The Tempest Continues, Fee Schedules in Collision: Medicare and Genomic Tests Prepare for 2013

FOLEY HOAG LLP

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Bruce Quinn MD PhD
Senior Health Policy Specialist
Foley Hoag LLP
bquinn@foleyhoag.com
www.foleyhoag.com
617 832 1291

Increasingly we will see individual genome sequences become a formal entry in our medical records, just like allergies and history of previous surgeries….Personalized medicine is more than DNA. Your individual genome is the original blueprint, or plans, but the final human body actually reflects a complex system of environmental and genetic influences, expressed through more than a million different proteins. Advanced computing and a systems-engineering approach to massive databases will open even more sophisticated and useful personalized medicine fields, and a new healthcare revolution will begin.

Bill Frist MD, July 10, 2012
Senate Majority Leader, 2003-2007[1]

We understand that stakeholders in the molecular pathology community continue to debate whether Medicare should pay for molecular pathology tests under the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. Medicare pays for clinical diagnostic laboratory tests through the CLFS and for services that ordinarily require physician work through the PFS. We…would benefit from additional public comments on whether these tests are clinical diagnostic laboratory tests…or whether they are physicians' services.

Medicare, July 5, 2012
Proposed Physician Fee Schedule Rule, CY2013[2]

Understanding the genomic basis of the disease is the biological revolution of our times. Scientists are learning how to discover and validate the clinical meaning of genomic data; pharmaceutical companies are learning how to apply it for a new generation of medicines; the FDA is grappling with how to insure quality standards in the most rapidly advancing wave of biotechnology ever.[3] Public health agencies, like the Agency for Healthcare Quality and Research (AHRQ), are working to fold genomic advances into "evidence-based medicine" and the Institute of Medicine holds policy meetings on genomics almost quarterly.[4] Insurers are trying to understand when new molecular diagnostics tests pass a border assumed to exist between "investigational" and "medically necessary" services.[5]

Medicare is trying to figure out how to use five-digit codes to identify genomic tests and how to assign prices to them. As many readers will know, since the 1990s, the U.S. insurance payment system has used generic codes for DNA extraction, DNA sequencing, etc. – "stack codes" – to represent all genetic testing services to insurers.[6] As described in a previous white paper in this series, released in November 2011, the AMA CPT committee published over 100 new genomic codes in October 2011 for use beginning in January 2012, but Medicare declined to allow use of the codes in 2012.[7] This initial code set is just the beginning of many advances that will allow genomic tests to be recorded in standard formats in medical records and in transactions between providers and insurers, because the use of genomic testing in cancer, pharmacology, and prognostic medicine is rolling forward quickly. Imminently, other new technologies, such as next-generation sequencing, will need coding and communications systems as well. Nonetheless, how Medicare sets policy for these 100-odd first genomic codes will be precedential and is being watched closely.

Medicare's inability to *use* these CPT codes during 2012 stemmed in large part from its inability to *set prices* for the codes, prices to govern payments made by its regional contractors for services to Medicare patients. Although the codes represented tests *already* conveyed to Medicare and other insurers by the "stacked codes" – which were all priced and paid on the Clinical Laboratory Fee Schedule – one set of stakeholders proposed shifting the tests to an entirely different pricing basis and policy system, the Physician Fee Schedule. The genetic codes arrived at Medicare in mid-2011 with valuations set by a committee of physician specialists of the RUC, the AMA/Specialty Society Relative Value Scale Update Committee.[8] The RUC acts "as an expert panel in developing relative value recommendations to CMS,"[9] recommendations that CMS nearly always accepts.[10] But in the case of genetic tests, CMS declined to accept the recommendations in November 2011, although it remained silent about its reasons until July 2012.[11] This white paper discusses CMS's current policymaking and describes the likely outcomes for the 2012 policymaking process.

1. The Evolution of Medicare's Distinctions between Clinical Laboratory Tests and Physician Pathology Services

The Medicare program was born in the mid-1960s after several years of acute disputes over how a healthcare insurance program for the elderly could be conceived in legislation. Because of opposition of the then-powerful American Medical Association,[12] early versions of 1960s health reform paid for hospital services only, although some versions included services of radiologists and pathologists directly amongst the "services of hospitals." The final version of Medicare parted the sea and placed to one side legislation for hospital services – Medicare Part A – and to the other, legislation for physician's services – Medicare Part B. Necessarily, the Medicare Act commented that Part A services can be paid only by Part A, and Part B services only by Part B. Part B was defined as physician services for the care of individual patients. This distinction was also crucial because at the beginning of Medicare hospitals were paid on the basis of "reasonable costs" and physicians on the contrasting and separately regulated basis of "reasonable charges."[13] These were completely different approaches to setting the government's payments. By 1970, it was already clear there would be runaway growth in total expenses of the Medicare program in relation to forecast expenditures. Every few years, new efforts to constrict Medicare spending in one way or another occurred.

By the late 1970s, Medicare had undergone several spasms of amendments directly aimed at curbing the substantial rise of physician incomes. As Part B charges were constricted, pathologists and radiologists in some hospitals sought more and more of their income under the rubric of "hospital costs" by claiming salaries that could literally double year to year, according to contemporary OIG reports. In part, this was possible because of the very rudimentary definition of Part A and Part B services in the original 1965 legislation. More clarity was needed. In any case, these rapidly escalating salaries remained payable because they were passed through to CMS under the heading of "hospital costs."[14] That is, the salaries of hospital-staff pathologists rose rapidly and the bill was reflexively paid by Medicare.

In 1980, CMS suddenly responded with a program notice appearing in the Federal Register that entirely banned pathologist fees for clinical laboratory tests.[15] The College of American Pathologists won an injunction against this policy announcement in federal court, asserting that the Medicare agency had no statutory authority to define what was and what was not a physician service.[16] Soon thereafter, in the spring of 1982, Congress gave CMS the specific authority to define what it would and would not allow as "services of a physician" including pathologists.[17] (This is remembered by pathologists over age 60 as "TEFRA 108" and created new language at SSA §1887.).

CMS rapidly responded to the new authority Congress had given it by issuing two regulations, finalized by early in 1983. One regulation allowed CMS to formally define what in general it would view as "services of a physician."[18] The second regulation was more specialized and allowed CMS to stringently define what it considered in Part B as "services of a pathologist."[19] *There is no similar regulation for any other specialty* (no regulation for the detailed medical types services payable to a surgeon, to an internist, to an endocrinologist.) Although these regulations have been moved to new locations in the Code of Federal Regulations and slightly amended in the intervening three decades from

1982 to 2012, they remain the controlling definition of what is a payable laboratory diagnostic test on the physician fee schedule.[20] Like the 1980 policy announcement, these 1983 regulations were also challenged in court and upheld, because, as the court noted, CMS clearly had the Congressional authority to define a physician's services and had done so through public rulemaking.[21]

The framework created after TEFRA lists the following "conditions for fee schedule payment for physician services" (42 CFR 415.102(a)(1-3)):

- The services are personally furnished for an individual beneficiary by a physician.
- The services contribute directly to the diagnosis or treatment of an individual beneficiary.
- The services "ordinarily require performance" by a physician.

This third bullet point is the standard that Medicare has cited both in its announcement of the one-day summer CLFS meeting in July 2012,[22] and in its proposed rulemaking for CY 2013.[23] CMS clarified the meaning of these regulations both when it originally promulgated them, when it responded to public comment on them, and when it defended them in federal appeals court, leaving behind an extensive public record. For example, CMS stated that the services in question must "ordinarily require" performance by a physician. CMS noted in the context of a lawsuit that the counter-party (College of American Pathologists) had admitted that "virtually all clinical laboratory tests are performed by non-physicians" and that "if a pathologist began to personally operate [equipment] or sign each test result, the Congressional intent would be subverted that services paid under Part B are truly medical ones….Appellants protest this requirement strenuously, relying on the tautology that if a physician ever does it, it must be a professional medical service."[24] CMS gave the example that at present, obstetric delivery services can be seen to "ordinarily" require a physician, but if they came to be routinely and usually performed by nurse-midwives more than one-half of the time, they may cease to be required physician services.[25]

Concurrent with the implementation of TEFRA in regulations, Medicare created a second regulation specific to pathologists. To avoid pedantry, we will work with the current regulation (at 42 CFR 415.130) rather than the original regulation to which there have been several minor revisions.[26] CMS states in its court case that "Performing clinical laboratory tests, factually reporting laboratory observations, furnishing information concerning the nature of tests, and supervising laboratory procedures are usually done by non-physicians…It is well-settled that these activities do not constitute the practice of medicine. CAP's own accreditation program, which is designed 'to ensure quality pathology services,' provides that clinical laboratories properly may be directed by non-physicians…It is only when laboratory personnel give opinions on the diagnosis or treatment of a patient that medicine is practiced."[27] These provide context for the regulation itself, which states:

> *42 CFR 415.130 Physician pathology services.* The carrier pays for pathology services furnished by a physician to an individual beneficiary on a fee schedule basis only if the services meet the conditions for payment in § 415.102(a)* and are one of the following services:

(1) Surgical pathology services.

(2) Specific cytopathology, hematology, and blood banking services that have been identified to require performance by a physician and are listed in program operating instructions.

(3) Clinical consultation services that meet the requirements in paragraph (c) of this section.

(4) Clinical laboratory interpretative services that meet the requirements of paragraphs (C)(1), (c)(3), and (c)(4) of this section and that are specifically listed in program operating instructions.

* 415.102(a) requires the services be ordinarily performed by a physician and directly contribute to the diagnosis of an individual patient, echoing and slightly amplifying statutory text at §1887 .

We will walk through the structure of this four-part regulation section by section. First, genetic tests cannot to be seen as falling under option (1), "surgical pathology services." Nor are genetic tests passable under option (2), enumerated services that "require performance by a physician." Even if genetic tests were defined as a type of "cytopathology, hematology [or] blood banking service" (option 2), genetic tests do not require the performance of a physician. That is, there is no question that under CLIA guidances, New York State guidelines, guidance of the American College of Human Genetics or CAP, a genetics laboratory can be run by an appropriately trained PhD – a physician is not required. The original 1982 rulemaking that generated these terms made crystal clear that CMS applied a "general standard" of "ordinarily requiring" a physician to most payable physician services (42 CFR 415.102), while simultaneously, CMS deliberately applied a stricter standard "requiring a physician" to laboratory tests (42 CFR 415.130).[1]

This dispenses with options (1) and (2) as mechanisms to classify genetic tests as complete physician services in the form of diagnostic tests. (Physician services in the form of "diagnostic tests" have technical and professional components, as does an MRI test or an immunohistochemistry test, both priced by RVUs. This partition of the payment and service into two parts allows some contexts where only the interpretation fee is paid, such as hospital inpatients.) What about Options 3 and 4?

Options (3) and (4) are not "whole tests" but only the physician's time for consultations and interpretations. Option (3) is a consultation between the pathologist and the treating physician, requested by the latter, on an abnormal and completed clinical chemistry result (CPT codes 80500-502, valued $20 to $65.) Option (4) is a physician interpretation of a clinical chemistry test. This fourth and

[1] A common example would be the difference between routine screening of Pap smears, which requires a cytotechnologist, and the diagnosis of a malignant Pap smear, which is referred to a physician. A pathologist could screen routine Pap smears, but this work would be recognized at the rate of a cytotechnologist since the work is not "ordinarily" done by a physician. But, the concept of cervical cytology literally "requiring a physician" is embedded in the language of CPT code 88141, thus reflecting the regulatory language at 415.130.

final payment category is exemplified by the physician interpretation code that comes at the end of the current molecular "stack codes," code 83912, physician interpretation of genetic test, $20, paid for a test conducted with the molecular chemistry codes, 93890-909.[28] The "program operating instructions" that the reader of category (4) is asked to look for is found in the Benefit Policy Manual, Physician Services, Section 60.E, which enumerates a special handful of tests that are priced on the CLFS but have small additional physician interpretation fees priced on the PFS.

So what happened after this regulation 415.130 was promulgated? CMS quickly found itself in a lawsuit. In its briefs to the court in 1983, the College of American Pathologists argued that the above regulation, if implemented as written, would ban pathologist fees for nearly all medical laboratory tests. This became the one point in a tall stack of court documents where CMS agreed with CAP: CMS concurred in its response to the court that that was exactly the intention and effect of the regulations it had drafted. The Federal Appeals Court found that the intention of TEFRA, in the legislative record (and likely considering documentation such as the then-recent 1980 OIG report), was to allow CMS to define and restrict payments to pathologists. The regulations were designed by CMS policy staff to be self-implementing, by using clear terms that could easily be interpreted by future CMS staff and by its contractors. Stung by the protracted series of lawsuits, CMS had successfully retaliated by creating binding public regulations that defined, with little ambiguity, what it would allow as services of a pathologist.[29]

2. Medicare throws down the gauntlet: Laboratory Rulemaking July 2012

Medicare law divides laboratory pricing into two quite distinct processes. For tests on the clinical laboratory fee schedule, law and regulations require CMS to announce the new CPT codes in June; hold a public meeting in July to take comment on pricing for the codes; and announce draft pricing decisions in September.[30] Final pricing decisions are announced in November to be effective in the upcoming calendar year. In contrast, the services of a physician are calculated in Relative Value Units which meld physician time with practice expenses, staff time, and an allowance for overhead costs. These RVUs are converted to dollars at a rate of about $35 per RVU.

This year, CMS placed all the new genetic codes on the agenda of the public CLFS meeting (July 16, 2012).[31] It entirely excluded from discussion in that meeting whether the codes ought be paid on that fee schedule or on the Physician Fee Schedule. In the Physician Fee Schedule proposed rule, CMS explains its strategy. CMS has placed all the genetic codes into the ordinary pipeline for CLFS pricing, marching through a series of policy-creating events from June to December. Meanwhile, in parallel, through the Physician Fee Schedule public comment process, Medicare will entertain comments on the appropriate fee schedule placement for genetic tests from July 6, 2012 through September 4, 2012. If CMS determines that the codes should be placed on the physician fee schedule, CMS will announce its decision in the final PFS rule for 2013, which will appear about November 1, 2012.

The College of American Pathologists responded quickly, announcing publicly that it was "hopeful" that the tests would be placed on the physician fee schedule.[32] In comments to CMS on the 2012 rulemaking, the College had criticized Medicare's delay in placing the tests on the PFS.[33] Recognizing (as we have just seen) that the current regulations are a substantial barrier to payment of genetic tests as physician services, CMS observed that "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." For example (although CMS does not offer any example of such a regulatory revision) a category of "molecular pathology services" could be added immediately below the current pathologist category of "surgical pathology services." In fact, a reading of both 415.102 and 415.130 indicates that CMS would probably have to also modify the overlying regulation 415.102, because no party has argued that currently, genetic tests are "ordinarily performed" by a pathologist. CMS would also be required to distinguish in the regulation between molecular pathology test performed for infectious disease diagnosis and molecular pathology tests performed on human genes.

CMS generally describes its regulations correctly at pages 213-214, but states that "with regard to pathology services, [the PFS] pays for both the professional and technical components of the services of a pathologist as defined in 415.130 <u>including</u> surgical pathology, cytopathology, hematology, certain blood banking services, <u>clinical consultations</u>, and <u>interpretative laboratory services</u>." (For clinical consultations and interpretative laboratory services, CMS pays for the professional service and <u>no</u> technical service.) I have been puzzled that CMS repeated asks whether genetic tests "<u>ordinarily require</u>" physician work although the requirement in current regulations for pathology/laboratory tests

is that they "require" physician work. CMS may mean that it views the 415.130 regulation for pathologists as subordinate to the 415.102 regulation. However, because CMS makes 415.130 subordinate to 415.102, it would have to establish that genetic tests "ordinarily require performance" by a physician before adding a category of genetic tests to 415.130.

Comment on the option of placing genetic tests on one fee schedule or another will no doubt be animated. Public comments will be available on the CMS website by September 2012; many associations submit comments only near the comment deadline and in recent years and has taken CMS up to a few weeks to post the comments after that.

For the first time, CMS made a number of concrete policy statements regarding the placement of genetic tests. In response to the hypothesis that some genomic tests might be PFS tests and some might be CLFS tests, CMS states that it will price all the codes on a single fee schedule. "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." CMS later restates this as reflecting "the homogeneity of the laboratory methodologies behind the laboratory test codes." CMS states concerns that the two fee schedules vary so much in administrative pricing methodology that there may be growing incentives (of unstated direction) to choose certain lab tests over another if different tests are scattered to different fee schedules.

CMS does not discuss the remarkable and even unprecedented event that the lab tests would be lifted out of one class of healthcare service and dropped into another simply by the creation of new administrative codes to represent them, although some public commentators are likely to note this. CMS also does not mention that the result of the fee schedule move would (equally remarkably) place infectious disease gene sequencing tests on a completely different pricing basis that human gene sequencing tests, although both could be run on virtually the same equipment and by the same PhD laboratory staff. CMS does note that many genetic tests yield relatively simple and often normal results, and thus do not require an elaborate "interpretation." A personal judgment rendered in an individualized narrative analysis and interpretation is usually the physician's entry point to the interpretation of a test, whether an MRI or a pathology test.

Assuming that the tests are ultimately priced on the CLFS, such tests can be priced by "cross-walking" or "gap-filling." CMS uses the gap-filling methodology very rarely, sometimes not using it at all for several years in a row. In the past, my observation has been that the gap-filling method has been resorted to only when there is substantial variance among stakeholders as to the correct crosswalk and CMS is unable to find a bright line that distinguishes the correct stakeholders from the others. In the gap-filling methodology, CMS solicits payment estimates from its contractors for the lab tests for one calendar year, at the end of which it sets permanent prices for the lab tests at the medium of its contractors' prices.[34]

CMS found numerous and substantial problems with the RVU valuation of genetic tests, and presents its concerns to the public in an unguarded way. It is commonly understood that RVUs are set by a combination of physician time, practice expense costs, and malpractice costs. (The latter are

usually only 2-3% of CMS fees.)[35] Somewhat paradoxically, while CMS states early in its discussion that all tests should appear on one fee schedule due to the methodologic homogeneity of genetic tests, the agency turns about and states in its discussion of the submitted AMA RVU valuations that "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 in large batches….CAP and the AMA RUC made assumptions about the typical laboratory setting and batch size to determine the typical practice expense inputs. Given that many of these services are furnished by private laboratories, providing recommendations on the typical inputs was challenging." What CMS means is that the AMA RUC is designed to price physician services best in a traditional "Norman Rockwell" doctor's office, with easily assessed rent, staff time, overhead costs, physician time, and minor pieces of capital equipment. In contrast, genomics may increasingly be performed either by automated advanced desktop machines,[36] on the one hand, or at huge centralized facilities more akin to a Google server farm than Dr. Welby's office. In addition, the AMA RUC panel is grounded in the fundamental principle that physicians of various groups can sit around a table and make reasonable comments on each other's services, such as a 30 minute office surgery in one case, or a 40 minute office visit in another. It is doubtful that the non-pathologist members of the RUC (which means virtually all of them) had even the faintest idea what complex and convoluted new-generation genomic technology and equipment they were endorsing as to-the-penny correct values.

CMS saw a second barrier to use of the RVU valuations. CMS would need to calculate to the penny the impact of moving the tests to the RVU system, due to global price-setting constraints.[37] CMS states that it has no accurate way to determine the current number of tests for the 100-odd genetic tests, and this would be disruptive to the allocated balance amongst all physician services within the RVU pricing system. CMS sums up these concerns by stating they are so severe, that "if" CMS placed the tests on the PFS, CMS would make them all contractor-priced tests. (Of course, as contractor priced PFS tests, they would still have exactly the same impact on SGR calculations). This proposal to make the tests PFS-based, contractor-priced tests should not be confused with the gap-fill process for the CLFS. When a Clinical Laboratory Fee Schedule test is put into the gapfill process, it is for one year, and a fixed administrative median price results. In the PFS system, genetic tests would remain on the contractor-priced list forever, or until CMS was able to resolve all of the the daunting number of issues for practice expense "by the penny" bottom-up pricing to create final, meticulously detailed RVU tables.

3. RVUs for Genomic Tests: What hath the RUC wrought?

For the first time since it obtained RUC RVU values for genetic tests in the spring of 2011, CMS published the values, as CAP and the AMA had been asking it to do. CMS did not, however, publish the paragraph-long verbal vignettes on which the pricing cases were based. The valuations are now subject to public review, and show a strange collision between the actual dynamics of genomic laboratories and the doctor's office assumptions on which RVU valuations are based.

Within the PFS rule itself, CMS published the RUC's valuation for physician interpretation fees for the genetic tests, which ranged in time from 7 to 80 minutes, with a median intra-service time of 18 minutes per CMS. RVU values ranged from 0.13 to 2.35, with a median value of .45 (an RVU currently pays about $35). CMS notes that the RUC's new proposed median value of .45 is higher than the existing value for 83912 of 0.37. However, this observation the raw median (each test assigned equal value) of the new numbers with the value of the current interpretation, so the comparison is not necessarily valid. The average RVU under the new numbers could be the same or less than .37, depending on the volume distribution of tests at different per test values.

Of more interest, against the possibility that all the codes might be moved entirely to the PFS, CMS published a table of values for the technical components of the genomic tests themselves. In 2011, there was speculation that PFS RVU values might be lower than CLFS values under code stacking methods. It is not clear that is the case, although it could be. We should note that CMS published RUC tables for raw practice expense inputs, which are in "dollar" values, but CMS would only pay for the tests in RVUs after the sharp downward blow of budget neutrality discounts and the slight upward draft of indirect practice expense.[38] That said, the raw RUC values for clinical labor, capital equipment, and supplies are worth examining. What exactly happened when the RUC attempted to squeeze genomic tests into the RVU model?

There are four tables on the CMS CY2013 RVU website:

- A summary table of "recommended clinical labor costs", "recommended supply costs", and "recommended equipment costs."
- A table of clinical labor inputs by minutes
- A table of capital equipment, including capital cost, lifetime in years, and minutes per test
- A table of chemistry and other disposable supplies

The summary table includes summary dollar values and a full-sum value. While some tests have no values at all (every column is zero; BRCA, 81211) there are dozens of tests (68 of them) which have Clinical Labor values on the Clinical Labor spreadsheet, but a corresponding zero value for clinical labor on the summary spreadsheet. This could be a preparation error. In any case, the spreadsheets are complex. For example, the Capital Equipment spreadsheet has 989 lines and the Supplies spreadsheet has 3,458 lines.

Again remembering that CMS presents these values in raw practice expense dollars rather than in the relative prices CMS would actually pay, in the AMA RUC tables total practice expense values range from **$27.30** (81242, FANCC gene) up to **$9,395** (81280, Long QT Full Sequence). There are 16 genes valued at over $1000; 18 genes between $500 and $1000; 27 genes between $250 and $500; and 20 genes between $100 and $250. This leaves 14 genes falling below $100.

In order to make better sense of the pricing range, I picked **four representative tests: Long QT (81280), MSH (81298), BRC-ABL (81206), and KRAS (81275).** The pricing breakdown for these tests is:

HCPCS	Descriptor	Recommended Clinical Labor Costs	Recommended Supply Costs	Recommended Equipment Costs	**Recommended Total Direct Input Costs**
81280	**Long qt synd gene full seq**	$0.00	$9,150.43	$157.53	**$9,395.35**
81298	**Msh6 gene full seq**	$0.00	$1,417.67	$28.31	**$1,496.92**
81206	**Bcr/abl1 gene major bp**	$39.69	$252.09	$19.46	**$350.92**
81275	**Kras gene**	$0.00	$67.10	$2.77	**$87.52**

(As noted earlier, all of these tests show clinical labor values in the specific clinical labor spreadsheet, while for three of the tests I picked, the clinical labor is missing in the AMA summary spreadsheet which I have copied above.)

We can see, in the table just shown, that among practice expense costs, the more expensive tests are dominated by supply costs. Supply costs in term were primarily sequencing chemistry. The capital equipment costs were simply negligible, ranging from 2-6% of all practice expense costs:

		Supply	Equipment	Total
81280	**Long qt synd gene full seq**	**97%**	**2%**	**$9,395.35**
81298	**Msh6 gene full seq**	**95%**	**2%**	**$1,496.92**
81206	**Bcr/abl1 gene major bp**	**72%**	**6%**	**$350.92**
81275	**Kras gene**	**77%**	**3%**	**$87.52**

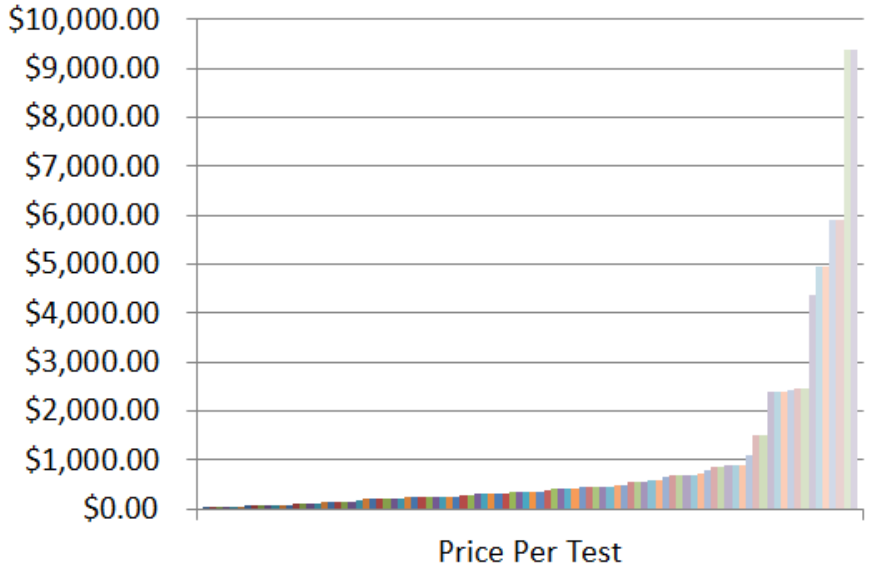
Turning to the AMA RUC clinical labor tables, proposed minutes of lab technician work for the four representative tests were as follows:

		MD Minutes	Clin Labor Minutes
81280	**Long qt synd gene full seq**	NA	199
81298	**Msh6 gene full seq**	30	118
81206	**Bcr/abl1 gene major bp**	15	93
81275	**Kras gene**	20	44

Technician time is valued at 40-50 cents per minute, and physician time at about 1 RVU ($35) per half hour, or about $1 per minute.

Showing only those tests that are priced below $1000, those tests are distributed by price as follows:

The distribution in the next figure below shows the full price range, including all tests from **$25** to **$10,000**:



Tier Two codes are "grab bag" codes that represent different complexities of tests that do not have an individual CPT code. The distribution for the **Tier Two Codes** (81400-81400) ranges from $191 to $9,150 as follows:[39]

			MD Minutes	Staff Minutes	**Supply Costs**	**% Supply Cost**	**% Tech Cost**	**% MD Cost**
81400	Mopath procedure level 1	**$216**	10.00	53	$192	85%	12%	4%
81401	Mopath procedure level 2	**$251**	15.00	75	$211	79%	14%	6%
81402	Mopath procedure level 3	**$397**	20.00	83	$353	85%	10%	5%
81403	Mopath procedure level 4	**$564**	28.00	102	$503	85%	9%	5%
81404	Mopath procedure level 5	**$890**	30.00	109	$827	90%	6%	3%
81405	Mopath procedure level 6	**$1,497**	30.00	118	$1,418	93%	4%	2%
81406	Mopath procedure level 7	**$2,396**	60.00	129	$2,299	94%	3%	2%
81407	Mopath procedure level 8	**$4,941**	60.00	158	$4,779	96%	2%	1%
81408	Mopath procedure level 9	**$9,395**	80.00	199	$9,150	97%	1%	1%

Although the priced tests have 26 tests with practice expenses below $215, and as low as only $27, the Tier Two codes have no option to pay less than $216.

4. What conclusions can be drawn?

Taken at face value, current regulations seem to strongly favor placement of genetic tests on the clinical laboratory fee schedule, since they do not "require" a physician. The end result of genetic testing is a laboratory result that describes the chemistry found in a test tube: as was stated in the 1980s, "factually reporting laboratory observations" is the end product of clinical chemistry and clinical laboratory tests. The gene is a chemical, and it reflects the aberration for Huntington's disease, or it does not. The equipment and interpretation may be consummately complex, but that does not make them "the work of a physician." For example, extraordinarily complex renal dialysis equipment may go awry, but the most complex electronic circuit board problems or software glitches do not lead the staff to run for the MD-trained nephrologists. Determining the practical sensitivity of a laboratory technique to in-dels (insertion-deletions) or calculating the percent sensitivity to a tumor mutation among non mutant cells is not the intrinsic medical work of a physician per se, such that anyone else doing the calculations is "impersonating a physician" and ought to be jailed. While genetic tests may "make a diagnosis" this is a byproduct of the fact that the chemistry of the genetic test is in itself pathognomonic for a disease in some cases.

However, CMS could alter its current regulations to all genetic tests to be physician laboratory services, measured and paid in RVUs. As CMS states, it would need to revise its current regulations to do so. It seems highly unlikely that CMS would do so abruptly in the final rule alone, without allowing public comment on the form and implications of any particular formula for new regulatory language.

The end product of such rulemaking would be to price genomics by RVUs, based on chemistry, capital equipment, and clinical labor time. Period. Based on the RVU frameworks released by CMS, the RVU system seems a poor match for the actual economics of laboratory testing. There is no valuation whatever for genomics and informatics – these would either be uncompensated at all, or would be considered part of the "overhead cost" of pathology. But the traditional pathology lab's overhead cost is dominated by the space and rent for a room in which to make paraffin blocks and run stains. The overhead costs of an advanced genomics center, with teams of PhD staff involved in quality control and informatics services, is vastly higher than that of a paraffin block lab, particularly in a system where overhead is allocated by minutes of physician time per test. There is no evidence from the RVUs published so far and the practice expense tables behind them that this is a system accurately molded to the real costs and value of molecular diagnostics.

[1] http://thehill.com/blogs/congress-blog/healthcare/237155-personalized-medicine-

[2] http://www.ofr.gov/OFRUpload/OFRData/2012-16814_PI.pdf The archival and typeset publication will appear in the Federal Register on July 30, 2012.

[3] Ultra High Throughput Sequencing for Clinical Diagnostic Applications - Approaches to Assess Analytical Validity, June 23, 2011. http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm255327.htm

[4] Recent IOM meetings on genomics policy were held in November 2011, March 2012, May 2012, and July 2012. http://www.iom.edu/Activities/Research/GenomicBasedResearch.aspx

[5] UnitedHealth: Personalized Medicine: Trends and prospects for the new science of genetic testing and molecular diagnostics. March, 2012. http://www.unitedhealthgroup.com/hrm/UNH_WorkingPaper7.pdf

[6] Quinn B (2012) Rapid changes in reimbursement protocols for molecular tests. Personalized Medicine in Oncology 1:36-41. http://www.personalizedmedonc.com/

[7] Quinn B (2011) Tempest in the melting pot: Genomics reimbursement in 2012. http://www.foleyhoag.com/NewsCenter/Publications/General/Tempest-in-the-Melting-Pot.aspx

[8] http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/the-rvs-update-committee.page July 2012: http://goo.gl/ZJegP

[9] Ibid.

[10] Blankenship JC (2012) The AMA and CMS: Productive collaboration or pathologic collusion? http://paymentinnovations.cardiosource.org/Article-of-the-Month/2012/07/AMA-and-CMS-Productive-Collaboration-or-Pathologic-Collusion.aspx Citing and discussing: Laugesen MJ et al. (2012) In Setting Doctors' Medicare Fees, CMS Almost Always Accepts The Relative Value Update Panel's Advice On Work Values. Health Affairs 31:965-72. http://content.healthaffairs.org/content/31/5/965.abstract The quoted figure for what percent of RUC valuations CMS accepts varies; but the most important thing is that CMS makes tiny value changes in a proportion of codes, but makes major changes (greater than 5-10%) very rarely.

[1111] In November 2011, CMS stated concisely that: "We note that the AMA RUC also reviewed over 100 CPT codes describing molecular pathology services. These CPT codes are new for CY 2012, however, they will not be valid for Medicare purposes for CY 2012 – For CY 2012 Medicare will continue to use the current "stacking" codes for the reporting and payment for these services." 76 Fed Reg 73190, 11/28/2012. Thus, CMS said very little about its reasons for not using the codes for Medicare purposes. CMS had, however, held a public comment meeting in July 2011 specifically for the purpose of gathering information from stakeholders as to the correct fee schedule placement of the disputed codes. See e.g. "CMS to conduct public meeting on genetic and molecular test billing", July 6, 2011, at: http://www.darkdaily.com/cms-to-conduct-public-meeting-on-genetic-and-molecular-laboratory-test-billing-070611#axzz20SMkZawu

[12] Oberlander J (2003) The political life of Medicare. University of Chicago. Skidmore MJ (1970) Medicare and the American rhetoric of reconciliation. Univ Alabama, esp. pp. 93, 94, 114.

[13] There was some hope of paying hospitals on the basis of "reasonable cost" which comprised building, property, nursing staff, administrative and support staff, and supplies. On the other hand, it would be very difficult to pay a solo 1960's doctor's medical practice on the basis of "reasonable cost" as the "reasonable" salary for the doctor would have to be set.

[14] 1980, Office of the Inspector General, HHS: Report on the need for more restrictive policy and procedures covering Medicare reimbursement for medical services provided by hospital-based physicians. "The Medicare program does not have procedures in effect to control the reasonableness of program payments to physician specialists who are compensated through hospital arrangements...compensation seemed arbitrary and illogical...increased 102% in a two year period." (Copy available from the author).

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

[16] Arkansas Soc. of Pathologists v. Harris, MEDICARE & MEDICAID GUIDE (CCH) at 30,546 (E.D. Ark. 1980). granting an injunction against implementation of the 1980 CMS policy.

[17] Section 108 of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, amending Title XVIII of the Social Security Act by adding a new Section 1887 (42 USC § 1395xx(a)(1).

[18] Today found at 42 CFR 415.102. The Statute at §1887 states "The Secretary shall by regulation determine criteria for distinguishing those services … which constitute professional medical services, which are personally 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 under part B." The regulation at 415.102 adds the services must "directly" contribute to diagnosis or treatment and must be "ordinarily performed" by a physician.

[19] 47 Fed. Reg. 43,578 (Oct. 1, 1982); final at 48 Fed. Reg. 8931 (Mar. 2, 1983). Originally codified at 42 CFR 405.483; later moved to present location, at 42 CFR 415.130, with minor intervening revisions. Further regulatory history is available from the author. This article focuses on CMS's controls for Part B pathology billing; separately, Medicare established caps (in the form of safe harbors) on the annual salary reportable by a hospital for a staff pathologist for Part A services.

[20] Parts of this paragraph have been repeated from my previous white paper, Tempest in the Melting Pot (2011).

[21] 734 F 2d 859, College of American Pathologists v Heckler. (May 11, 1984) http://bulk.resource.org/courts.gov/c/F2/734/734.F2d.859.83-1706.html A number of the briefs in the court proceedings were obtained from federal archives by the author and are available from him as PDFs.

[22] CMS, Public Meeting in Calendar Year 2012 for New Clinical Laboratory Test Payment Determinations. 77 Fed REg 31620, 5/29/2012. "Medicare pays for services that ordinarily require physician work through the PFS."

[23] CY2013 PFS rulemaking, page 212 (archival version to appear in Federal Register 7/30/2012): "This section first discusses and requests comment on whether these molecular pathology CPT codes describe services that ordinarily require physician work."

[24] Brief of appellee, page 32. US Court of Appeals, District of Columbia Circuit, 83-1706.

[25] Brief of appellee, page 35. US Court of Appeals, District of Columbia Circuit, 83-1706.

[26] A discussion of differences between the 1982 regulations and the current regulations is available from the author.

[27] Brief of appellee, page 8-9. US Court of Appeals, District of Columbia Circuit, 83-1706. Emphasis added.

[28] The Benefit Policy Manual, Physician Services (Chapter 15) states that most codes in the 80000 series are clinical laboratory codes. Surgical pathology codes payable to a physician are listed numerically at 60.B, the "specific hematology, cytopathology, and blood banking services" at 60.C, and physician-interpretable CLFS tests are listed at 60.E (including stack codes, immunoelectropheresis, and a few others.) Again, these codes are paid on the CLFS with interpretation fees on the PFS.

[29] I have again borrowed, with revision, several paragraphs from Tempest in the Melting Pot.

[30] Extensive regulations found at 42 CFR 414.500ff.

[31] http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2013-Public-Meeting-New-Test-Codes-aeth.pdf 35 pages, including 100+ genetic codes.

[32] CMS Advances Payment Reforms in 2013 Proposed Physician Fee Schedule. CAP Statline Special Early (July 9, 2012). Link (78/13/2012): http://goo.gl/Nn2XW

[33] Comments, 8/30/2011, http://www.cap.org/apps/docs/advocacy/comments/proposed_physician_fee_schedule_2012.pdf

[34] The actual process is a bit more complex and is found in part in regulations at 415.500ff and in part in policy announcements made during rulemaking.

[35] The surgical pathology code 88305 pays $105, of which 0.02 of 3.1 RVUs are for malpractice (~1%). The code for obstetric care with vaginal delivery 59400 pays $2,120, of which 9/62 RVUs are for malpractice (~15%).

[36] http://www.cepheid.com/ ; http://www.gen-probe.com/ ; http://www.nanosphere.us/products/human-genetic-tests

[37] The nuances of this extend beyond my expertise, but the SGR applies to a range of Part B services (including CLFS tests and PFS services) while the PFS has rules governing the distribution of RVU's as well. For example, recently CMS removed incident-to injected drugs from the SGR, while the administration services for the drugs still balance into complex RVU calculations.

[38] The AMA has noted repeated that there are now many CPT codes where the final reimbursement in RVUs is less than the total cost of the practice expenses. http://www.ama-assn.org/ama1/pub/upload/mm/399/cms-mei-pqri-revisions.pdf

[39] For the percentage columns in this figure only, MD costs were estimated at $1/minute and added to total supply cost shown in impute a total cost.