If we established our own criteria in order to resolve the lack of standardization between the standards adopted by the various national accreditation organizations for PCMH, it is possible that the accrediting bodies would then be able to assist us in determining compliance with the CMS criteria. Depending on the nature of the criteria, the CMS criteria may cost less to implement but would likely require a practice to incur the cost for an accrediting body to review the practice's compliance. We invite public comment on the potential approaches we could use to identify advanced primary care practices for purposes of Medicare payment, including the possible use of one or more national accrediting organizations (and whether meaningful use of certified electronic health record technology should be required for such accreditation) as part of a Medicare approval process, as well as any other potential approaches to accrediting advanced primary care practices that we have not discussed here.

c. Beneficiary Attribution for Purposes of Payment

One potential issue surrounding comprehensive primary care services delivered in an advanced primary care practice is attribution of a beneficiary to an advanced primary care practice. We would not expect that there would be more than one practice functioning as an advanced primary care practice for a beneficiary at any given time. However, in a fee-for-service environment we would need to determine which practice is currently serving as the advanced primary care practice for the beneficiary in order to ensure appropriate payment. One method of attribution could be that each beneficiary prospectively chooses an advanced primary care practice. We seek comment on how such a choice might be documented and incorporated into the fee-for-service environment. Other attribution methodologies might examine the quantity and type of E/M or other designated services furnished to that beneficiary by the practice. We welcome input on the most appropriate approach to the issue of how to best determine the practice that is functioning as the advanced primary care practice for each beneficiary. We are not considering proposals that would restrict a beneficiary's free choice of practitioners.

In summary, we believe that targeting primary care management payments to advanced primary care practices would have many merits including ensuring a basic level of care coordination and care management. We recognize that the advanced primary care model has demonstrated efficacy in improving the value of health care in several contexts, and we are exploring whether we can achieve these outcomes for the Medicare population through several demonstration projects. Careful analysis of the outcomes of these demonstration projects will inform our understanding of how this model of care affects the Medicare population and of potential PFS payment mechanisms for these services. At the same time, we also believe that there are many policy and operational issues to be considered when nationally implementing such a program within the PFS. Therefore, we generally invite broad public comment on the accreditation and attribution issues discussed above and any other aspect, including payment, of integrating an advanced primary care model in to the PFS.

I. Payment for Molecular Pathology Services

For CY 2012, the AMA CPT Editorial Panel began creating new CPT codes to replace the current codes used to bill for molecular pathology services. The new codes describe distinct molecular pathology tests and test methods. CPT divided these new molecular pathology codes into Tiers. Tier 1 codes describe common gene-specific and genomic procedures. Tier 2 codes capture reporting for less common tests and each Tier 2 code represents a group of tests that involve similar technical resources and interpretive work. For CY 2012, CPT created 101 new molecular pathology codes; 92 new Tier 1 codes for individual tests and nine Tier 2 codes for common groups of tests. These codes appear in Table 21. We anticipate that CPT will create additional molecular pathology codes for CY 2013.

We stated in our notice for the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting (to be held July 16–17, 2012 at CMS headquarters in Baltimore, Maryland, more information at *https://www.cms.gov//Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Public_Meetings.html*) that we are following our process to determine the appropriate basis and payment amounts for new clinical diagnostic laboratory tests, including the molecular pathology tests, under the CLFS for CY 2013. However, we also stated that we understand stakeholders in the molecular pathology community continue to debate whether Medicare should pay for molecular pathology tests under the CLFS or the PFS. Medicare pays for clinical diagnostic laboratory tests through the CLFS and for services that ordinarily require physician work through the PFS. We stated that we believe we would benefit from additional public comments on whether these tests are clinical diagnostic laboratory tests that should be paid under the CLFS or whether they are physicians' services that should be paid under the PFS. Therefore, we said that we intend to solicit comment on this issue in this proposed rule, as well as public comment on pricing policies for these tests under the CLFS at the Annual Public Meeting. This section first discusses and requests comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work, and then discusses our proposal to address payment for these CPT codes on the PFS, pending public comment on the first question. This proposal is parallel to the invitation to discuss at the CLFS Annual Public Meeting, the appropriate basis for establishing a payment amount for the molecular pathology CPT codes as clinical diagnostic laboratory tests under the CLFS.

As detailed in section II.B.1. of this proposed rule, Medicare establishes payment under the PFS by setting RVUs for physician work, practice expense (PE), and malpractice expense for services that ordinarily require physician work. To establish RVUs for physician work, we conduct a clinical review of the relative physician work (time by intensity) required for each PFS service. This clinical review includes the review of RVUs recommended by the American Medical Association Relative Value Scale Update Committee (AMA RUC) and others. The AMA RUC-recommended physician work RVUs typically are based in part on results of a survey conducted by the relevant specialty society for a service. CMS establishes RVUs for PE under a resource-based PE methodology that considers the cost of direct inputs, as well as indirect PE costs. The AMA RUC, through the Practice Expense Subcommittee, recommends direct PE inputs to CMS, and the relevant specialty societies provide pricing information for those direct inputs to CMS. After we determine the appropriate direct PE inputs, the PE methodology is used to develop proposed PE RVUs. Physician work and PE RVUs for each CPT code are constructed to reflect the typical case; that is, they reflect the service as it is furnished in greater than 50 percent of Medicare cases. CMS establishes resource-based malpractice expense RVUs using weighted specialty-specific malpractice insurance premium data collected from commercial and

physician-owned insurers in CY 2010 (74 FR 61758). For most services paid under the PFS, beneficiary cost-sharing is 20 percent of the payment amount.

CMS establishes a payment rate for new clinical diagnostic laboratory tests under the CLFS by either crosswalking or gap-filling. Crosswalking is used when a new test code is comparable to an existing test code, multiple existing test codes, or a portion of an existing test code on the CLFS. Under this methodology, the new test code is assigned the local fee schedule amounts and the national limitation amount (NLA) of the existing test, with payment made at the lesser of the local fee schedule amount or the NLA. Gap-filling is used when no comparable test exists on the CLFS. In the first year, carrier-specific amounts are established for the new test code using the following sources of information: Charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. For the second year, the NLA is calculated, which is the median of the carrier-specific amounts. See § 414.508. Services paid under the CLFS do not include any physician work, although tests paid under the CLFS can involve interpretation by a laboratory technician, a chemist, or a geneticist—none of which are occupations that meet the statutory definition of a physician. While payments can vary geographically due to contractor discretion across locality areas (which are the same localities used for the GPCIs under the PFS), payments cannot exceed a NLA nor can they be adjusted once rates are determined. In the CY 2008 PFS final rule with comment period, we adopted a prospective reconsideration process for new tests paid under the CLFS, allowing a single year for Medicare and stakeholders to review pricing for new tests after the payment is initially established (72 FR 66275 through 66279, 66401 through 66402). Finally, the statute waives beneficiary cost-sharing for clinical laboratory diagnostic tests paid on the CLFS.

For a handful of clinical laboratory services paid under the CLFS, we allow an additional payment under the PFS for the professional services of a pathologist when they meet the requirements for clinical consultation service as defined in § 415.130. The PFS pays for services that ordinarily require the work of a physician and, with regard to pathology services, explicitly pays for both the professional and technical component of the services of a pathologist as defined in § 415.130 including surgical pathology, cytopathology, hematology, certain blood banking services, clinical consultations, and interpretive clinical laboratory services.

Molecular pathology tests are currently billed using combinations of longstanding CPT codes that describe each of the various steps required to perform a given test. This billing method is called "stacking" because different "stacks" of codes are billed depending on the components of the furnished test. Currently, all of the stacking codes are paid through the CLFS. One stacking code, CPT code 83912 (molecular diagnostics; interpretation and report) is paid on both the CLFS and the PFS. Payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the PFS using the professional component (PC, or 26) of CPT code 83912 (83912–26). Payment for the interpretation and report of a molecular pathology test when furnished by non-physician laboratory staff is made under the CLFS using CPT code 83912.

Since the creation of new molecular pathology CPT codes, there has been significant debate in the stakeholder community regarding whether these new molecular pathology codes describe physicians' services that ordinarily require physician work and would be paid under the PFS, or whether they describe clinical diagnostic laboratory tests that would be paid on the CLFS. The AMA RUC reviewed the 101 new molecular pathology CPT codes and concluded that 79 of 101 new molecular pathology codes include work furnished by a physician. The American Clinical Laboratory Association (ACLA) has indicated that 32 of the 101 new molecular pathology codes are interpreted by a physician and that a physician may perform the technical component associated with 2 of the 101 CPT codes. Only 15 of the 101 new codes appear on both the AMA RUC and ACLA list of codes that each believe include work furnished by a physician. Additionally, some stakeholders have suggested that all molecular pathology tests require physician interpretation and report. Other stakeholders have suggested that the interpretation and report of a molecular pathology test is not ordinarily required because the majority of the molecular pathology tests are clearly negative so interpretation and reporting generally are not necessary. In addition, some stakeholders have argued that molecular pathology tests are becoming more and more automated, and therefore generally do not require interpretation by a physician.

In the CY 2012 PFS final rule (76 FR 73190), we stated that for CY 2012, Medicare would continue to use the existing stacking codes for the reporting and payment of these molecular pathology services, and that the 101 new CPT codes would not be valid for payment for CY 2012. We did this because we were concerned that we did not have sufficient information to know whether these new molecular pathology CPT codes describe clinical diagnostic laboratory tests or services that ordinarily require physician work. For CY 2013, we continue to have many of the same concerns that led us not to recognize the 101 molecular pathology CPT codes for payment for CY 2012. Specifically, we acknowledge that we are lacking definitive answers to the following questions:

- Do each of the 101 molecular pathology CPT codes describe services that are ordinarily furnished by a physician?
- Do each of these molecular pathology CPT codes ordinarily require interpretation and report?
- What is the nature of that interpretation and does it typically require physician work?
- Who furnishes interpretation services and how frequently?

We are seeking public comment on these questions and the broader issue of whether the new molecular pathology codes describe physicians' services that should be paid under the PFS, or if they describe clinical diagnostic laboratory tests that should be paid under the CLFS.

As we continue to consider public comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work, we want to ensure that there is a payment mechanism in place to pay for these CPT codes for CY 2013. We propose to price all of the 101 new molecular pathology codes through a single fee schedule, either the CLFS or the PFS. After meeting with stakeholders and reviewing each CPT code, we believe that there is little variation in the laboratory methodologies, as all of them employ gene sequencing processes. However, there are very different processes for establishing payment rates under the PFS and the CLFS. As discussed above, Medicare sets payment under the CLFS by either crosswalking or gap-filling and, after the prospective reconsideration process, currently cannot adjust the payment amount

further. In contrast, Medicare sets payment under the PFS through a set of resource-based methodologies for physician work, PE, and malpractice expense, and payment can be reviewed and adjusted as the resources required to furnish a service change. We are concerned that establishing different prices for comparable laboratory services across two different payment systems would create a financial incentive to choose one test over another simply because of its fee schedule placement. We are also concerned that the differences in prices would become more pronounced over time as the PFS continues to review the values for physician work and PE inputs relative to established CLFS prices. Therefore, because of the homogeneity of the laboratory methodologies behind these procedure test codes, we believe that it is appropriate for all 101 new molecular pathology CPT codes to be priced on the same fee schedule using the same methodology. We invite public comment on this proposal.

In our effort to determine the appropriate Medicare payment for these new molecular pathology codes, stakeholders will have the opportunity to discuss the CLFS payment basis for establishing payment amounts for the molecular pathology codes discussed above at the CLFS Annual Public Meeting in July 2012. Section 1833(h)(8)(A) of the Act, which discusses the CLFS, requires the Secretary to "establish by regulation procedures for determining the basis for, and amount of, payment [under the CLFS] for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005." Clauses (i) and (ii) of section 1833(h)(8)(B) of the Act requires the Secretary to: 1) Make "available to the public (through an Internet Web site and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount * * * is being considered for a year;" and, "on the same day such list is made available, causes to have published in the **Federal Register** notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis * * * for establishing payment amounts for the tests on such list." Because we believe that these molecular pathology codes may be clinical diagnostic laboratory tests payable on the CLFS, comments and recommendations from the public on the appropriate basis for establishing payment amounts on the CLFS will be discussed at the CY 2013 CLFS Annual Public Meeting. More information on the CLFS Annual Public Meeting is available in the **Federal Register** at 77 FR 31620 through 31622 and on the CMS Web site at *http://www.cms.hhs.gov/ClinicalLabFeeSched.*

As a parallel to our invitation to discuss these molecular pathology codes as clinical diagnostic laboratory tests at the CLFS Annual Public Meeting in July 2012, we also propose payment amounts for these codes under the PFS for CY 2013. The AMA RUC provided CMS with recommendations for physician work RVUs and PE inputs for the 79 CPT codes it believes include physician work. At our request, CAP provided CMS with direct PE input recommendations for 15 of the remaining 22 CPT codes to the best of their ability. We do not have recommendations on physician work RVUs or direct PE inputs for 7 of 101 codes which represent tests that are patented, and therefore the methodology used to furnish the service is proprietary and has been unavailable to the AMA RUC or CMS to support developing appropriate direct PE inputs. For the 79 CPT codes, the AMA RUC-recommended physician work RVUs range from 0.13 to 2.35, with a median work RVU of 0.45. The AMA RUC-recommended physician intra-service times (which, for these codes, equals the total times) range from 7 minutes to 80 minutes, with a median intra-service time of 18 minutes. We would note that the physician work RVU for CPT code 83912–26 and all but one of the other clinical diagnostic laboratory services for which CMS recognizes payment for clinical interpretation is 0.37. Table 21 lists AMA RUC-recommended physician work RVUs and times for these services.

Molecular pathology tests can be furnished in laboratories of different types and sizes (for example a large commercial laboratory or a pathologist's office), and tests may be furnished in small or large batches. The methodologies used and resources involved in furnishing a specific test can vary from laboratory to laboratory. When developing direct PE input recommendations for CMS, CAP and the AMA RUC made assumptions about the typical laboratory setting and batch size to determine the typical direct PE inputs for each service. Given that many of these services are furnished by private laboratories, providing recommendations on the typical inputs was challenging for many services, and not possible for other services. The AMA RUC and CAP-recommended direct PE inputs are available on the CMS Web site in the files supporting this CY 2013 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* We appreciate all of the effort CAP has made to develop national pricing inputs. However, we agree with its view that, in many cases, there is no established protocol for executing many of these tests and that the potential means to execute these tests can vary considerably.

In addition to recommendations on physician work and direct PE inputs, the AMA RUC provided CMS with recommended utilization crosswalks for the 79 molecular pathology services it believes are typically furnished by a physician. When there are coding changes, the utilization crosswalk tracks Medicare utilization from an existing code to a new code. The existing code utilization figures are drawn from Medicare claims data. We use utilization crosswalk assumptions to ensure PFS BN and to create PE RVUs through the PE methodology. Currently, payment for the interpretation and report of a molecular pathology test when furnished and billed by a physician is made under the PFS using CPT code 83912–26. Because CPT created the new molecular pathology codes to replace the current stacking codes, when recommending utilization crosswalks, the AMA RUC started with the total utilization for CPT code 83912–26, and divided that utilization among the 79 CPT codes. CAP has indicated that it distributed the utilization based, in part, on ICD–9 diagnosis data. Table 22 lists the AMA RUC-recommended utilization crosswalks for these services.

We are concerned that the RUC-recommended utilization is too low because it is based on the utilization of CPT code 83912–26 only. Instead, we believe that the utilization assumptions for the technical component of the 101 new CPT codes should be based on the utilization of the corresponding CPT codes currently billed on the CLFS. Several laboratories provided us with a list of the molecular pathology tests that they perform, and identified the stacking codes that are currently used to bill for each test and the new CPT code that would be billed for each test. However, because the same molecular pathology test may be billed using different stacks, and the same stack may be billed for different tests, it is not possible to determine which stacks match which new CPT codes for all Medicare claims. Additionally, if a beneficiary has more than one test on the same date of service and both stacks

are billed on the same Medicare claim, it is not possible to determine which stacking codes on the claim make up each stack. Furthermore, some tests described by the new CPT codes are currently billed using general "not otherwise classified" (NOC) pathology CPT codes that capture a range of services and not just the molecular pathology tests described by the new CPT codes. Given these factors, it is difficult to estimate the utilization of the 101 new molecular pathology codes based on the Medicare billing of the current stacking and NOC codes.

If we were to finalize payment for molecular pathology services under the PFS, we do not believe that we could propose national payment rates at this time. Many outstanding questions remain including:

- If these services are furnished by a physician, what are the appropriate physician work RVUs and times relative to other similar services?
- Where and how are each of these services typically furnished—for example, what is the typical laboratory setting and batch size?
- What is the correct projected utilization for each of these services?

Given these major areas of uncertainty, if CMS determined that new molecular pathology CPT codes should be paid under the PFS for CY 2013, we are proposing to allow the Medicare contractors to price these codes because we do not believe we have sufficient information to engage in accurate national pricing and because the price of tests can vary locally. As previously discussed, this proposal is a parallel to the invitation to discuss at the CLFS Annual Public Meeting the appropriate basis for establishing a payment amount for these molecular pathology tests as clinical diagnostic laboratory tests under the CLFS. If we decide to finalize payment for these new codes under the PFS, we would consider modifying § 415.130 as appropriate to provide for payment to a pathologist for molecular pathology services.

After reviewing comments received on the proposals contained within this CY 2013 PFS proposed rule, and after hearing the discussion at the CLFS Annual Public Meeting, we will determine the appropriate basis for establishing payment amounts for the new molecular pathology codes. We intend to publish our final decision in the CY 2013 PFS final rule with comment period and, at the same time that rule is published, as stated in the CLFS Public Meeting Notice, to post final payment determinations, if any, for the molecular pathology tests that will be paid under the CLFS.

TABLE 21—AMA RUC–RECOMMENDED PHYSICIAN WORK RVUS AND TIMES FOR NEW MOLECULAR PATHOLOGY CPT CODES

CPT Code	Short descriptor	AMA RUC–Recommended physician work RVU	AMA RUC–Recommended physician intra-service time (minutes)
81206	Bcr/abl1 gene major bp	0.37	15
81207	Bcr/abl1 gene minor bp	0.15	11
81208	Bcr/abl1 gene other bp	0.46	18
81210	Braf gene	0.37	15
81220	Cftr gene com variants	0.15	10
81221	Cftr gene known fam variants	0.40	20
81222	Cftr gene dup/delet variants	0.22	13
81223	Cftr gene full sequence	0.40	20
81224	Cftr gene intron poly t	0.15	10
81225	Cyp2c19 gene com variants	0.37	13
81226	Cyp2d6 gene com variants	0.43	15
81227	Cyp2c9 gene com variants	0.38	14
81240	F2 gene	0.13	7
81241	F5 gene	0.13	8
81243	Fmr1 gene detection	0.37	15
81244	Fmr1 gene characterization	0.51	20
81245	Flt3 gene	0.37	15
81256	Hfe gene	0.13	7
81257	Hba1/hba2 gene	0.50	20
81261	Igh gene rearrange amp meth	0.52	21
81262	Igh gene rearrang dir probe	0.61	20
81263	Igh vari regional mutation	0.52	23
81264	Igk rearrangeabn clonal pop	0.58	22
81265	Str markers specimen anal	0.40	17
81266	Str markers spec anal addl	0.41	15
81267	Chimerism anal no cell selec	0.45	18
81268	Chimerism anal w/cell select	0.51	20
81270	Jak2 gene	0.15	10
81275	Kras gene	0.50	20
81291	Mthfr gene	0.15	10
81292	Mlh1 gene full seq	1.40	60
81293	Mlh1 gene known variants	0.52	28
81294	Mlh1 gene dup/delete variant	0.80	30
81295	Msh2 gene full seq	1.40	60
81296	Msh2 gene known variants	0.52	28
81297	Msh2 gene dup/delete variant	0.80	30
81298	Msh6 gene full seq	0.80	30
81299	Msh6 gene known variants	0.52	28
81300	Msh6 gene dup/delete variant	0.65	30
81301	Microsatellite instability	0.50	20

TABLE 21—AMA RUC–RECOMMENDED PHYSICIAN WORK RVUS AND TIMES FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

CPT Code	Short descriptor	AMA RUC–Recommended physician work RVU	AMA RUC–Recommended physician intra-service time (minutes)
81302	Mecp2 gene full seq	0.65	30
81303	Mecp2 gene known variant	0.52	28
81304	Mecp2 gene dup/delet variant	0.52	28
81310	Npm1 gene	0.39	19
81315	Pml/raralpha com breakpoints	0.37	15
81316	Pml/raralpha 1 breakpoint	0.22	12
81317	Pms2 gene full seq analysis	1.40	60
81318	Pms2 known familial variants	0.52	28
81319	Pms2 gene dup/delet variants	0.80	30
81331	Snrpn/ube3a gene	0.39	15
81332	Serpina1 gene	0.40	15
81340	Trb@ gene rearrange amplify	0.63	25
81341	Trb@ gene rearrange dirprobe	0.45	19
81342	Trg gene rearrangement anal	0.57	25
81350	Ugt1a1 gene	0.37	15
81355	Vkorc1 gene	0.38	15
81370	Hla i & ii typing lr	0.54	15
81371	Hla i & ii type verify lr	0.60	30
81372	Hla i typing complete lr	0.52	15
81373	Hla i typing 1 locus lr	0.37	15
81374	Hla i typing 1 antigen lr	0.34	13
81375	Hla ii typing ag equiv lr	0.60	15
81376	Hla ii typing 1 locus lr	0.50	15
81377	Hla ii type 1 ag equiv lr	0.43	15
81378	Hla i & ii typing hr	0.45	20
81379	Hla i typing complete hr	0.45	15
81380	Hla i typing 1 locus hr	0.45	15
81381	Hla i typing 1 allele hr	0.45	12
81382	Hla ii typing 1 loc hr	0.45	15
81383	Hla ii typing 1 allele hr	0.45	15
81400	Mopath procedure level 1	0.32	10
81401	Mopath procedure level 2	0.40	15
81402	Mopath procedure level 3	0.50	20
81403	Mopath procedure level 4	0.52	28
81404	Mopath procedure level 5	0.65	30
81405	Mopath procedure level 6	0.80	30
81406	Mopath procedure level 7	1.40	60
81407	Mopath procedure level 8	1.85	60
81408	Mopath procedure level 9	2.35	80

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES

Source	Destination	Analytic ratio*
83912 26	81206	0.116
83912 26	81207	0.003
83912 26	81208	0.003
83912 26	81210	0.020
83912 26	81220	0.017
83912 26	81221	0.003
83912 26	81222	0.003
83912 26	81223	0.003
83912 26	81224	0.003
83912 26	81225	0.006
83912 26	81226	0.006
83912 26	81227	0.011
83912 26	81240	0.073
83912 26	81241	0.110
83912 26	81243	0.003
83912 26	81244	0.000
83912 26	81245	0.014
83912 26	81256	0.050

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

Source	Destination	Analytic ratio*
83912 26	81257	0.014
83912 26	81261	0.014
83912 26	81262	0.002
83912 26	81263	0.001
83912 26	81264	0.011
83912 26	81265	0.043
83912 26	81266	0.001
83912 26	81267	0.006
83912 26	81268	0.001
83912 26	81270	0.050
83912 26	81275	0.050
83912 26	81291	0.017
83912 26	81292	0.003
83912 26	81293	0.001
83912 26	81294	0.002
83912 26	81295	0.003
83912 26	81296	0.001
83912 26	81297	0.002

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

Source	Destination	Analytic ratio*
83912 26	81298	0.001
83912 26	81299	0.002
83912 26	81300	0.001
83912 26	81301	0.003
83912 26	81302	0.001
83912 26	81303	0.000
83912 26	81304	0.000
83912 26	81310	0.014
83912 26	81315	0.017
83912 26	81316	0.003
83912 26	81317	0.002
83912 26	81318	0.001
83912 26	81319	0.001
83912 26	81331	0.001
83912 26	81332	0.003
83912 26	81340	0.011
83912 26	81341	0.003
83912 26	81342	0.017

TABLE 22—AMA RUC–RECOMMENDED UTILIZATION CROSSWALKS FOR NEW MOLECULAR PATHOLOGY CPT CODES—Continued

Source	Destination	Analytic ratio*
83912 26	81350	0.002
83912 26	81355	0.011
83912 26	81370	0.043
83912 26	81371	0.029
83912 26	81372	0.011
83912 26	81373	0.011
83912 26	81374	0.029
83912 26	81375	0.006
83912 26	81376	0.006
83912 26	81377	0.006
83912 26	81378	0.006
83912 26	81379	0.003
83912 26	81380	0.003
83912 26	81381	0.003
83912 26	81382	0.003
83912 26	81383	0.003
83912 26	81400	0.007
83912 26	81401	0.007
83912 26	81402	0.007
83912 26	81403	0.007
83912 26	81404	0.007
83912 26	81405	0.007
83912 26	81406	0.003
83912 26	81407	0.003
83912 26	81408	0.003

*Percentage of source code utilization transferred to the destination code

J. Payment for New Preventive Service HCPCS G-Codes

Under section 1861(ddd) of the Act, as amended by Section 4105 of the Affordable Care Act, CMS is authorized to add coverage of "additional preventive services" if certain statutory criteria are met as determined through the national coverage determination (NCD) process, including that the service meets all of the following criteria: (1) They must be reasonable and necessary for the prevention or early detection of illness or disability, (2) they must be recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and (3) they must be appropriate for individuals entitled to benefits under Part A or enrolled under Part B. After reviewing the USPSTF recommendations for the preventive services, conducting evidence reviews, and considering public comments under the NCD process, we determined that the above criteria were met for the services listed in Table 23. Medicare now covers each of the following preventive services:

- Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse, effective October 14, 2011;
- Screening for Depression in Adults, effective October 14, 2011;
- Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling (HIBC) to Prevent STIs, effective November 8, 2011;
- Intensive Behavioral Therapy for Cardiovascular Disease, effective November 8, 2011; and
- Intensive Behavioral Therapy for Obesity, effective November 29, 2011.

Table 23 lists the HCPCS G-codes created for reporting and payment of these services. The Medicare PFS payment rates for these services are discussed below. The NCD process establishing coverage of these preventive services was not complete at the time of publication of the CY 2012 PFS final rule in early November, so we could not indicate interim RVUs for these preventive services in our final rule addenda. However, we were able to include HCPCS G-codes and national payment amounts for these services in the CY 2012 PFS national relative value files, which became available at the end of the year and were effective January 1, 2012. From the effective date of each service to December 31, 2011, the payment amount for these codes was established by the Medicare Administrative Contractors.

TABLE 23—NEW PREVENTIVE SERVICE HCPCS G-CODES

HCPCS Code	HCPCS Code long descriptor	CMS National Coverage Determination (NCD)	CMS Change Request (CR)
G0442	Annual alcohol misuse screening, 15 minutes	Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8).	CR7633
G0443	Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes.	Screening Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse (NCD 210.8).	CR7633
G0444	Annual Depression Screening, 15 minutes	Screening for Depression in Adults (NCD 210.9)	CR7637
G0445	High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual, includes: education, skills training, and guidance on how to change sexual behavior; performed semi-annually, 30 minutes.	Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to prevent STIs (NCD 210.10).	CR7610
G0446	Annual, face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes.	Intensive Behavioral Therapy for Cardiovascular Disease (NCD 210.11).	CR7636
G0447	Face-to-face behavioral counseling for obesity, 15 minutes.	Intensive Behavioral Therapy for Obesity (NCD 210.12).	CR7641

Two new HCPCS codes, G0442 (Annual alcohol misuse screening, 15 minutes), and G0443 (Brief face-to-face behavioral counseling for alcohol misuse, 15 minutes), were created for the reporting and payment of screening and behavioral counseling interventions in primary care to reduce alcohol misuse.

We believe that the screening service described by HCPCS code G0442 requires similar physician work as CPT code 99211 (Level 1 office or other outpatient visit, established patient), that may not require the presence of a physician. CPT code 99211 has a work RVU of 0.18 and we believe HCPCS code G0442 should be valued similarly. As such, we are proposing a work RVU of 0.18 for HCPCS code G0442 for CY 2013. For physician time, we are proposing 15 minutes, which is the amount of time specified in the HCPCS code descriptor. For malpractice expense, we are proposing a malpractice expense crosswalk to CPT code 99211. The proposed direct PE inputs are reflected in the CY 2013 proposed direct PE input database, available on the CMS Web site under the downloads for the CY 2013 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/*. We request public comment on these CY 2013 proposed values for HCPCS code G0442, which are the same as the current (CY 2012) values for this service.

We believe that the behavioral counseling service described by HCPCS

Memo

Date:	September 13, 2012
To:	Office of the General Counsel Centers for Medicare & Medicaid Services Division U.S. Department of Health and Human Services
From:	American Clinical Laboratory Association Coalition for 21st Century Medicine
Regarding:	Placement of Molecular Diagnostics on Clinical Laboratory Fee Schedule for CY 2013

The American Clinical Laboratory Association (ACLA) and the Coalition for 21st Century Medicine (C21) submit this joint memorandum on our legal analysis and conclusion in response to the question posed by the Proposed Physician Fee Schedule Rule for CY2013: whether the new molecular pathology procedure codes describe "*clinical diagnostic laboratory tests*" (and should thus be paid on the Clinical Laboratory Fee Schedule) or whether these codes describe "*physician's services that ordinarily require physician work*" (and should thus be paid on the Physician Fee Schedule).[1]

It is our conclusion that the statutory language in Section 1887(a) of the Social Security Act and the existing Centers for Medicare & Medicaid Services (CMS) regulations (specifically 42 C.F.R. § 415.102 and 42 C.F.R. § 415.130) clearly preclude placement of these Current Procedural Terminology (CPT) molecular diagnostic test codes on the Physician Fee Schedule (PFS) because the tests in question do not require interpretation by a physician, and thus require placement on the Clinical Laboratory Fee Schedule (CLFS). It is also our opinion that under the Administrative Procedure Act and Section 1871(a) of the Social Security Act, CMS does not have the legal authority to abruptly amend the existing governing regulations in the PFS Final Rule for CY2013 in order to make — and simultaneously implement — a major change in longstanding policy affecting a wide range of stakeholders.

BACKGROUND

As CMS properly recognizes in the Proposed Rule, in order to use the new molecular CPT codes (81200-81408) for Medicare claims processing in 2013, CMS needs to assign the

[1] 77 Fed. Reg. 44,722 (July 30, 2012).

codes to a Medicare fee schedule. Last year, in the CY2012 PFS final rule, CMS announced that the new codes would not be valid for Medicare purposes in 2012.[2] The new codes were initially classified as Status "I" (invalid for Medicare purposes) in the Final Rule,[3] and reclassified as Status "B" (bundled payment) in Transmittal 2365 (December 9, 2011).[4]

For CY 2013, CMS proposes "to price all of the 101 new molecular pathology codes through a single fee schedule, either the CLFS or the PFS."[5] This memorandum explains why current CMS regulations preclude placement of these clinical laboratory tests on the PFS, and thus require CMS to place these codes on the CLFS. Current CMS regulations explicitly and exclusively define several types of tests that are payable as physician pathology services on the PFS. These genetic tests cannot be classified in any of these allowed categories, since physician involvement is not required for the conduct of these tests.[6] As such, when CMS adopts these and other similar new human genetic CPT codes for Medicare use, the codes should be classified on the CLFS and priced using the CLFS-specific methodologies prescribed in statute and regulation.[7]

Both ACLA and CMS data clearly and unambiguously indicate that that the vast majority of genetic tests are interpreted by nonphysicians. First, CMS data show that physician interpretation of genetic tests is uncommon and 80% of genetic tests are interpreted by non-physicians such as PhDs.[8] Second, the major large genetic test laboratories, most of whom are ACLA and/or C21 members, annually produce tens of thousands of complex genetic test reports — under College of American Pathologists accreditation — with no involvement of physicians.[9] Indeed, ACLA's recent survey of its members established that the vast majority of genetic test services are performed without physicians. This survey included all 180 tier 1 and 2 codes that have been finalized by AMA. ACLA members provided results for 93% of the 180 codes surveyed, thus providing representation of a large volume of these services. The results are clear:

- 99% of the time the TC of the test was performed by a laboratory technician.
- 100% of the time there was a separate interpretation performed.
- 90% of the time that interpretation is performed by a PhD; 10% by a pathologist; and 1% computer-assisted.

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[2] 76 Fed. Reg. 73,026, 73,190 (Nov. 28, 2011).
[3] *Id.* at 73,190.
[4] Although the codes were not valid for payment purposes in 2012, CMS requested that the codes be added to stack code claims for Part B services (Transmittal 2365, Dec. 9, 2011 (Change Request 7654)), and also requested that hospitals report these codes when billing under the OPPS system Transmittal 2386, Jan. 13, 2012 (Change Request 7672).
[5] 44 Fed. Reg. at 44,783 (emphasis added).
[6] *See, e.g.*, 42 C.F.R. § 415.130(c)(4) (permitting payment on the physician fee schedule only where the test [r]equire[s] the exercise of medical judgment by" a physician).
[7] Social Security Act § 1833(h)(1)(A); 42 C.F.R. § 414.500 *et seq.*
[8] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PartBNationalSummaryDataFile.html
[9] Myriad Genetics, Inc., is a member of ACLA and the Coalition for 21st Century Medicine.

LEGAL ANALYSIS

A. The Statute and CMS Regulations Prohibit the Classification of Genetic Tests as Physician Pathology Tests

Under both the Social Security Act and current CMS regulations, the new CPT codes proposed for existing Medicare-approved genetic test services are ineligible for assignment to the PFS, and must instead continue to be assigned to the CLFS. This is clear from the plain language of 42 C.F.R. § 415.102 and 42 C.F.R. § 415.130(b) (governing the fee schedule assignment of laboratory tests). The same conclusion is equally supported by the regulatory history of § 415.130(b), and has been affirmed over the past two decades in CMS precedent, and CMS manual policy.

1. The Statute and Regulations

Medicare policy and common practice have long segregated laboratory tests into two groups: physician pathology services (dependent on the work of a physician to produce the completed test) and clinical laboratory services (e.g., clinical chemistry).[10] Like all types of physician diagnostic tests, physician pathology services are divided into "professional interpretation" payments and "technical component" payments, because CMS must disaggregate physician interpretation work from other work, particularly in regard to hospital inpatients and outpatients.[11] In contrast, since 1984, the statute has required that clinical laboratory tests be paid on the CLFS, which has numerous characteristics that are statutorily distinct from the physician fee schedule or hospital ambulatory payment classifications.[12]

CMS has defined physician pathology tests narrowly since at least 1980.[13] Laboratory tests that do not meet the definition of physician pathology tests are classified as clinical laboratory tests.[14] In 1980, pathologists reacted to CMS's new and narrow definition of payable pathologist services with a series of court actions. Then, in 1982, Congress enacted the Tax Equity and Fiscal Responsibility Act (TEFRA), which expressly authorized CMS to define the services of a physician.[15] Codified at Section 1887(a)(1)(A) of the Social Security Act, the relevant provision states that the Secretary is required to determine which services of a physician "constitute professional medical services, which are personally

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[10] *See, e.g.*, 56 Fed. Reg. 59,510 (Nov. 25, 1991). For additional examples where CMS segregates laboratory tests into two groups, see Social Security Act §1877(h)(5) ("clinical laboratory tests and pathological examination services"). Similarly, CMS created date of services rules for laboratory tests in one year for clinical laboratory tests, and in a subsequent year for physician pathology services; see the regulatory history of 42 C.F.R. § 410.510.

[11] For inpatients, the pathology test technical component is not paid separately, although the pathologist's interpretation is. For non-hospital surgical specimens, separation of the pathology technical and interpretation components allow either to be undertaken by and reimbursed to different laboratories.

[12] Omnibus Deficit Reduction Act of 1984, Pub. L. No. 98-369, *codified at* Social Security Act § 1833(h)(1)(A).

[13] 45 Fed. Reg. 15,550 (Mar. 11, 1980).

[14] 56 Fed. Reg. 59,510 (Nov. 25, 1991).

[15] Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Pub. L. No. 97-248 § 108, 96 Stat. 324, 337 -38 (Sept. 3, 1982), (amending Title XVIII of the Social Security Act by adding a new Section 1887 (42 USC § 1395xx(a)(1)).

rendered for an individual patient by a physician and which contribute to the diagnosis or treatment of an individual patient, and which may be reimbursed as physicians' services . . . ." (emphasis supplied).

CMS subsequently established regulations that narrowly and unambiguously defined the types of laboratory tests payable to a physician, currently codified as 42 C.F.R. § 415.130.[16] This regulation is clearly exclusionary: only laboratory tests, interpretations, or consultations that meet the specified categories are payable to physicians. As stated by 42 C.F.R. § 415.130(b), allowable physician pathology tests can only be paid if they first meet threshold criteria of 42 C.F.R. § 415.102(a)(1) ("the services are personally furnished for an individual beneficiary by a physician") and 42 C.F.R. § 415.102(a)(3) ("the services ordinarily require performance by a physician.").

As discussed below, CMS made crystal clear in contemporaneous rulemaking and response to public comment that the phrase "ordinarily require" was a high bar, meant to allow physician payment for services either only physicians could provide, or services which, in rare cases, might safely be performed by a nonphysician. With application of this criterion to pathology tests, CMS made clear that numerous abstract supervisory roles of a physician in a laboratory did not qualify as personal services to the patient. Instead, a laboratory test payable to a pathologist must require the direct personal work of the physician in every case.[17]

2. These Tests Fail to Meet the Threshold Criteria for PFS Assignment.

Molecular diagnostic tests (and most or all genetic tests) fail to meet both threshold criteria: requiring performance by a physician and being ordinarily performed by a physician. Under the Clinical Laboratory Improvement Amendments, Pub. L. 100-578, 102 Stat. 2903 (Oct. 31, 1988) (CLIA), state laws, and other guidelines, genetic laboratories can be managed by a PhD scientist with appropriate training.[18] Therefore, genetic laboratories do not "ordinarily require" performance by a physician, which is the physician service criterion of 42 C.F.R. § 415.102(a)(3). In contrast, those tests classified by Medicare as requiring physician pathology services at § 415.130(b)(1) and (b)(2) match directly to those services for which CLIA also requires a physician (e.g. morphologic and cellular analysis, histopathology; 42 C.F.R. § 493). In 2007, in discussing whether to create an additional CLIA test category for molecular genetic tests, CMS affirmed that molecular genetic tests

[16] The pathology test regulation was originally created at 42 C.F.R. § 405.556 (48 Fed. Reg. 8931 (Mar. 2, 1983)). It was moderately revised to its present form in 1991 (56 Fed. Reg. 59,510; 59,565; 59,622-24 (Nov. 25, 1991), and later recodified to its present location at 42 C.F.R. § 415.130 (60 Fed. Reg. 63,142 (Dec. 8, 1995)).

[17] *See* 48 Fed. Reg. 8931-32 (Mar, 2, 1983), excerpted in Appendix A. *See also* 48 Fed. Reg. 8902ff (Mar. 3, 1983); 47 Fed. Reg. 43,578 (Oct. 1, 1982).

[18] *See e.g.*, Mass. Gen. Laws c. 111D, § 7 (specifying that the director of a clinical laboratory licensed in the Commonwealth of Massachusetts may, but is not required to, be a physician).

would continue to be classified as complex chemistry tests not requiring physician management or reporting (*see* 42 C.F.R. § 493).[19]

CMS rulemaking has also made it clear that for a laboratory test to be payable to a physician, each and every such laboratory test must require the personal performance in person by a physician. In its 1983 regulations on reimbursement for laboratory services (see excerpt in Appendix A), CMS specifically and expressly rejected the contention that physician medical activities such as abstract help, standby help, or guidance in setting up original protocols or tabulated reference lists of mutation classifications would constitute personally-rendered physician-pathologist services for the purposes of a laboratory test.[20] In no uncertain terms, CMS stated that "[d]irection, administration, quality control activities, setting standards, and similar activities are services furnished by both physician and nonphysician laboratory directors. Such services, in themselves, do not require performance 'by a physician.'"[21] CMS further stated that "personal services include establishing ranges of normalcy, supervising employees, ordering equipment, establishing quality control procedures, and in some instances, analysis of results and the discussion of procedures and results with patients' attending physicians. These services also are furnished by both physician and nonphysician laboratory directors and do not require performance by a physician in person . . . ."[22]

Nevertheless, some stakeholders opposed to CLFS assignment — perhaps unaware of the longstanding CMS interpretation dating back to 1983 — have suggested in their recent comments on the CY2013 PFS Proposed Rule that these laboratory tests require physician performance because the data must be translated and interpreted, because patient reports must be generated, and because physicians do this work. Yet as the preamble to the 1983 CMS rule makes clear, the analysis of results and discussions of those results with patient's attending physicians do not, as a matter of law, meet the threshold for services that "ordinarily require performance by a physician."[23] And the classification of genetic results as normal, benign variants, or deleterious variants is not made anew over and over with each test; the reporting classifications are (in the typical case) standardized and tabulated.

The meaning of the phrase "ordinarily required" was made clear by CMS. In the 1983 regulatory preamble, CMS explained that it deliberately adopted the phrase "ordinarily requiring" the performance of a physician (as opposed to "absolutely" requiring the performance of a physician) in order to avoid forbidding physician payment for services for

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[19] *See* Letter from Judith Yost, CLIA, to Genetics & Public Policy Center (Aug. 15, 2007), *at* http://www.dnapolicy.org/resources/CMSresponse8.15.07.pdf

[20] *See* 48 Fed. Reg. 8931-32 (Mar, 2, 1983), excerpted in Appendix A.

[21] *Id.*

[22] *Id.*

[23] In the same portion of its response, CMS noted that "[o]nly discussions with attending physicians and analysis of results may present involvement of the laboratory physician in activities for an individual patient sufficient to quality as physicians' services reimbursable on a reasonable charge basis. These qualify when they are part of necessary medical consultations." CMS has consistently, for several decades, distinguished the consultation codes when a laboratory test is completed from the operation and production of the clinical laboratory test itself.

which "in a relatively few situations or circumstance [where] the service may be safely performed by a nonphysician."[24] That is, "ordinarily require" means "most of the time." The empirical facts fail to support the central assertion of opponents to CLFS assignment: that "most" genetic tests are interpreted by physicians. To bolster this claim, opponents intentionally focus on an irrelevant statistic – the percentage of all individuals who at some point in a year Code 83912 (genetic interpretation) at least once, who are also physicians. That statistic reveals nothing about the only germane factor: the volume of such tests performed by physicians versus nonphysicians.[25] Opponents of CLFS classification studiously avoid reference to the most important and easily-available key indicator, and for good reason. Publicly-available CMS data indicate that approximately 80% of all genetic interpretations are, in fact, performed by nonphysicians, while only 20% are performed by physicians.[26,27] In light of this CMS data, interpretation of genetic tests cannot possibly be viewed as "ordinarily" requiring a physician.

In the alternative, even if these tests did meet either of the two cross-referenced threshold criteria found at 42 C.F.R. § 415.102(a), genetic tests would further fail to meet any of the four pathology test categories established in 42 C.F.R. § 415.130(b):[28]

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[24] *Id.* at 8909, excerpted in Appendix A.

[25] In other words, opponents imply that if ten different physicians were each to bill Code 83912 once (for 10 tests total), while ten different PhDs were to each bill Code 83912 four times (for 40 tests total), it is nevertheless reasonable to conclude that such interpretation is done by physicians half of the time, rather than only twenty percent of the time. Such logic strains credulity.

[26] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PartBNationalSummaryDataFile.html

[27] Under longstanding policy, claims billed as 83912-26 with a performing physician NPI pay about $20 on the physician fee schedule; claims billed as 83912 (no modifier) pay about $5 on the CLFS schedule. It would strain credulity, based on Medicare's long experience with all types of billing practices, that physicians perform genetic interpretations bill them at the drastically lower PhD rate. Therefore, the count of 83912-26 and 83912 claims segregate physician and PhD interpretations.

[28] CMS applies § 415.130 to the definition of pathology tests at all sites of service, including both inpatient and outpatient. *See* Medicare Claims Processing Manual, Pub. 100-04, Chapter 12.60, *at* https://www.cms.gov/manuals/downloads/clm104c12.pdf

Pathology Test Categories (42 C.F.R. § 415.130(b))			
	Category	**Manual**[29]	**Genetic tests?**
(b)(1)	Surgical pathology services	Claims 12:60(B)	No.
(b)(2)	Specific cytopathology or hematopathology services that require performance by a physician (program operating instructions)	Claims 12:60(C)	No.
(b)(3)	Clinical consultation services (meeting criteria of paragraph (c)(1-4))	Claims 12:60(D)	Consultation only, on a previously completed genetic test (CPT 80500/80502).
(b)(4)	Clinical laboratory test interpretation services (meeting criteria (c)(1), (c)(3), (c)(4))	Claims 12:60(E)	Interpretation only, of a genetic test paid on CLFS (CPT 83912).

Foreseeing that tests would be classified in two groups — physician tests and CLFS tests — the regulatory structure of 42 C.F.R. § 415.130 was crafted by CMS to be objective, definitive, and equally binding on pathologists, laboratories, and CMS policy staff. In the table above, based directly on regulation, categories (b)(1) and (b)(2) describe and exhaust the types of complete tests that are payable as pathology services. Such complete pathology tests have both a physician component and a technical component, analogous to other medical tests such as imaging. Neither category (b)(1) or (b)(2) can be applied to genetic tests.

It is telling that, at 42 C.F.R. § 415.102, CMS uses the standard that physician services must "ordinarily require" a physician. A stronger standard is used to determine whether physician pathologist tests are payable as physician services. 42 C.F.R. § 415.130 gives only two opportunities, at (b)(1) and at (b)(2), under which the entire test (interpretation and technical component) is payable to a physician. At § 415.130(b)(1), surgical pathology tests are allowed - tests that require a physician under CLIA. At § 415.130(b)(2), additional types of tests are allowed (such as cytopathology), but only if they absolutely "require" a physician. In short, the entire pathology test is payable to the physician himself only when no other staff are able to perform it. This is ultimately the most objective and transparent approach, because physicians, nonphysician PhDs, and laboratory staff can all perform an endlessly wide range of tests, but only a few types of test are truly restricted to physicians. It is those tests that CMS, since 1983, has placed on the PFS. By absolutely requiring a physician's work for pathologist services, CMS created a regulatory framework that caused its physician pathology tests to match closely to CLIA's tests that require a physician — a class that does not include genetic tests.

Categories (b)(3) and (b)(4) describe physician work after a test is completed and reported. Category (b)(3) provides for RUC-valued reimbursement of a physician's consultation with another physician to discuss an abnormal and unexpected test result, but not on routine or expected test results. Category (b)(4) selectively allows for the provision of

[29] *Id.*

a RUC-valued interpretation fee for the physician, but this fourth and final category of pathologist service is limited to the interpretation event and does not include performance of the underlying test, which is a clinical laboratory test.[30]

Notably, even when tests are more novel or complex, they do not "require" participation of a physician for their technical component. Much of the complexity of genetic testing is reflected in development and overhead costs in professional time, trials, and software, but these costs are never reimbursed as individual physician services because they are not services by a physician to a specific patient. Advanced tests may require more PhD or physician time in interpretation of an individual test after the technical component is completed. PhD laboratory staff are not a category of physician, but the CLFS coding system and Medicare policy already allow PhD interpretation as a separate line item within the CLFS (code 83912 for interpretation of genetic test by a PhD).

Opponents of CLFS assignment even concede in their own PFS comments — as they must — that genetic tests are frequently interpreted by "specifically trained doctoral scientists." Nonetheless, opponents contend that these PhDs are "unique" in that they have been board-certified in Clinical Molecular Genetics and attained "physician-level skills." Yet as noted, the PFS statute and regulations hinge solely on what services require a physician – that is, services that can only rarely (if ever) be performed safely by anyone else. It is a fact that laboratorians, regardless of their "special skills," are not "physicians" as defined by §1861(r)(1) of the Social Security Act. Nor does performing a specific service that is also sometimes performed by a medical doctor either qualify PhD laboratorians to practice medicine or hold themselves out as physicians. (Indeed, PhD laboratorians would be subject to severe criminal penalties in every state in the nation if they so much as attempted to do so.) Opponents of CLFS assignment, despite their intent to illustrate otherwise, thus affirmatively concede the key point: that where upwards of 80% of the genetic tests at issue are widely and typically interpreted by nonphysicians, these tests cannot be construed as ordinarily requiring performance by a physician.

In closing, CMS should not consider ad hoc arguments about whether genetic tests might be interpreted by physicians, or are sometimes interpreted by physicians, or whether pathologists may usefully advise clinicians on the use of such tests after they are completed. CMS data show that physician interpretation of genetic tests is uncommon and 80% of genetic tests are interpreted by non-physicians such as PhDs.[31] At § 415.130(b)(4), CMS has created a regulatory category which is designed for tests like genetic tests. A physician interpretation is payable for these and several other specific CLFS tests, in that adding modifier "-26" to interpretation-only code 83912 shifts it to payment based on RVUs on the physician fee schedule. This policy approach for a pathologist's interpretation of a select few CLFS tests has been used for many years. The test itself remains on the CLFS in accord

[30] It is this category of service, § 415.130(b)(4), that allows a physician interpretation fee to be paid currently for molecular genetic tests reimbursed on the CLFS. The code for this interpretation is 83912.

[31] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PartBNationalSummaryDataFile.html

with the relevant laws, because in the great majority of cases, interpretation is not done by a physician and does not require a physician.[32]

B. CMS is Prohibited by Law from Amending its Governing Regulations Without Proper Notice and Comment.

In its Proposed Rule, CMS suggests that "[i]f we decide to finalize payment for these new codes under the PFS, we would consider modifying § 415.130 as appropriate to provide for payment to a pathologist for molecular pathology services."[33] In so stating, CMS all but concedes that under existing CMS regulations, payment for these codes is required to be on the CLFS. We agree with this conclusion, for the reasons we have set forth above.

Legally troubling, however, is CMS's proposed possible alternative: to assign the codes to the PFS via the Final PFS Rule, and to simultaneously amend the governing regulation itself to authorize such an assignment. Such a decision, under the present circumstances, would be directly contrary to the provisions of the Administrative Procedure Act, and would be prohibited by law.

Pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(b), it is well-established that an administrative agency that wishes to amend its governing regulations is required to provide sufficient notice of the proposed change, in order to allow for adequate public notice and comment. Subsection 553(b) requires, among other things, that the notice of a proposed rulemaking include "either the terms of substance of the proposed rule or a description of the subjects and issues involved." *Id.* In sharp contrast, PFS CY2013 Proposed Rule offers no "terms of substance" or "description of the subjects and issues involved," as to the potential regulatory amendment to § 415.130, save the vague statement that CMS would "consider modifying § 415.130 as appropriate." Such a statement provides the public with no basis on which to provide responsive comments, and fails to constitute sufficient notice as a matter of law. See Sharp Healthcare, et al. v. Leavitt, Order Granting Motion for a Preliminary Injunction, 08-CV-0170W (S.D. Cal. Apr. 8, 2008).

In the preamble to its 1983 regulations, CMS provided an affirmative and definitive interpretation in the specific laboratory test context of what activities did and did not qualify as "services that require performance by a physician" (see Appendix A). It is well-settled that "[o]nce an agency gives its regulation an interpretation, it can only change that interpretation as it would formally modify the regulation itself: through the process of notice and comment rulemaking." Paralyzed Veterans of America v. D.C. Arena, 117 F.3d 579, 586 (D.C. Cir. 1997). In Alaska Professional Hunters Ass'n, Inc. v. Federal Aviation Admin., 177 F.3d 1030 (D.C. Cir. 1999), the court reaffirmed the Paralyzed Veterans doctrine, stating that "an agency has less leeway in its choice of the method of changing its interpretation of its regulations than in altering its construction of a statute." The Alaska Professional Hunters court noted further that "'[r]ule making,' as defined in the APA, includes not only the

[32] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/NonIdentifiableDataFiles/PartBNationalSummaryDataFile.html

[33] 77 Fed. Reg. 44,785.

agency's process of formulating a rule, but also the agency's process of modifying a rule." Id., 5 U.S.C. § 551(5). See also Paralyzed Veterans, 117 F.3d at 586. In short, "[w]hen an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended its rule, something it may not accomplish without notice and comment." See also Syncor Int'l Corp. v. Shalala, 127 F.3d 90, 94-95 (D.C. Cir. 1997) (a modification of an interpretive rule construing an agency's substantive regulation will "likely require a notice and comment procedure.").

Here, CMS has given 42 C.F.R. § 415.130 a definitive interpretation for years: tests that do not "ordinarily require" performance by a physician are not to be placed on the PFS. Indeed, as articulated above, CMS successfully defended precisely such an interpretation of its own regulation in federal court. In such circumstances, CMS is clearly constrained by the Paralyzed Veterans and Alaska Professional Hunters line of cases, which prohibits significant revisions to an agency's definitive interpretation of a regulation — much less an outright revision of the regulation itself — in the absence of the proper notice and comment period required by law. Where CMS provided no such notice and comment period relating to the suggestion that it would "consider modifying § 415.130 as appropriate to provide for payment to a pathologist for molecular pathology services," such an amendment cannot be accomplished simply through the publication of such a significant change in the Final PFS Rule.

In addition, section 1871(a)(4) of the Social Security Act expressly prohibits CMS from immediately implementing "a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule." The statute instead instructs that in such circumstances, "such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation." *Id.* Here, a PFS CY2013 Final Rule that amended § 415.130 in the manner suggested would not constitute a "logical outgrowth" of a properly and previously published notice of proposed rulemaking, and thus by law could not become operative until there was an appropriate public comment period. As a result, the Social Security Act expressly precludes such an amendment to § 415.130 from becoming operative as a matter of law prior to or at the time of the publication of the Final CY2013 PFS Rule. Thus, placement of these codes on the PFS would be without legal basis, given the existing and unamended provisions of § 415.130.

Finally, even if CMS wished to reconcile the potential proposed modification of § 415.130 with the requirements of the Administrative Procedure Act, CMS could not do so by simply issuing the Final PFS Rule as an "interim final rule with comment." This is because the legally required minimum time period for public comment would almost certainly extend beyond the date on which Final PFS Rule would need to become effective. CMS has stated that it intends "to ensure that there is a payment mechanism in place to pay for these CPT codes for CY 2013."[34] In other words, the "stacking codes" currently being used for these tests will no longer be available for billing as of January 1, 2013. As a result, the new codes

[34] 77 Fed. Reg. 44,783.

must be in effect and available for billing by that date. Even if the proposed modification of § 415.130 were released as part of an interim final, the legal comment period would in all likelihood not expire until after January 1, 2013, leading to the anomalous result of no billable codes being available for any of these existing tests on January 1, 2013. Such a result is untenable, and should be rejected.

In short, CMS has a legal obligation to assign the new codes to the appropriate fee schedule as determined by the regulatory standards that exist at the time of the issuance of the Proposed Rule. An agency cannot both change the rules and apply the changed rule at the same time. To do so would allow agencies unfettered discretion to amend regulations at a whim, enabling them to impermissibly cater rules of general applicability in order to fit specific circumstances. Such an approach to rulemaking would violate the express requirements of 5 U.S.C. § 706 that agency regulations not be arbitrary, capricious, made in abuse of discretion, or otherwise not in accordance with law. If CMS wishes to amend § 415.130, it must do so in accordance with 5 U.S.C. § 553(b).

Conclusion

CMS's longstanding and clear regulatory precedents regarding the fee schedule placement of laboratory tests require placement of genetic test codes on the CLFS. Based on the above analysis, we encourage CMS to formally clarify in the PFS Final Rule for CY2103 that existing law requires placement of the genetic test codes on the CLFS. Public resolution of the continuing ambiguity regarding the fee schedule status of these CPT codes and confirmation of the relevant CMS general regulatory precedent will be exceptionally valuable, providing much-needed regulatory predictability for test developers, Medicare contractors, and providers alike.

Appendix A

48 Fed. Reg. 8909 & 8931-32

federal register

Wednesday
March 2, 1983

Part II

Department of Health and Human Services

Health Care Financing Administration

Medicare Program; Payment for Physician Services Furnished in Hospitals, Skilled Nursing Facilities, and Comprehensive Outpatient Rehabilitation Facilities; Final Rule With Comment Period

applied to the practice of medicine generally, this provision would disqualify many physician services and, in effect, redefine the practice of medicine across the country.

C. Response to Comments

First, we wish to make clear that we do not intend to redefine the practice of medicine, or to disqualify physician services for reimbursement. Our regulations govern only how services furnished to Medicare beneficiaries are paid for, that is, whether on the basis of costs or charges, or from the Part A or Part B trust funds, and how the amounts to be paid are determined. We wish to assure both physicians and the public that all physician services, whether services to individual patients, or services to providers, that are covered under the Medicare program will still be reimbursable under these regulations.

Section 108 of Pub. L. 97-248 clearly requires the Secretary to establish in regulations criteria to determine which services furnished by physicians in hospitals may be reimbursed on a reasonable charge basis under Part B. There is an obvious need to distinguish between the administrative type services that benefit patients generally, e.g., managing a department, quality control, etc., that physicians furnish in hospitals that are properly classified as hospital services reimbursable on a reasonable cost basis, and the services furnished by physicians to individual patients that are reimbursable on a reasonable charge basis. The latter type of services, which we refer to as "physicians' services," are covered only under Part B of Medicare [sections 1832(a)[1], 1861(s)(1)] and, therefore, may be reimbursed only on a reasonable charge basis.

Section 108 directs the secretary to develop criteria for distinguishing between physicians' services to individual patients reimbursable on a reasonable charge basis and professional services of physicians that benefit patients generally. In developing these criteria, in these regulations we incorporated the statute's descriptive language that physicians' services are personally rendered for an individual patient and that they contribute to that patient's diagnosis or treatment. The third requirement, that the service ordinarily requires performance by a physician, further implements the first two requirements. Indeed, as indicated in the legislative history, it is implicit in the statutory language. In addition, it ensures that payment for a service at a level appropriate for physicians is warranted.

We proposed to add language to that of the statute (that is, that "services ordinarily require performance by a physician, and are not frequently and consistently furnished by nonphysicians") because we believe that this criterion expresses the underlying intent of Congress as reflected in the legislative history, and is implicit in the language of sections 1887(a)(1)(A). In some cases, this principle can be clearly applied, such as to physicians working as administrators. Admittedly, in other cases application is more difficult, such as when a physician supervises other health care personnel in the immediate delivery of services.

Because we still hold that this distinction is essential and necessary to implementation of the statute, we are retaining the requirement that, to be reimbursable on a reasonable charge basis, a service must "ordinarily require performance by a physician". However, we have revised the third criterion of the regulation by deleting "and are not frequently and consistently furnished by nonphysicians." Based on comments received, we agree that it would be difficult to administer this part of the third requirement. It is not essential to determine the degree to which a service is performed by nonphysicians in order to decide whether the service requires performance by a physician.

We believe retaining the qualifier "ordinarily", referring to performance by a physician, will be beneficial to all parties concerned in the determinations of whether particular services qualify for reasonable charge reimbursement. An absolute rule would provide no flexibility to permit determinations that services may be reimbursed on a charge basis when in a relatively few situations or circumstances the particular service is being safely performed by nonphysicians. We recognize that there is a continuous evolutionary process in the practice of medicine whereby nonphysicians are trained by physicians to perform services that previously were performed only by physicians. This evolutionary process can result in cost savings and more efficient utilization of physicians' time. We want our criterion to be consistent with this process, particularly to continue to recognize as physicians' services those services that are in the changing process but for which the service does not always require performance by a physician.

We are confident that we, the Medicare contractors, and their medical staffs will be able to apply this criterion in consultation with outside sources of expert medical advice. The vast majority of services reimbursable on a charge basis are readily identifiable, and the cases for which identification is difficult or questionable should be satisfactorily resolvable.

V. Payment for Physician Services to Providers

A. Allocation and Reporting of Compensation Costs

Section 1887(a)(2)(A) of the Act requires that only the part of the total physician compensation cost that is allocated to professional services of the physician to the provider (that is, services related to the physician's professional medical expertise, not for services that may reasonably be furnished by nonphysicians, such as business management, to which the general reimbursement rules are applicable) be considered an allowable provider cost for professional services and taken into account in determining reimbursement to the provider. To implement this, under these regulations, a provider will be able to obtain payment for physician compensation costs only if it can demonstrate to the satisfaction of its Medicare intermediary that a significant and measurable proportion of the physician's time is devoted to services to the provider.

To be paid on this basis, the provider must submit a written allocation agreement between the provider and the compensated physician (that is, any physician who receives compensation, as defined in the regulations, by or through the provider or another organization, such as an organization related to the provider, for furnishing services in the provider) showing the respective amounts of time the physician spends in furnishing physician services to the provider, physician services to patients, and services that are not reimbursable under Medicare. Time records, or other documentation that supports the allocation, must be available for verification by the intermediary upon request.

For purposes of determining these costs, "physician compensation" includes monetary payments, fringe benefits, deferred compensation, and other items of value (but excluding free office space related to treatment of private patients, or billing and collection services) a provider or other organization furnishes a physician in return for the physician's services to it. Other provider costs related to the services, including the capital and operating costs for the space (including office space), equipment, personnel, and other resource inputs necessary to produce the services, are not included in the allocation agreement and are not

purpose. We wish to emphasize, however, that the purpose of this and the other Part B charge limitations we are imposing is to limit Medicare Part B charge payments to what is reasonable.

Comment: The American College of Radiology (ACR) challenged the 40 percent test of reasonableness because they indicate that total hospital costs are higher than total office costs.

Response: It is not the cost of the radiology services that is at issue; it is the reasonable charge for the interpretation. Even though hospital costs for the technical components of a service may be higher than the costs for similar services furnished in a non-hospital office, Medicare's liability for interpretation should be the same because the service furnished by the physicians in interpreting the result of the test is the same.

Comment: The proposed section 405.555(a) states that special rules for determining reasonable charges for radiology services will apply to services furnished in a "* * * hospital radiology department or any other setting that is part of a provider * * *." What criteria are used to determine if a particular setting is "part of a provider?"

Response: Generally, a department or facility is part of a provider if it:

- Is located in the provider, or is operated under the supervision of the provider or the provider's medical staff; and
- Serves the provider's patients.

The purpose of determining whether the facility or department is part of a provider is to ensure that reimbursement is made from the proper trust funds. If the facility is a department of the provider, the overhead costs and operating expenses may be reimbursed only on a reasonable cost basis to the provider. Only charges for the physicians' services may be billed and reimbursed under Part B.

XI. Pathology Services

A. Differentiating Physician and Provider Services: Anatomical Pathology

The laboratory services received by provider patients can be classified either as anatomical pathology services, or as clinical pathology services. Anatomical pathology generally requires examination of body tissue, fluid or cells by the pathologist (or another physician functioning in the capacity of a pathologist) or other direct participation by the pathologist in the performance of the service. In the NPRM, we described anatomical pathology services as generally falling in three subcategories:

- Histopathology (gross and microscopic examination of organ tissue or bone);
- Cytopathology (examination of fluid or cells, including cytogenetics, but generally excluding hematology); and
- Oral pathology.

Since anatomical pathology services are personally furnished for an individual by a physician, ordinarily require performance by a physician, and contribute to the diagnosis of an individual patient's condition, these services are classified under Medicare as physician services, and are paid for on a reasonable charge basis under Medicare Part B, under both existing regulations and these revised regulations.

Comment: Autopsies are considered anatomic pathology services. Does this mean Medicare will pay under Part B on a reasonable charge basis for these services?

Response: While autopsies may be classified as anatomical pathology services, they are not covered under Medicare as physicians' services to patients, since the beneficiary is deceased. An autopsy does not contribute to the diagnosis or treatment of an individual patient's condition. However, the costs of these services are allowable for purposes of determining reasonable cost reimbursement for provider services.

B. Differentiating Physician and Provider Services: Clinical Laboratory Services

Clinical laboratory services generally include microbiological, serological, chemical, hematological, biophysical, cytological, immunohematological, and pathological examinations performed on material derived from the human body. These services are performed to provide information for the diagnosis, prevention, or treatment of a disease, or for assessment of a medical condition, and are performed both in independent laboratories and in hospital laboratories. Most clinical laboratory services are routinely performed by nonphysicians, such as medical technologists, laboratory technicians or, in the case of some tests, by automated laboratory equipment, and do not require performance by a physician.

In regard to this matter, the American Society of Medical Technology points out in its comments on our proposed rule: "* * * that even the accreditation rules used by the College of American Pathologists (CAP) for its laboratory inspection and accreditation program also clearly permit independent clinical laboratories to be directed by non-physician personnel."

In support, they quote Standard III of CAP's accreditation program, which states in part:

> The director of an independent laboratory shall be a physician with training and experience in pathology, or a clinical scientist with adequate training and experience in clinical laboratory work who meets the requirements of a laboratory director under the Clinical Laboratory Improvement Act of 1967.

To the extent that clinical laboratory services do not ordinarily require performance by a physician, our existing regulations, at 42 CFR 405.483(a), have prohibited paying for them on a Part B reasonable charge basis. However, those regulations have not been implemented uniformly, and carriers in some areas have improperly paid Part B reasonable charges for clinical pathology services to provider patients. As discussed in section IV. Above, we attempted, through a notice published on March 11, 1980, to establish uniform implementation and preclude payment on a reasonable charge basis for all clinical pathology services furnished in providers to provider patients.

We have reconsidered this position and are now revising our regulations to specify that under certain conditions Medicare will pay Part B reasonable charges for some clinical laboratory services. The rules governing payment for laboratory services apply to all such services furnished in the provider, including, for example, a pulmonary function department. Under these regulations, the carrier will pay for clinical laboratory services on a charge basis only if the services are personally furnished for an individual patient by a physician, ordinarily require performance by a physician, and directly contribute to the diagnosis or treatment of an individual patient.

The regulations list the following as physician laboratory services that we recognize as meeting the above criteria and, therefore, as reimbursable on a reasonable charge basis:

- Anatomical pathology services;
- Services performed by a pathologist in personal administration of test devices, isotopes, or other materials to an individual patient; and
- Consultations that meet certain criteria.

The last two items on this list include those clinical laboratory services that would meet our tests for payment on the basis of reasonable charges.

Comment: The CAP asserts that every clinical pathology procedure for every patient depends on the professional medical services performed by the

pathologist. They claim that these services are "personally rendered" by the pathologist and "contribute to the diagnosis or treatment" of each individual patient for whom a laboratory test is performed. More specifically, they claim that the pathologist establishes ranges of normalcy for each clinical procedure and must be prepared to analyze results and consult with the attending physician. In addition, as a physician, the pathologist evaluates and prescribes procedures and equipment, professionally directs the laboratory and verifies test results.

Response: Section 1887 requires the Secretary to determine in regulations those services of a physician that constitute professional medical services, that are personally rendered for an individual patient by a physician, and that may be reimbursed on a reasonable charge basis under Part B.

The services for which the commenter seeks reasonable charge payment are specific clinical laboratory tests. Each test has a code number for identification, and when the carrier is billed, the test is so identified. The items billed, that is, the coded services, are rarely "personally rendered" by the physician. The tests are run by technologists, often using automated equipment.

The laboratory physician is required to do nothing with regard to a specific test. He does not order the test, perform the test, or interpret the results; he does nothing for the individual patient that he would not have done if that specific patient had not been admitted to the hospital. Direction, administration, quality control activities, setting standards, and similar activities are services furnished by both physician and nonphysician laboratory directors. Such services, in themselves, do not require performance by a physician.

The services that are "personally rendered" by the laboratory physicians are not the individual tests. The personal services include establishing ranges of normalcy, supervising employees, ordering equipment, establishing quality control procedures, and, in some instances, analysis of results and the discussion of procedures and results with patients' attending physicians. These services also are furnished by both physician and nonphysician laboratory directors and do not require performance by a physician in person. Even though a physician may direct the laboratory and furnish the indicated services, it is not necessary for a physician to do so.

Further, these activities are not done for individual patients, but are professional services rendered for the general benefit of patients. These are administration and supervision of the laboratory department. They are done for the general benefit of all patients utilizing the laboratory. Only discussions with attending physicians and analysis of results may present involvement of the laboratory physician in activities for an individual patient sufficient to qualify as physicians' services reimbursable on a reasonable charge basis. These qualify when they are part of necessary medical consultations.

Comment: If a hospital pathologist continued to bill separately for all clinical laboratory services furnished to non-Medicare patients and received reimbursement from the hospital for such services to Medicare patients, would the compensation received from the hospital be considered to be for services to Medicare and non-Medicare patients?

Response: No. If the hospital reimburses a physician solely for services to Medicare patients, the hospital's reasonable cost for these services is totally a Medicare cost.

Comment: Will the final regulations provide for the carriers to grant equity adjustments to customary and prevailing charge profiles for the pathologist's anatomical pathology and consultative pathology services?

Response: Equity adjustments to customary charges for a pathologist's services will be made by carriers on the same basis as adjustments are made for other physicians. Equity adjustments are not made to prevailing charges.

Comment: One commenter informed us of its belief that some hospital laboratory physicians have made efforts to have hospital rules on laboratory services revised to require attending physicians to request a consultation from a laboratory physician on each patient's laboratory services. This is intended to result in those services being reimbursable on a reasonable charge basis.

Response: These rules specify how and to what extent Medicare will pay for laboratory services furnished in provider settings. They are not subject to modifications by hospital or medical staff rules, nor by State or local law or regulation. Such attempts to circumvent these rules may be made, but we do not expect them to be widespread. To be a covered service, a laboratory consultation must be medically necessary. A significant change in practice pattern, or a difference between otherwise comparable hospitals, would be cause for close review.

Comment: The same commenter also reported allegations that some physicians would seek to evade these rules through misrepresentation of their services.

Response: When instances of misrepresentation are reported to us, we will investigate and take appropriate action.

If it later seems that this problematic practice has increased in response to these regulations, we will initiate tighter review procedures.

Comment: Some commenters suggest that we should allow a physician or entity that incurs the cost of operating a laboratory on a hospital's premises to be reimbursed on a reasonable charge basis for all diagnostic laboratory services furnished by that laboratory to hospital patients, as we do an independent laboratory.

Response: An independent laboratory may bill Part B directly for any laboratory services it is certified to perform for Medicare patients. The Medicare regulations in 42 CFR Part 405, Subpart M, specify the conditions for coverage of services of independent laboratories. In particular, the regulations of 42 CFR 405.1310(a)(1) provide that a laboratory that is located in a hospital and serves the hospital's patients is not an independent laboratory. Thus, a laboratory of this type is not an independent laboratory for Medicare purposes merely because a physician (or other entity) assumes all the costs of operating the laboratory, leases only space from the hospital, and also serves community patients. On the contrary, it is considered a hospital laboratory. Since it is a hospital laboratory, the costs incurred to operate it, and to furnish services to hospital patients, are hospital costs and Medicare reimbursement is on a reasonable cost basis notwithstanding the lease arrangement.

Comment: A number of commenters have indicated that we should permit laboratories in hospitals to be certified as independent laboratories. As such, they could bill for all the services they furnish on a charge basis.

Response: We do not concur. The regulations at 42 CFR 405.1310 state, in pertinent part:

(a) *Independent Laboratory.* An independent laboratory performing diagnostic tests means one which is independent both of the attending physician's office and of a hospital which meets at least the requirement specified in section 1861(e) of the Act to qualify for payment for emergency hospital services under section 1814(d) of the Act. A laboratory which: (1) Is located in a hospital which meets at least the

MEMORANDUM

Date: September 19, 2012

To: Office of General Counsel,
U.S. Department of Health
and Human Services

From: American Clinical Laboratory
Association
Coalition for 21st Century
Medicine

Re: Calendar Year 2013 Centers for Medicare and Medicaid Services (CMS) New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes And Preliminary Payment Determinations: Multi-analyte Assays with Algorithmic Analyses (MAAAs)

On behalf of the American Clinical Laboratory Association ("ACLA") and the Coalition for 21st Century Medicine ("C21CM"), the following memorandum provides our joint legal analysis and response to the Centers for Medicare & Medicaid Services' ("CMS") above-captioned preliminary determination for the Calendar Year 2013 Clinical Laboratory Fee Schedule ("CY2013 CLFS") payment for Multi-analyte Assays with Algorithmic Analyses ("MAAAs")(the "Preliminary Determination"). We believe the preliminary determination that "CMS uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done and does not recommend separately pricing the MAAAs codes" reflects a fundamental misunderstanding of what MAAAs are and, therefore, draws an impermissible conclusion about the benefit category under which these clinical diagnostic laboratory tests fall. As explained below:

- MAAAs represent discrete clinical diagnostic laboratory tests—they are not algorithms or computations that can be separated from "underlying clinical laboratory tests." These are specific tests the performance characteristics for which have been established, as required, by Clinical Laboratory Improvement Amendments (CLIA)-certified, and state-licensed clinical laboratories. MAAAs—not the individual biomarker assays—are specifically ordered by the treating physician, and the MAAA results are used in patient management.

- The tests described under the new MAAA heading of the Physicians' Current Procedural Terminology ("CPT") include many well-established tests that have been covered and paid by Medicare for several years. The term "MAAA" was created as a matter of coding clarity to enable Medicare contractors to identify specifically the tests ordered by treating physicians and billed to the Medicare program. The MAAA coding section was created to address the need for granular coding consistent with the goals and objectives of CMS's own Molecular Diagnostics Services Program (MolDx) initiated in 2012 by Palmetto Government Benefits Administrators. In fact, CMS's Preliminary Determination recommending that MAAAs should be reported and paid as a stack of codes associated with the component biomarker assays is completely inconsistent with the MolDx program.

- Refusing to pay for MAAAs and recommending that clinical laboratories report and bill for multiple biomarker assays would violate both CLIA regulations and Medicare's own billing rules. Laboratories may not report and may not bill for tests that are not ordered by a treating physician.

- Many laboratory tests paid under the CLFS involve calculations, computations, or algorithms that transform raw results into the reportable result ordered by the treating physician. Like MAAAs, these tests are clinical diagnostic laboratory tests paid under the CLFS, and CMS has never suggested that these fall under a different benefit category.

- Recognizing the new MAAA codes and paying appropriately for the tests described by these codes will not set a precedent that CMS will now pay for algorithms or computations that may be performed incidental to biomarker assays that are ordered by treating physicians. Unlike simple calculations that may be reported by clinical laboratories for the convenience of physician interpretation of the underlying tests, which are not separately billed to or paid by Medicare, MAAAs are, in fact, the clinical diagnostic laboratory tests that are ordered by and reported to the treating physician. There are no "underlying tests."

- Failure to pay appropriately for the resources involved in developing, validating, maintaining, and updating MAAAs, will result in a denial of access to these tests for Medicare beneficiaries. Laboratories simply cannot be expected to spend tens of millions of dollars on the development of these tests if Medicare will pay no more for these tests than the cost for a limited number of the operational steps involved with furnishing these tests. In fact, CMS's Preliminary Determination is likely to incentivize laboratories to develop tests with greater rather than fewer markers since Medicare payment will increase depending upon the number of biomarker assays that comprise the MAAA—without consideration for the incremental clinical information furnished.

- Working on a case-by-case basis with these tests over the past several years, Medicare's contractors have developed approaches to fair and reasonable payment for the tests that are now described as MAAAs. In the Final Determination, CMS should defer to its local contractors in pricing these tests.

A. MAAAs are Clinical Diagnostic Laboratory Tests

In the Preliminary Determination, CMS describes MAAAs as "numeric score(s) or a probability (i.e., "p-score") based on the results of laboratory tests and, in some cases, patient information".[1] Similarly (albeit with additional detail), the American Medical Association (AMA) describes MAAAs as:

> ... [P]rocedures that utilize multiple results derived from assays 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.[2]

MAAAs reflect some of the most advanced tests that clinical laboratories furnish today. Many of these tests comprise genetic or proteomic markers that individually may have no clinical meaning to the treating physician, but when combined together and possibly including additional information, do provide clinically meaningful information to the treating physician that is used in patient management.

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[1] Centers for Medicare and Medicaid Services, New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes and Preliminary Payment Determinations, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Preliminary-Payment-Determinations.pdf (last visited Sept. 7, 2012).

[2] American Medical Association, Multianalyte Assays with Algorithmic Analyses Codes (Aug. 20, 2012), http://www.ama-assn.org/resources/doc/cpt/maaadesc.pdf.

For example, the Onco*type* DX® Breast Cancer Assay involves an analysis of the expression of 21 genes that is used to determine the likelihood of recurrence of breast cancer and the treatment benefit of chemotherapy in women with early stage breast cancer.[3] The test was introduced in 2004 and Medicare began to cover and pay for the test in early 2006. The assay is widely accepted in clinical guidelines[4] and is used in approximately half of patients with early stage breast cancer to help guide decisions about the use of adjuvant chemotherapy. Published data show substantial savings to payers through avoidance of unnecessary chemotherapy associated with the use of this test.[5] This test was developed and is performed solely by Genomic Health, a CLIA-certified, CAP-accredited, and multiple-state licensed clinical laboratory located in Redwood City, California. This test involves the determination of the quantitative expression of 21 genes that is run through an algorithm to produce a Recurrence Score. The performance characteristics of the Recurrence Score were established by Genomic Health as required under CLIA. Treating physicians order Onco*type* DX to obtain the Recurrence Score. The laboratory does not report separately the quantitative expression of the 21 genes because the gene expression values generally have no independent meaning to the treating physician.[6] S/he does not order the gene expression values as "underlying tests;" s/he would not know how to use most of these values in the treatment of the patient.

Onco*type* DX is not unique in this regard. There are many similar assays where the test developed and validated by the clinical laboratory and ordered by and reported to the treating physician involves a set of biomarkers transformed into an interpretive value using an algorithm derived from a substantial investment in bioinformatics. These include AlloMap (XDx), Mammaprint (Agendia), Afirma (Veracyte), PreDx (Tethys), Veristrat (Biodesix), Vectra DA (Crescendo Bioscience), Celiac PLUS (Prometheus), and many others currently offered or in development. Each of these tests is offered by a CLIA-certified laboratory and represents a specific test offering by the laboratory—not an add-on calculation or computation to a test that is otherwise ordered and interpreted by the treating physician.

In the Preliminary Determination, CMS indicates "Medicare does not recognize a calculated or algorithmically derived rate or result as a clinical laboratory test since the calculated or algorithmically derived rate or result alone does not indicate the presence or absence of a substance or organism in the body."[7] It is unclear on what basis CMS has established "presence or absence of a substance or organism in the body" as the definition of a clinical diagnostic laboratory test. This definition is not found under the Social Security Act or implementing regulations, and it is not consistent with the definition of a clinical laboratory under CLIA.

There are many diverse clinical diagnostic laboratory tests paid under the CLFS, which, like MAAAs, result in reports that do not indicate "the presence or absence of a substance or organism" in the body. Major examples include the following:

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[3] Genomic Health, Inc., Onco*type* DX Breast Cancer Assay: Overview, http://www.oncotypedx.com/en-US/Breast/HealthcareProfessionalsInvasive/Overview/Overview (last visited September 18, 2012).

[4] Genomic Health, Inc., What Do Major Guidelines Say About the Onco*type* DX Assay?, http://www.oncotypedx.com/en-US/Breast/HealthcareProfessionalsInvasive/Guidelines/Guidelines (last visited September 18, 2012).

[5] *See, e.g.*, Hornberger J, Chien R, Krebs K, Hochheiser L. US insurance program's experience with a multigene assay for early-stage breast cancer. *J Oncology Practice* 2011;7:e38s-e45s.

[6] The laboratory does report the gene expression values for 3 of the 21 genes—those representing the expression of the estrogen receptor gene, the progesterone receptor gene, and the gene for Her-2. These values are reported as a quality measure to help explain the Recurrence Score. These values are not ordered separately by the treating physician nor are these biomarker assays billed to Medicare or any other payer.

[7] Centers for Medicare and Medicaid Services, New and Reconsidered Clinical Laboratory Fee Schedule (CLFS) Test Codes and Preliminary Payment Determinations, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Preliminary-Payment-Determinations.pdf (last visited Sept. 7, 2012).

- Functionality. Examples include the services reported using CPT codes 82820 "Hemoglobin-oxygen affinity (pO_2 for 50% hemoglobin saturation with oxygen)", 85397 "Coagulation and fibrinolysis, functional activity, not otherwise specified (eg, ADAMTS-13), each analyte", 85576 "Platelet, aggregation (in vitro), each agent", and 85651 "Sedimentation rate, erythrocyte; non-automated".

- Enzymatic activity. Examples include the services reported using CPT codes 82657 "Enzyme activity in blood cells, cultured cells, or tissue, not elsewhere specified; nonradioactive substrate, each specimen", and 87905 "Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)".

- Antibiotic sensitivity. Examples include the services reported using CPT code 87184 "Susceptibility studies, antimicrobial agent; disk method, per plate (12 or fewer agents)".

- Time. Examples include the services reported using CPT codes 85002 "Bleeding time", 85175 "Clot lysis time, whole blood dilution", 85345 "Coagulation time, Lee and White", 85347 "Coagulation time; activity", 85348 "Coagulation time; other methods", and 85610 "Prothrombin time".

- Concentration. Examples include the service reported using CPT code 83930 "Osmolality, blood".

None of the tests listed above indicates the presence or absence of a substance or organism in the body yet these are appropriately considered to be clinical diagnostic laboratory tests. It is unclear why CMS now proposes this definition to exclude MAAAs from coverage as clinical diagnostic laboratory tests when the Agency has a longstanding policy of coverage for many tests that do not meet this definition as clinical diagnostic laboratory tests.

Chapter 15, § 80.1 of the Medicare Benefit Policy Manual states that covered clinical laboratory services – as described by sections 1833 and 1861 of the Social Security Act – involve the "biological, microbiological, serological, chemical, immunohematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition."[8] This is almost precisely the definition of clinical laboratory that is found under CLIA.[9]

MAAAs are clinical diagnostic laboratory tests that are validated as required under CLIA and corresponding state licensure requirements. Under CLIA, a laboratory that introduces a test system that is not subject to FDA clearance or approval (e.g., a MAAA) must validate "any… performance characteristic required for test performance"[10] – including any algorithm that is used to derive the result reported for the test. In addition, laboratories that perform MAAAs (or any other laboratory-developed test) on a sample taken from a patient in New York must obtain written approval from the state's Department of Health. Prior to giving this approval, the state requires a laboratory to establish and

[8] Medicare Benefit Policy Manual, Chapter 16, § 80.1.

[9] 42 C.F.R. § 493.2 ("Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.")

[10] 42 C.F.R. § 493.1253(b)(2).

validate the performance characteristics of the assay, including any algorithm used to derive the patient-reported result.[11] Insofar as laboratories accepting specimens nationwide must be licensed in New York, both the CLIA and New York requirements are broadly applicable to the laboratories that offer MAAAs.

B. MAAAs Represent New Codes Created for Purposes of Granularity—MAAAs are Not a New Type of Test for which a Novel Benefit Category Determination Must be Made

The term MAAA was created as the result of a CPT Work Group process that grew out of concerns expressed by payers—including Medicare's own contractors—that current CPT coding was not sufficiently granular to allow contractors to identify the specific clinical diagnostic laboratory test ordered by the treating physician and reported and billed by the clinical laboratory. MAAAs were intended to replace previous coding policy that involved the use of stacked codes or unlisted codes and to provide for test-specific coding for these multi-biomarker assays. This new section of codes—now introduced as part of CPT 2013—is consistent with the MolDx program initiated by Palmetto Government Benefit Administrators in 2012, under which Palmetto, for Medicare region J1, is now requiring test-specific reporting using Z-codes or Palmetto Test Identifiers.[12]

The adoption of a new series of codes to describe these tests does not mean, however, that the tests are new or that their coverage as clinical diagnostic laboratory services and payment under the CLFS is a matter of first impression for 2013. To the contrary, many of these tests have been billed and paid by Medicare's contractors for a number of years. We are not aware of any contractor's ever having questioned whether these tests were clinical diagnostic laboratory tests. Insofar as they meet the CLIA definition of a clinical laboratory and have been developed and furnished by CLIA-certified laboratories and ordered by and reported to treating physicians as discrete tests, Medicare contractors have appropriately recognized these tests as clinical diagnostic laboratory tests and have paid for them under the CLFS.

The Preliminary Determination is completely inconsistent with the goals and objectives of the MolDx program. Rather than recognizing test-specific coding that allows contractors to identify the specific clinical diagnostic laboratory test ordered, the Preliminary Determination recommends that laboratories report the individual biomarker assays that comprise the MAAA, which would hide from the contractors what specifically was ordered, furnished, and reported. This would represent a major step backward in coding and payment policy.

C. Refusing to Recognize MAAA Codes and Instructing Laboratories to Bill for the "Underlying Test" Would Violate CLIA Regulations and Medicare Billing Requirements

In the Preliminary Determination, CMS announced: "CMS uses other codes for payment of the underlying clinical laboratory tests on which the MAAA is done and does not recommend separately pricing the MAAAs codes." In follow up discussions with CMS staff, we confirmed that CMS intends to assign MAAA codes a status that will not recognize these codes for Medicare purposes. The only way to bill for these tests would then be to report those biomarker assays which are measured as part of the

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[11] Wadsworth Center – New York State Department of Health. Laboratory-Developed Tests, http://www.wadsworth.org/labcert/TestApproval/LDAapproval.htm (last visited September 10, 2012).

[12] *See* Palmetto GBA, Jurisdiction 1 Part B: Molecular Diagnostic Services (MolDx) Program (May 30, 2012), http://www.palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~Jurisdiction%201%20Part%20B~Browse%20by%20Topic~MolDx~General~8R5QUL0858?open&navmenu=||.

MAAA for which established codes may exist or to use unlisted codes for those markers for which no codes have been established.

By concluding that a MAAA is paid by reporting the multiple biomarker assays that comprise the MAAA, CMS assumes that clinical laboratories report the biomarkers measured as part of the MAAA as independent tests. For the most part, they do not do so. As noted above, for most MAAAs, the biomarker assays that comprise the MAAAs do not have any independent clinical meaning to treating physicians. This includes most gene expression or protein expression signatures that are involved in certain MAAA tests. Under CLIA, laboratories are permitted to perform and report only those tests that have been ordered by an authorized person (e.g., treating physician).[13] Clinical laboratories cannot report, as distinct tests, the results of individual biomarker assays comprising a MAAA if the treating physician has not ordered these tests. When a treating physician orders a MAAA s/he does not typically order any of the biomarker assays comprising the MAAA as a separate test and, therefore, it would not be appropriate for the laboratory to report the biomarker assays separately as distinct test results.

Similarly, under Medicare billing rules, clinical laboratories may bill only for tests that have been ordered by the treating physician and which will be used by him/her in the management of the patient.[14] As noted above, for most MAAAs, few if any of the multiple biomarker assays that comprise the MAAAs are reported as separate tests. Even if a physician does order one or more of the biomarker assays as a distinct test, it would be extremely unusual for the treating physician to order all such assays as separate tests. Therefore, it would be wholly inappropriate for the clinical laboratory to bill for the multiple biomarker assays comprising a MAAA as CMS suggests in the Preliminary Determination.

D. Many Laboratory Tests Paid under the CLFS Involve Calculations, Computations, or Algorithms that Transform Raw Results into the Reportable Result Ordered by the Treating Physician

In the Preliminary Determination, CMS indicates that it does not pay for calculations or computations. However, calculations and computations transforming raw laboratory results into patient-reportable results are inherent in nearly all clinical diagnostic laboratory tests paid under the CLFS. Moreover, CMS has accepted and assigned payment rates for specific tests which substantially comprise algorithms or computations.

For example, essentially all molecular testing (i.e., analysis of DNA or RNA) requires some computational analysis to interpret the raw signals. This will become increasingly important as these molecular technologies advance with the introduction of next generation sequencing technologies.

Even more traditional laboratory testing comprises the use of calculations to transform raw results. For example, measurement of prothrombin time actually involves the determination of the ratio of the patient's prothrombin time to a reference value, which is then taken to the power of an international

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[13] 42 C.F.R. § 493.1241 (stating that a laboratory "must have a written or electronic request for patient testing from an authorized person").

[14] *See* 42 C.F.R. § 410.32(a) ("All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary."); Medicare Benefit Policy Manual, Chapter 15, § 80.6.1 (defining the term "treating physician" as "a physician, as defined in § 1861(r) of the Social Security Act (the Act), who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem").

standard and reported as an international normalized ratio ($INR=[PT_{pt}/PT_{ref}]^{ISI}$).[15] The INR clearly involves an algorithmic transformation of a patient-specific value, yet Medicare has never suggested (nor should it) that the PT comprises a clinical diagnostic laboratory test and that the INR represents an algorithm that is not a clinical diagnostic laboratory test. MAAAs represent the same type of analysis—multiple biomarkers are transformed through an algorithm to provide the patient-reportable result that the physician uses in the treatment of the patient.

In addition, CMS has accepted and assigned payment under the CLFS to codes that specifically reflect algorithmic transformations and bioinformatics. For example, CPT 87900 "Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics"—is a code representing analysis of data only, yet has been covered as a clinical diagnostic laboratory service and paid under the CLFS for many years.[16] The AMA describes the 87900 service as follows:

> This service is widely used in the management of HIV patients on antiretroviral therapy. This service provides a quantitative prediction of drug susceptibility phenotype for each antiretroviral drug and provides the clinician with a numeric measure of susceptibility or resistance on which to base the selection of multi-drug regimens necessary for effective HIV disease management.
>
> The prediction of phenotypic behavior derives from comparison of the genotypic patterns of the patient with a large relational database of actual phenotypic and genotypic information that is continuously updated with recent clinical isolates representing the changing nature of the pandemic.[17]

CMS appropriately recognizes code 87900 as a clinical diagnostic laboratory test paid under the CLFS. It is unclear how CMS distinguishes these examples to argue that MAAAs are something outside the clinical diagnostic laboratory benefit and not payable under the CLFS.

E. Recognizing the New MAAA Codes and Paying Appropriately for the Tests Described by These Codes Will Not Set a Precedent that CMS Will Now Pay for Algorithms or Computations that May Be Performed Incidental to Biomarker Assays that are Ordered by Treating Physicians

Clinical laboratories will, at times, report simple calculations that transform results of tests that treating physicians have requested in order to help the physician interpret the results of the requested tests. These include results, such as albumin:globulin ratios (reported when albumin and globulin are ordered in addition to the report of the albumin and globulin levels), free thyroxine index (reported when thyroxine and tri-iodothyronine uptake values are ordered and reported in addition to the thyroxine and tri-iodothyronine uptake levels), and anion gap (reported when electrolytes are ordered and reported in addition to sodium, chloride, and CO_2). Unlike MAAAs, these simple calculations are reported separately as a matter of convenience for the physician. These are not ordered separately by the physician nor are these calculated results billed as discrete clinical diagnostic laboratory tests to payers.

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[15] *See, e.g.*, World Health Organization, Annex 3: Guidelines for thromboplastins and plasma used to control oral anticoagulant therapy. *WHO Technical Report Series* 1999;889:64-93.

[16] The CY 2012 NLA is $184.62. CLFS available at: http://www.cms.gov/apps/ama/license.asp?file=/ClinicalLabFeeSched/downloads/12CLAB.ZIP.

[17] American Medical Association, CPT Changes 2006: An Insider's View (2005).

In 1998, the Office of Inspector General (OIG) stated that, in general, it is inappropriate for a laboratory to bill for both a clinical diagnostic laboratory test and the calculations underlying such test.[18] As explained above for many common tests, these simple computational results are not ordered by the treating physician and reflect well-known, publicly-available, calculations that physicians could perform themselves but are provided by the laboratory as a matter of convenience for the physician. Insofar as the OIG's statement is intended to address the performance of these simple, non-proprietary calculations in conjunction with a clinical diagnostic laboratory test, we agree that it would be inappropriate for a laboratory to bill for both the test and the associated calculations, and it is our understanding that laboratories do not bill these computations to Medicare or other payers.

It would not be appropriate, however, to treat MAAAs in a similar manner. The algorithm comprising a MAAA is not a known or simple calculation, nor is it derivable by a physician in clinical practice using the raw analyte measures. Substantial primary research goes into developing and validating the MAAA including the algorithm component. These algorithms analyze high-dimensional data spaces with anywhere from a few to many thousands of data points to provide a clinically meaningful and actionable result for a physician and patient to further guide treatment. Oftentimes, these algorithms are validated through multicenter clinical trials, which are then published in widely-known and well-respected medical journals. As such, the research, discovery and validation of an algorithm with adequate robustness to guide clinical treatment reflects a substantial investment on the part of the clinical laboratory—investments that are greater by orders of magnitude than has commonly been the case for diagnostics generally. It would not be possible to offer these tests if the payment for them did not reflect the resources required to validate and maintain the algorithm.

Regardless of the resources, however, in the case of MAAAs, there is no separation between the multiple biomarker assays and the result of the algorithm or computation. As noted in section A, above, the MAAA inherently comprises two or more biomarkers measured and interpreted multidimensionally through an algorithm to produce the test result. Unlike the albumin:globulin ratio, the free thyroxine index, or the anion gap, the MAAA is not an add-on of incremental information to the true test of interest to the treating physician. The MAAA is the test ordered by the treating physician.

CMS need not worry that paying for MAAAs as distinct tests will create a precedent to pay for simple calculations, like the albumin:globulin ratio, free thyroxine index, or anion gap. By definition, the MAAA is intended to be a comprehensive code incorporating any biomarker assays. Even where a biomarker assay could be reported separately, by the coding policies adopted with the creation of the MAAA series, it would not be appropriate to report these tests separately. Moreover, a critical threshold to seeking coverage and payment for a MAAA is convincing the CPT Editorial Panel to adopt a Category I MAAA code. The CPT Editorial Panel has very high standards for published proof of clinical validity to support adoption of a Category I MAAA code. Therefore, measures that are not independently useful and validated will not be assigned Category I MAAA codes for pricing by CMS.

F. Failure to Pay Appropriately for the Resources Involved in Developing, Validating, Maintaining, and Updating MAAAs Will Result in a Denial of Access to These Tests for Medicare Beneficiaries

Mapping the human genome has enabled revolutionary advances in understanding a wide variety of diseases, and ushered in an era where treatment can be tailored to individual patients based on their DNA

[18] Office of Inspector General, Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076, 45,081 (Aug. 24, 1998).

and specific molecular character of their disease. Complex clinical diagnostic laboratory tests – including MAAAs – make such "personalized medicine" possible.

By understanding the molecular nature of disease, MAAAs increasingly allow clinicians and patients to pick individualized treatment options, rather than basing treatment choices on broad assessments of what works best for a population. Although these genomic technologies are often costly to develop and validate, they commonly eliminate the need for even more expensive diagnostic procedures such as extra imaging studies or diagnostic surgeries, or inappropriate chemotherapeutic and other pharmaceutical costs. Indeed, many MAAAs have been shown through economic studies to produce net significant health cost savings.

To ensure that laboratories (and those who fund their research investments) continue to have a financial incentive to develop MAAAs to improve patient outcomes, and to ensure that MAAAs are available to Medicare beneficiaries, it is critical that the reimbursement for such tests reflect the substantial resources expended to develop these tests. By refusing to consider the costs associated with developing and validating the algorithm(s), however, the rate-setting methodology described in the Preliminary Determination would drastically under-reimburse providers for the costs associated with developing and furnishing MAAAs.

Finalization of the Preliminary Determination with respect to MAAAs will stop investment in these critically important tests used in personalized medicine and will deny Medicare beneficiaries' access to these tests. Laboratories simply cannot be expected to spend tens of millions of dollars on the development of these tests if Medicare will pay no more for these tests than the cost for a limited number of the operational steps involved with furnishing these tests, i.e., only those biomarkers for which there are established codes and payment rates and would be independently covered for the patient's condition. In fact, CMS's Preliminary Determination is likely to incentivize laboratories to develop tests with greater rather than fewer markers since Medicare payment will increase depending upon the number of biomarker assays that comprise the MAAA—without consideration for the incremental clinical information furnished.

G. In the Final Determination, CMS Should Defer to its Local Contractors in Pricing These Tests

Working on a case-by-case basis with these tests over the past several years, Medicare's contractors have developed approaches to fair and reasonable payment for the clinical diagnostic laboratory tests that are now described as MAAAs. For the most part, the contractors have followed a gap-fill-like process.[19] Following this process, the contractors have looked at the following kinds of factors in rate-setting: (1) laboratory charges, (2) rates paid for the test by other payers considering contracts with private payers as well as median or mean payments on fully-adjudicated claims, (3) resources, including laboratory operations and research and development costs to develop the tests, and (4) the health economic impact of the information provided by the test in patient management. Where these distinct factors point to similar rate ranges, the contractors have determined a payment rate within that range. This process has been developed most fully by Palmetto GBA under the MolDx program, but other contractors have employed similar approaches.

[19] The process has not strictly fallen under the gap-fill regulations because the tests often have been billed using an unlisted service code or an unlisted service code combined with a combination of established codes—not a new/revised code under the national gap-fill process. *See* 42 C.F.R. § 414.508(b).

Therefore, we recommend that, in the Final Determination, CMS defer to local contractor gap-filling to determine the payment rate for MAAAs recognizing that these tests are clinical diagnostic laboratory services that are appropriately paid under the CLFS.

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We appreciate the opportunity to share this legal analysis with you and look forward to discussing it during our meeting on September 28, 2012.