The Comments Are In: Stakeholders Categorize Genomic Tests

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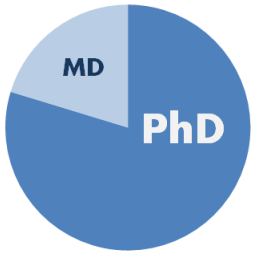
"Under the [TEFRA] amendment, the Secretary is required to differentiate those services that require a physician to personally perform in the diagnosis or treatment of a patient's illness."

Carolyne K. Davis, Administrator of HCFA
October 1, 1982[1]
(Quoting Sen. Robert Dole)

Proportion of Molecular Pathology Interpretations performed by **Non-Physicians** in 2010: **79.7%** Source: American Medical Association	

"Molecular pathology services fall within the purview of 'surgical pathology' services….[Surgical pathology is] microscopic examination of organ tissue performed by a physician…Blood is generally considered a type of tissue….Microscopic is defined to mean small or precise.

"DNA and RNA molecules derived from human organ tissues…examination is conducted at the very small, fine and precise (e.g. microscopic) subcellular or molecular level….the examination of unique genetic characteristics…[is] covered by the definition of surgical pathology."

College of American Pathologists
Comments on Physician Fee Schedule CY2013
September 4, 2012

This is the third white paper in a series[2] documenting Medicare's efforts to begin using 100-plus new CPT codes for molecular diagnostic tests. The codes were approved by the AMA CPT editorial panel in October 2010 and February 2011, allowing publication in October 2011 for use on January 1, 2012.

The first white paper, "Tempest in the Melting Pot: Genomics Reimbursement 2012," appeared in November 2011 and described Medicare's decision to defer use of the CPT codes until 2013. The second white paper, "Tempest Continues: Fee Schedules in Collision," appeared in July 2012 and described Medicare's dilemma, by then already a year old, in assigning the genetic codes to the clinical laboratory or the physician fee schedule. This third white paper, appearing in September 2012, discusses the broad range of stakeholder comments received by CMS. These public comments will inform the decision that CMS will announce in the first week of November, 2012.

From the first widespread clinical use of genetic sequencing tests in the early 1990s up to the present, Medicare, CLIA, and the FDA have classified these tests as clinical laboratory tests. Accordingly, a section of the Medicare statute instructs CMS how it is to reimburse clinical laboratory tests, via a statutory mechanism called the Clinical Laboratory Fee Schedule. With the most complex arguments being introduced by the College of American Pathologists, four major and well-respected stakeholder groups submitted public comments to CMS requesting that genetic tests be transferred to the Physician Fee Schedule, a different payment and policy system. This white paper discusses those comments in the light of existing CMS policy and precedents, and in the light of CMS data described by other stakeholders who believe the tests are best classified as clinical laboratory tests.

What is going on?

The search phrase, "What is going on?" currently triggers 70 million Google hits, and is an appropriate starting point. Medicare is a conglomerate of policies, with variably similar or disparate principles governing the coverage and payment of hospital services (inpatients and outpatients have separate rules), ambulance services, physician services, clinical laboratory test services, and many other categories. It is generally accepted what a laboratory test is, as it has been defined expansively by CLIA to bring all laboratory tests under its umbrella:

> 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.[3]

Both PhD laboratory professionals and physicians have long been equally qualified to supervise and sign out clinical laboratory tests. In some cases, the capability to perform certain laboratory tests has originated with physicians, but migrated to non-physician professionals (for example, only physicians performed urinalysis into the early 1890s, after which, this service was equally rendered by laboratory

staff without physician assistance and review.)[4] Physician pathology services are recognized by CMS as those which require a physician:

> 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…by the pathologist or other direct participation by the pathologist in the performance of the service…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 by Medicare as physician services.[5]

The same dichotomy is recognized by CLIA without regard to Medicare-specific policies. For example, in 1988, CLIA noted it had been using a definition of "clinical laboratory" historically found at 42 CFR 405.130 which stated that a "clinical laboratory" conducted microbiological, serological, chemical, pathological, cytological [etc], examinations. CLIA stated that this definition confused some parties, because "anatomic services" (physician pathology services) are "generally not considered" to be part of "clinical laboratory" services.[6] Another example of the division of laboratory tests is the separate boards for physicians in clinical pathology versus anatomic pathology.

CLIA provides numerous categories of laboratory services, with separate professional qualifications for each (see 42 CFR 493). A category by category review shows that most CLIA categories can be supervised by pathologists or non-pathologist professionals. However, there are several categories, such as anatomic pathology, that require physicians. These pathologist categories in CLIA foot to the categories recognized by CMS in its manual as physician pathology services (Claims Processing Manual, Chapter 12 § 60.) While TEFRA rulemaking in 1982 focused on hospital pathologist services, both CLIA regulations and Medicare's general policy manual make exactly the same distinctions without regard to hospital-based services.

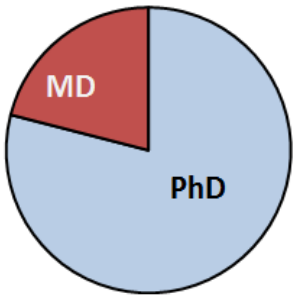
A distinction between physician pathology tests and clinical laboratory tests is hardly new, and the distinction has been necessary for decades in order for CMS to apply numerous policies that require separation between the two classes of test. To begin with the most obvious, the statute requires point blank that clinical laboratory tests are paid on the clinical laboratory fee schedule (SSA 1833(h)(1)(B)). Absent a separate definition in SSA 1833 (and there is none), the definition must have been self-evident, whether based on the principle of common usage or by Medicare's own policies (such as the 1982 TEFRA rulemaking conducted just prior to the 1984 CLFS law.) CMS created date of service regulations in one year for "clinical diagnostic laboratory tests" and in the next year for physician pathology tests (42 CFR 414.510, "EITHER a clinical laboratory test OR the technical component of a physician pathology service."). Similarly, the anti-markup regulation applies to diagnostic tests "other than clinical diagnostic laboratory tests," requiring that such a category be clearly defined in order to implement the rule (42 CFR 414.50(a)(1).) The statute refers to "a request by a pathologist for clinical diagnostic laboratory tests AND pathological examination services" (1877(h)(5)). In every case, Medicare was distinguishing those tests that "required" a pathologist versus those that did not. This is brilliantly efficient: If you looked to tests that could be undertaken by either a PhD or a pathologist, an infinite kaleidoscope of tests would be in question. If you look to which tests "require" a pathologist, CLIA

regulations and other sources make the result plain and simple. CMS explicitly reviewed and redetermined in 2003 that genetic tests do not require an MD, and classified genetic tests in 2007 as complex clinical laboratory tests in a category that require no physician.[7] CLIA specifically authorizes appropriately trained and credentialed PhD staff to provide a full range of clinical support, able to guide the appropriateness of the testing ordered and interpretation of test results; provide clinical consultation to the laboratory's clients; ensuring appropriate tests are ordered to meet clinical expectations; ensure that reports included require patient information in their interpretation regarding specific patient clinical conditions.[8] The FDA classifies sequencing tests as clinical chemistry (vide infra; 21 CFR 864.7280.)

Most genetic laboratories are directed by PhD staff, and the newest authoritative U.S. guidelines for CLIA/CDC on performing genetic tests were written by a PhD team including no physician.[9] Similarly, CMS data indicates that 80% of molecular pathology interpretations are rendered by PhDs:

Medicare data shows that some 80% of genetic tests interpretations are signed out by PhDs and 20% are signed out by MDs.[10] CMS data separately reports 83912 (no modifier = CLFS = $5) and 83912-26 (physician signature; PFS; about $20).

CPT MDX Interp.	Global + "26"	"26" only (MD)	Total – MD = PhD
83912	367,386	76,317	291,051
	100%	21%	79%
AMA RVRVS Database 2012 (CMS Pt B, 2010 Utilization Data)			



Because there is a four-fold difference in payment for the two 83912 interpretations, and the policy has existed for many, many years, it is beyond rationale belief that most labs are unaware of this and that many MD's sign out for the $5 fee. The above data represent the difference in MD and PhD sign out proportions.

Independent laboratories have publicly stated, at least as represented by the very, very large American Clinical Laboratory Association, that the overwhelming majority of genetic tests are managed and signed out by PhDs.[11] Also publicly, one of the largest genetic laboratories, Myriad Genetics, stated that its 250,000-plus tests per year are signed out by PhDs, rather than by MDs, and in a CAP-accredited laboratory.[12] (These industry positions comport with CMS 83912 data.) There is overwhelming and objective data from CLIA, from CMS utilization, and from very large laboratories that MDs cannot be personally and physically "required" to run and sign out each genetic test. It is so obvious that MDs are not required that arguing the opposite is counterfactual, like arguing that Dallas is north of Chicago.

There must be another point of view

The other point of view appears to be shifting. For example, the AMA RUC committee stated in public comments to CMS on October 1, 2011, that as a matter of committee policy, "the RUC does not make recommendations regarding the assignment of a service to a particular payment schedule." In its August 30, 2012 comment, the RUC took the exact opposite position: That it does make recommendations regarding the assignment of a service to a particular CMS schedule. Like the RUC, in 2011, the AMA made no comment as to which particular payment schedule the codes should be assigned (August 29, 2011). This year, the AMA stated that "policy factors dictate the placement of these codes on the physician fee schedule" (September 4, 2012).

Most remarkably, we surveyed the letters of six major commenters for any citation of the information (see pie chart above) that 80% of Medicare genetic interpretations were signed out by PhDs.[13] Despite access to the data (in the case of the AMA, actually publishing the data), none of the six had time, in dozens of cumulative pages of comment, to cite this key statistic. The RUC stated, without footnote, that "currently greater than 50% of the providers reporting these services are physicians." Apparently they had access to the full data - that no more than one-fifth of tests were signed out by physicians - and chose instead to use a head count of how many physicians had signed out at least 1 molecular report. Of course, the question at issue is to address Medicare's regulation that the service must "ordinarily require" a physician, and information that 1 case in 5 uses a physician falls far short of that standard, by any logic.[14] For example, if a laboratory had 10 cases signed out by 3 MDs, and 2,000 cases signed out by a PhD, one would conclude that the majority of professionals signing out cases were MDs. The data would hardly prove that the PhD was unable to sign out the cases because an MD was required.

Notably, in making this argument, the American Society of Clinical Pathology, the Alliance of Dedicated Cancer Centers, the Association of Molecular Pathology, and the College of American Pathologists all dated their letters on exactly September 4, 2012, the date the comment period closed, and a date that would block any other commenter from pointing out the illogic while the comment period was still open.

Aside from the bald claim that all genetic tests always require a pathologist to sign them out, there were two other primary policy arguments.

- The first is that genetic information requires a professional interpretation to be useful.
- The second is that genetic tests are surgical pathology.

1. Genetic tests require professional interpretation.

What this really means is that a raw sequence result (e.g. A410T) is not clinically meaningfully but its classification is ("dominant disease-causing mutation.") That act of classification is usually tabular and

may even be automated; it is not repeated as a new intellectual inquiry for each mutation each time a that gene is clinically sequenced in the U.S. In order to assess this, let's look just at two of the most common tests among the physician-requiring codes, 81240 and 81241 (Factor 2 and Factor 5 genetic tests) which together comprise 19% of genetic tests, per the AMA RUC (Comment, 8/31/2012). The Factor 2 test requires 7 minutes of physician work. The Factor 5 test is more difficult, and requires 14% more physician work to review, describe, and complete each test (8 minutes).[15] Illumina received FDA approval for these tests in May, 2010.[16] The VeraScan equipment "controls all Reader operations including initialization, scanning, and maintenance routines such as calibration…the GT Module analyzes scan data to call genotypes…the software displays data results and graphical visualizations to help the user interpret run success." Given the fact this is one of the most common genetic tests, and is classified by the RUC and CAP as "requiring" a physician, and is run by labs staffed by PhDs, it is difficult to conclude that each performance of the test (e.g. looking at graphic visualizations to interpret run success, as the FDA states) requires a physician. The mere review of run quality in a clinical chemistry lab can't possibly be claimed to be a "unique physician capability" such that anyone else undertaking it was violating practice of medicine laws.

Generally, the assignment of a mutation (e.g. A410T) to a classification is tabular or even automated. In the alternative, if such a table of mutations were markedly different for every laboratory, depending on the local whim of the physician (or PhD) from day to day, quality controls would be impossible and the genetics industry would be in a state of chaos that clearly does not exist. Thus, the tables *must generally be uniform*. Returning to 48 FR 8932, CMS responded that overall determination of a medically important panel of tests for the laboratory, or its "normal range," etc., are not "personally rendered" by the MD for each patient's test, and services were noneligible if they could be performed "by both physician and nonphysician laboratory directors."

To the general and tired argument that genetic tests are "medical" tests that involve "medical" impacts on patients, and that a physician may have been involving in setting up rules or laboratory protocols, this is a consideration that was completed rejected by CMS both in federal rulemaking in 1983 (48 FR 8932) and in the body of a readily available federal court case.[17] CMS heard and dismissed claims that "services are 'personally rendered' by a pathologist…pathologist establishes the range of normalcy [e.g. a table of mutations by reference to review articles]…as a physician, the pathologist…professionally directs the laboratory."

2. Genetic tests are surgical pathology services.

The College of American Pathologists has publicly determined that genetic tests can and should be classified, for regulatory purposes, as surgical pathology.

CAP appends to its September 4, 2012 comments its February 24, 2012 memorandum to CMS concluding that genetic tests are surgical pathology under applicable regulations.

> "Molecular pathology services fall within the purview of 'surgical pathology' services….[Surgical pathology is] microscopic examination of organ tissue performed by a physician…Blood is generally considered a type of tissue….Microscopic is defined to mean small or precise.
>
> "DNA and RNA molecules derived from human organ tissues…examination is conducted at the very small, fine and precise (e.g. microscopic) subcellular or molecular level….the examination of unique genetic characteristics…[is] covered by the definition of surgical pathology."

I find it unlikely that CMS will take this argument on its face and indicate its agreement in the final rule in November 2012, but we will have to see. I can speak with some authority as a board-certified anatomic pathologist and as a native English speaker. Surgical pathology is microscopic examination of organ tissue. But obviously the meaning of microscopic in this sentence is not "small or precise," the meaning is "with a microscope." One of the most senior Supreme Court justices, Antonin Scalia, has published a book this summer on canons of interpretation of regulations and statutes.[1] It was published on June 19, 2012, and thus can be considered germane to CAP's September 4 comment.[18] According to these authorities, a word takes its meaning from context. While there is a meaning of "microscopic" that means "itty bitty," and DNA is "itty bitty," in the context of healthcare pathology regulations, the word microscopic can only mean "with a microscope."[2] The equipment used to assess DNA is sequencing equipment, not microscopes.[19] For example, contra to CAP's argument, microscopes and microscope accessories are found at 21 CFR 864.3600 (under "Pathology Equipment") whereas e.g. Illumina sequencing equipment is classified as 21 CFR 862.2570 (under "Clinical Chemistry Equipment.") As noted early, genetic tests are classified by the FDA as clinical chemistry tests.[20] That is the FDA's view, based on very close examination of each test and decades of experience. With regard to CLIA, if genetic tests were surgical pathology, they could only in performed in laboratories managed by physicians. There seems to be little support for CAP's determination that genetic tests are surgical pathology, which would have wide-ranging impacts that dwarf the issue of fee schedule assignment. And finally, CMS bent over backwards to emphasize that genetic tests were a type of complex clinical chemistry test in 2007, in response to public requests to create a different categorization for genetics under CLIA.[21]

Finally, there are two minor policy arguments:

- Genetic tests are mostly performed by physicians at hospitals.

[1] Scalia has 25 years' experience on the Supreme Court. His coauthor is the editor of Black's Law Dictionary.
[2] Parenthetically, the argument lodged by CAP equally would lead to all viral genetic tests being classified as PFS tests, in that they examine the itty-bitty genes of viruses, though they are generally run on gene sequencing equipment using FDA kits and do not involve physicians (or microscopes). For that matter, glucose and cholesterol are even itty-bittier (more microscopic) than genes, and even more like surgical pathology…

- Other non-physician services are found on the PFS.

3. Genetic tests are mostly performed by physicians at hospitals.

Here, stakeholders argue against themselves, having argued that regulation 415.102 and 415.130 applies "only in hospitals" and then arguing the importance of pathologists for genetic tests in hospitals. Many cancer genetic tests would follow hospital rules, since CMS policy applies hospital billing rules as late as 30 days after the patient is discharged.[22] Regardless, as noted earlier, the narrowly allowed pathology tests at 415.130 are also general CMS policy, with no restriction to location, in Claims Manual 12 § 60.

Many CPT codes are only performed by physicians and only in hospitals.[23] For example, in 2010, CPT code 33945 was performed only by surgeons, only in hospitals. Diagnostic colonoscopy (43578) was performed only by physicians, 50% of the time in outpatient hospitals (most others in ASCs.) However, code 83912 was performed 1 time in 5 by physicians, and 98.5% of the time in "independent laboratories," not hospitals. Genetic interpretations were billed only 1% of the time by pathologists and only 1.5% of the time in a pathologist practice location. In contrast, those familiar services classed by Medicare as "pathology services" (e.g. 88305, surgical pathology) are very often billed by pathologists, and billed by them in pathologist practices, giving credibility to RUC survey data obtained by its physician members and for the physician-office paradigm of cost assessment.

4. Other non-physician services are found on the PFS.

This is true, for example, services of a clinical psychologist or a physical therapist.[24] These types of practitioners can enroll in Medicare and submit claims for direct payment. Their payments are found on the PFS. There is no other location for them. In contrast, the Medicare statute says point blank that clinical laboratory tests are paid on the clinical laboratory fee schedule. Something major has to intervene - for example, proof that they fail to be classifiable as clinical laboratory tests - to take them off the clinical laboratory fee schedule.

Coda: CMS Opines on MAAAs

On August 31, 2012, CMS published its "Preliminary Payment Determination" for new CLFS test codes.[25]

For CY2013, the AMA has created a new section of laboratory codes for "multi analyte assays with algorithmic analyses." In response to tests coded under this new section, CMS writes that:

> A MAAA is a numeric score(s) or a probability (i.e., "p-score") based on the results of laboratory tests and, in some cases, patient information. 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.

For readers who have not seen the original document, the heading of this section is "Rationale." CMS is stating that it does not recognize as a clinical laboratory test a test whose algorithmically derived rate "does not indicate the presence of absence of a substance or organism in the body." The text regarding "presence or absence of a substance" is not footnoted, but if the rationale were correct, somewhere in a prior policy document it is stated that payable tests must indicate "the presence or absence of a substance or organism."

It turns out this phrase was born on August 5, 1988 during CLIA rulemaking, although it is preserved in today's CLIA regulations at 42 CFR 493.2. Just as CAP used the term "microscopic" in a meaning clearly out of keeping with its context, we won't need to seek the personal opinion of Justice Scalia to recognize that a few words have been cherry-picked entirely out of their original context.[26]

The reader may recognize that CLIA '88 was passed in 1988, but not until October 31, 1988.[27] Earlier, in August, when the future of CLIA statutory change was highly uncertain (it had also been attempted in the 1970s), HHS proposed a reorganization and revision of existing CLIA regulations. CMS presented an expansive definition of laboratory tests, seemingly encompassing the whole university of anatomic and clinical laboratory tests for any purpose:

> **SENTENCE ONE:**
> The microbiological, serological, chemical, hematological, cytological, histological, pathological, immunohematological, radiobioassay, cytogenetical, toxicological, histocompatibility 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, or the assessment of the health, of human beings.

HHS announced that it was adding a follow-on sentence. They explained:

> "There have been questions concerning the applicability of CLIA to certain screening procedures, such as drug testing or HIV (AIDS) testing. Some people believe that these tests are not subject to regulation because they would indicate a drug level or presence of HIV virus and are not a diagnosis or an assessment of health and thus subject to regulation. However, these tests are currently reimbursed under Medicare and

> Medicaid and are considered test procedures for health assessment. Therefore, in moving the definition in § 74.2(a) and § 405.1310(b) to new § 493.2 we would expand it to provide uniformity between Medicare and CLIA and to clarify the types of procedures covered by the regulations."

So they added the following sentence which is IN ADDITION to the prior definitions of tests - examinations (from chemistry to cytology) that provide information for the purpose of diagnosis or treatment.

> **SENTENCE TWO:**
> These examinations **also include** screening procedures to determine the presence or absence of various substances and organisms in the body.

CMS changed this wording just slightly in final regulations. They may have noticed some slippage between the stated intention of Sentence Two (to cover screening tests and tests of drug levels) and the text shown above. The final form of Sentence Two was established in 1992 final regulations for CLIA and is the same we read today at 42 CFR 493.2:

> **SENTENCE TWO:**
> These examinations **also include** procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Thus, all the test of microbiology, pathology, cytology, chemistry, etc, were payable by CMS and were encompassed merely because they had some intention to impact a form of medical management, "providing information for diagnosis or treatment." Clearly, MAAAs do exactly that: the intention is "provide information for diagnosis or treatment." CLIA used Sentence Two to insure that even the simplest tests, like urine dipsticks, would be included under the CLIA umbrella. Even so, MAAAs also meet the meaning of Sentence Two, they "INCLUDE" procedures to measure various substances.

The sentence of "rationale" is all the more remarkable, in that taking the definition of laboratory tests in context (both sentences) MAAA's are defined as laboratory tests in that they "measure various substances" and "provide information for diagnosis or treatment." The two sentences at CLIA clearly lock in MAAAs as laboratory tests, matching the fact that the FDA classifies MAAAs as clinical chemistry tests (21 CFR 862.1163).[28] [29]

[1] HCFA, 47 Fed. Reg. 43579 (October 1, 1982). Quoting Congr. Record, 128:10902 (August 19, 1982).
[2] See www.tinyurl.com/brucequinnfoley
[3] CLIA regulations dating to at least 1988 (42 CFR 493.2); similarly, Public Health Services Act §353. The same text was used by CMS in 1982 in defining laboratory services. TEFRA rulemaking (47 FR 43591, October 1, 1982). Although the October 1, 1982 use of the laboratory test definition was not footnoted, CLIA 1988 rulemaking states the definition was found at 42 CFR 405. 1310 prior to 1987. (HHS 1988, 53 FR 29590).
[4] Timmermen C & Anderson J (2007) Devices and designs: Medical technologies in historical perspective. Palgrave MacMillan. Chapter 4: Crenner C, Laboratories and medical expertise in Boston circa 1900.
[5] HCFA, 47 FR 43591, October 1, 1982.
[6] HHS, 53 FR 29590.
[7] 2003: 68 Fed Reg 3640ff, January 24, 2003 (definitions of performance of complex tests.) 2007: 15 page letter from Judith Yost, CLIA: http://www.dnapolicy.org/resources/CMSresponse8.15.07.pdf
[8] 42 CFR 403. Clinical consultant (PhD or MD).
[9] McGovern et al. (1999) Quality assurance in molecular genetic testing laboratories. JAMA 281:835-842. Chen B et al. (2007) Good laboratory practices for molecular genetic testing. MMWR 58:1-29. New York State has recognized genetic testing as a clinical test category since 1990. See: SACGHS (2008) U.S. System of Oversight of Genetic Testing. Of many recommendations for improving of U.S. genetic test quality in this highly vetted, 15-author, 276-page federal report, none were greater use of physicians as the laboratory supervisor or the signer of the test result.
[10] AMA RBRVS Data Manager, 2012; containing CY2010 CMS utilization data for Part B billing. Similar data available from CMS website.
[11] ACLA, public comment, CLFS July 2011 public meeting.
[12] CLFS public comment, July 2012.
[13] AMA RUC (8/31/2012); AMA (8/31/2012); CAP (9/4/2012); AMP (9/4/2012); Alliance of Dedicated Cancer Centers (9/4/2012), and ASCP (9/4/2012).
[14] Walton D (2005) Fundamentals of Critical Argumentation: Critical Reasoning and Argumentation. Cambridge University Press.
[15] CMS, 77 FR 44786, July 30, 2012 (RUC data).
[16] http://investor.illumina.com/phoenix.zhtml?c=121127&p=irol-newsArticle&ID=1428526&highlight= For product approval data see: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K093128.pdf Regulatory classification, 21 CFR 862.2570 (Instrumentation clinical multiplex test systems); Panel: Clinical Chemistry (75). For Factor V mutation systems see: 21 CFR 864.7280.
http://www.illumina.com/Documents/products/technotes/technote_veracode_goldengate_genotyping.pdf
[17] 17 734 F 2d 859, College of American Pathologists v Heckler. (May 11, 1984)
[18] Scalia A & Garner BA (2012) Reading Law: The interpretation of legal texts. West, 608 pp.
[19] Patent experts may associate this line of argument with the "magic microscope" invoked in recent gene patent cases. See: http://news.sciencemag.org/scienceinsider/2011/04/us-court-puts-gene-patents-under.html
[20] http://www.accessdata.fda.gov/cdrh_docs/reviews/K082118.pdf
[21] Footnote 7, Yost, 2007.
[22] 42 CFR § 414.510 (Date of Service Rule).
[23] All date in this paragraph, AMA 2012 RBRVS Database, with CMS data for 2010.
[24] The result can be awkward. For example, non-physician 50 minute psychotherapy code 90806 is billed 48% of the time by social workers, 41% by psychologists, and 7% of the time by psychiatrists. It is valued for 50 minutes of physician time.
[25] http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CLFS-CY2013-Preliminary-Payment-Determinations.pdf
[26] See footnote 7 (Yost, 2007).
[27] http://thomas.loc.gov/cgi-bin/bdquery/z?d100:HR05471:@@@D&summ2=m&
[28] http://www.accessdata.fda.gov/cdrh_docs/reviews/K073482.pdf

[29] Other commenters have noted that CMS is reviewing under Exact Sciences colon cancer gene test, a MAAA, under its recent Parallel Review program with the FDA. It would be paradoxical if the text were approved by the FDA, assigned a benefit category and NCD coverage by the Coverage group, and then policy determined CMS could only pay 20% of the test's cost, excluding the R&D that created the algorithm.