established by each laboratory's local MAC at the time of Medicare coverage, and these indicate that the Preliminary NLAs are inconsistent with the resources required to develop and perform these tests.

Criterion (iv) refers to tests that are comparable or otherwise relevant. As the six tests are MAAAs, by definition, they are unique tests for which there are no other comparable tests. It was because there are no comparable tests that CMS choose to gapfill these tests codes rather than crosswalk them to exiting codes on the CLFS.

Although we have no transparency into the basis for the rates submitted by Cahaba, First Coast, NGS and Novitas, it appears that the rates are close to those initially proposed in 2015 for crosswalk for these six tests. As you know, after considerable discussion and presentation of evidence last Summer, CMS rejected crosswalk to such rates for these tests. One cannot allow such rates to return through a backdoor, opaque process by MACs who generally have no familiarity with these tests or who are not considering their own previous pricing determinations.

<u>The Preliminary NLAs are not Consistent with PAMA 216 and Would Result in Substantial Fluctuations in Rates Pre to Post PAMA Implementation</u>

As noted above, the laboratories provided information to the MACs on commercial payer rates to support the establishment of the current Medicare rates. In addition, when we were

engaged with congressional staff on PAMA 216, we provided them information on commercial rates for several member tests. Therefore, we know the commercial payer amounts that will be reported to CMS in 2017 for these tests will support the establishment of rates under PAMA 216 that are consistent with the current Medicare rates. It would be very disruptive – and highly unreasonable – for current rates to be reduced by 30- to 90-percent in 2017 only to rise again under PAMA 216 in 2018.

Although PAMA 216 is not yet in effect, if it were implemented consistent with the statutory timeline, PAMA 216 rates would be in effect in 2017. As you may recall, the only reason the six labs sought new codes for 2016 was to allow reporting of rates this year to support establishment of PAMA 216 rates in 2017. It is clearly inconsistent with congressional intent to impose 30- to 90-percent reductions in rates for tests in the year prior to PAMA 216 implementation when PAMA 216 itself does not permit reductions in rates greater than 10-percent year-over-year for the first three years of implementation.

Failure to Adjust the Final NLAs to be Consistent with Current Medicare Rates Will Jeopardize Continued Access to these Reasonable and Necessary and Valuable Precision Medicine Tests for Medicare Beneficiaries

The laboratories that offer the six tests generally offer only a single test or at most a very limited menu of tests. For several of the laboratories, Medicare-aged beneficiaries are the largest recipients of the testing because of the demographics of the test indication. If reductions in rates are adopted for 2017, it will be difficult for the laboratories to continue to offer these tests, and some of the laboratories may not be able to survive at all. It is little comfort that PAMA 216 rates will be published at the end of 2017 and may reverse such reductions if the laboratories are unable to make it through 2017 due to the drastic reductions.

The tests discussed here are some of the most innovative, clinically valuable precision medicine tests that have been developed over the past 10 to 20 years. They have been shown to help avoid unnecessary chemotherapy, endomyocardial biopsy to identify transplant rejection, thyroid surgery to remove non-malignant glands, and cardiovascular diagnostic testing in patients at low likelihood for coronary artery disease. Health outcomes studies have shown the clinical and economic benefits of these tests. These are exactly the kinds of tests that the President's Precision Medicine Initiative is looking to advance to support the identification of therapies that are personalized to the needs of individual patients. It would be very unfortunate for Medicare beneficiaries and for the Medicare program as a whole if these tests were no longer available because four MACs submit rates for these tests that are inconsistent with the gapfill criteria and inconsistent with the rates that have already been well-established for the advanced diagnostic tests.

* * * *

Thank you for your consideration of our comments. We are happy to discuss this information with you and the MACs at your convenience.

Sincerely,

Coalition for 21st Century Medicine and on behalf of our members:

Biodesix
Biotheranostics
CareDX
CardioDX
Genomic Health
Veracyte