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Tempest in the Melting Pot: Genomics Reimbursement in 2012

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Since the new Pathology and Laboratory section was updated in 1993, we have received many inquiries regarding the philosophy behind the new coding system…. To report gene rearrangements, use the Molecular Diagnostics codes 83890, 83892, 83894, 83896, 83989, as appropriate.

AMA CPT Assistant, Fall 1993

All that is solid melts into air.

Marx, 1848

Section 1.
Introduction

The core set of genetic test codes used by U.S. insurers and Medicare date to 1993. Only general information is conveyed by these codes to insurers – "DNA probe x 2." They lead to payment for genetic tests based on a fixed price per genetic test step (such as "DNA probe x 2" or "DNA amplification x 3"). The payment was set using rules for the Medicare clinical laboratory fee schedule, rules which date to 1984.

As genetic and genomic tests have rapidly become more common in the past decade, it has been widely recognized that neither the coding nor pricing system are very satisfactory. At least in retrospect, the problems that developed were predictable given the available systems, assumptions, rules, and stakeholders. However, the complexity of stakeholder positions is daunting and bears no relationship to the Spartan simplicity of the coding and pricing rules that are undergoing long-delayed and striking change. Some of the likely outcomes in the next two or there years can be forecast by study of the information already available.[1] Writing in Fall 2011, some of the most decisive choices will be made in the next few quarters.

In this essay, we present a concise description of changes in molecular test reimbursement and illustrate the widening stresses between stakeholders in the current system.[2] While the focus is on the present and the near future, the changes that are rapidly evolving are difficult to understand without realizing that decades-old regulations, political battles, and policy constraints are at play in the present. A modern local war may be played out by the current generation with contemporary weapons, but reflect cultural hostilities dating back generations. Similarly, the roots of tensions that are now reshaping molecular diagnostics policy must follow patterns laid down long before in political battles and government lawsuits that are preserved like fossils in the shape of today's regulations. Our title, "Tempest in the Melting Pot," is meant to convey the shoulder-by-shoulder activities of stakeholders with sometimes common, and sometimes very divergent goals – from CMS policy makers to AMA physicians to venture capital investors to hospitals and large laboratories -- in a policy and business metropolis where they struggle to communicate in the same language. The AMA CPT group has done an exceptional job in producing a well-considered and precise set of codes for over 100 commonly used genetic tests. The production and quality of these codes is higher than nearly anyone could have imagined just three years ago. However, the next year will inevitably set in motion a rapid clash of policies and stakeholder goals with great bearing on the future of clinical molecular diagnostics.

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[1] Bueno de Mesquita B (2009) The predictioneer's game: using the logic of brazen self interest to see and shape the future. Random house.

[2] For additional background on policy and reimbursement issues for molecular diagnostics see "The Reimbursement Landscape for Novel Diagnostics: Current Limitations, Real-World Impact, and Proposed Solutions" (2011) at http://www.healthadvances.com/experience/diagnostics-resources.html ; "The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care", prepared by Lewin Group for Advamed (2010); and "The Adverse Impact of the US Reimbursement System on the Development and Adoption of Personalized Medicine Diagnostics" (2011) at http://www.personalizedmedicinecoalition.org/policy/topics/public-and-private-sector-reimbursement .

Section 2.
The World of Yesterday

Many readers of this article will be familiar with the basics of U.S. lab coding and pricing policy. An overview or refresher of this policy is provided here.

The 1996 HIPPA law is best known and most important for its creation of strict privacy standards for medical records. However, the law also set some standards for uniformity of communications between medical providers and insurers (both private insurers and Medicare and Medicaid.) The law prescribes that the Secretary of Health determine a standard code set for describing medical procedures on healthcare claims. For most outpatient services, this is the "CPT", the Current Procedural Terminology, which is created under the auspices of the American Medical Association. CPT codes are five-digit numeric codes, of which there are about ten thousand. Laboratory codes start with "8" – the 80,000 series. When laboratories perform a blood test, they must select the most appropriate code to report that test to an insurer and request payment. The CPT system is updated annually by a standing committee, composed primarily of physicians, which meets under the auspices of the AMA three times a year – the CPT Editorial Panel.

It is here that we encounter the first wrinkle that is distinctive for laboratory test policy. While, in principle, anyone can suggest a new code to the AMA, laboratory codes are considered so arcane that they are handled by a special subcommittee, called the Pathology Coding Caucus, which convenes stakeholders from several associations in a closed door meeting to review and assess a nearly-binding recommendation to the Editorial Committee as a whole.

And it is also here that we encounter the second wrinkle, which is distinctive for molecular genetic testing codes. These codes were established in 1993 as "method" codes (see opening quotation.) For example, a genetic test might be encoded as "DNA extraction x 1", "DNA probes x 5" and "DNA amplification x 5". The eleven available chemistry steps represented by the eleven existing CPT code units would represent the symbolic CPT code description of the genetic test. The CPT codes for molecular diagnostics say nothing about what gene is tested, or what mutation is being evaluated. These "method" codes are also called molecular "stack codes" because they are usually reported as a series of codes and multiple units of service per code.

For whatever type of medical service, insurers receive claims which numerically denote what was provided – a surgery, an MRI scan, a lab test. Next, insurers are, in turn, free to contract as they will to make payment. Despite discussions of health care systems reform, an enormous number of healthcare services are still paid on a line-by-line, fee-for-service basis. And most are paid *relative to* a federal fee schedule established by Medicare. The best known and largest schedule is called the Physician Fee Schedule (PFS). To create this fee schedule, Medicare's federal policymaking staff do not set the price of services directly. Rather, that authority is delegated to the Resource Based Relative Value Scale Update Committee (RUC), also composed primarily of physicians and convened under the auspices of the AMA. The RUC committee assigns or allows detailed inputs for each service – capital equipment, disposables, nursing staff

time, and physician time. Medicare then turns these AMA RUC inputs -- through very elaborate calculations, discount factors, and indirect cost allowances – into units called RVUs.[3] Congress then provides rules for converting the RVUs to dollars. For example, today, a healthcare service valued at 3 RVUs pays about $90.

It is here that we encounter the third wrinkle that is unique to laboratory test policy. Lab tests may follow one of two very different "payment pathways," depending on whether the test is classed as a "physician laboratory test" or as "clinical laboratory test." Only a minority of laboratory tests are classified as "physician services" – that is, services of a pathologist. The archetypal service of a pathologist is diagnosing a biopsy by using a microscope to review a glass slide. For a simple biopsy, the RUC system allocates perhaps $30 for salary, $20 for technician costs, $15 for lab costs, and $35 for overhead, or $100. Medicare views this physician service as a diagnostic test, and splits the $100 value into two components – say, $40 for the physician service ($30 plus a bit of overhead) and $60 for the technical component – here, the paraffin block and glass slide prepared and ready to view. Medicare then assesses a 20% patient copay to both the physician service and technical component, and Medicare pays the remaining 80% (here, $32 and $48 as 80% of $40 and $60, respectively.) Other lab tests that do not require the direct professional analysis of a physician – the majority of blood-based lab tests – are considered "clinical laboratory fee schedule" or CLFS tests. These tests do not pass through the RUC committee. Most test prices on Medicare's fee schedule are crosswalked (with some inflation adjustments) back to the creation of the CLFS in the early 1980s. When new tests are created (by new CPT codes) the new codes are either assigned a price relative to existing codes or through a procedurally cumbersome "gapfill" process which is described later.

First Wrinkle	Laboratory CPT codes are created by a special coding caucus.
Second Wrinkle	Molecular test codes are "process" codes – e.g. DNA amplification x 10.
Third Wrinkle	Some laboratory tests are "physician services" and others are "clinical laboratory fee schedule services."

Private insurers do not need to pay for services (including laboratory tests), with any regard to Medicare's payment rates. However, because there are many thousands of CPT codes, and because Medicare's rates have credibility and are publicly accessible, most insurance contract to pay a proportion (80%, 100%, 120%) of the Medicare rate.

Section 3.
Cracks in the System Widen: 2007-2010

[3] Medicare also may reject the values set by the RUC and assign different resource values, although it rarely does so.

Each of the "wrinkles" noted in the previous section played a key role that contributed to the widening of cracks in the system after about 2006. Although the system of laboratory payment policies might seem like the pinnacle of a boring backwater in health policy, the stresses in the system among different stakeholders were acute enough that a 'truce" or appearance of "stability" could last only as long as no change whatever occurred. The introduction of the new genetic coding system is the falling domino that will lead to a series of new problems or conflicts.

The prices of generic lab tests developed (on the whole) good margins as long as laboratory service providers consolidated into organizations with large economies of scale and could procure their inputs – particularly diagnostic test kits – on a commodity basis. For example, a $5 test kit might underlie an $18 or $20 lab service with a fixed fee schedule price.

Lab service providers could also provide molecular diagnostics at a price which was to them fair, as long as the test did not involve an R&D investment or royalty fee and as long as the test involved enough lab chemistry steps (e.g. 10 steps at $22 each paid $220). Interestingly, outside of infectious disease applications, a great proportion of genetic or genomic lab tests emerged as, and remained, laboratory-developed tests neither subject to FDA review nor packaged in uniform kits by a manufacturer.

Laboratory test kit manufacturers not infrequently found themselves in a "squeeze" position, able to produce test kits and kit platforms often in competition with one another and needing to carefully triage research, regulatory, and marketing costs to fit within the forecast volume of sales under the ceiling of fixed fee schedules. These test kit manufacturers raise concerns that genetic tests can be difficult to supply to the healthcare marketplace as proprietary kits because of the ease with which a test could be copied by routine DNA chemistry in a molecular diagnostics lab (the "unlevel playing field" argument referring to the regulatory burden of meeting FDA manufacturing and approval standards). This skew toward laboratory developed tests creates wide use of tests that can evolve quickly, may be safe, are designed by individual laboratories, are not reviewed by the FDA, and generally involve high use of labor over capital[4] (capital being the one-time investment in manufactured kit design.) Nonetheless, by 2011, increasing numbers of molecular diagnostics manufacturers have announced plans to produce new series of genomic tests in kit-based and FDA-cleared form.

Far higher-priced tests began to be introduced, such as the Genomic Health Oncotype DX breast cancer prognostic test, the Myriad Genetics BRCA panel tests, and the Monogram Trofile test for HIV CCR5 tropism. Each of these tests garnered over $2000 in reimbursement. Successful tests in this price range are validated by large amounts of published data.

Physicians – pathologists – saw rapid growth and high community interest in genetic and genomic tests, especially after 2005. These tests remained in their traditional classification as "clinical laboratory tests" rather than as physician services, so pathologists had very little access to professional fees for the interpretation of the tests, for reasons that are discussed more fully later. These molecular pathology physicians comprised a small group within the main

[4] Kocher R & Sahni NR (2011) Rethinking health care labor. NEJM 365:1370-2

pathologist organization – the College of American Pathologists (CAP), and a larger part of a smaller organization, the Association for Molecular Pathology (AMP), whose membership includes both pathologists and PhD-trained molecular laboratorians.

Payors, attuned to the financial impact of diagnostic tests by the striking growth in imaging costs in the 1990s,[5] viewed the rising of genetic and genomic clinical laboratory tests with some alarm. For example, in November 2010, the Chief Medical Office at CMS termed this growth as a "tsunami of tests" that could soon become unaffordable.[6] Adding to their frustration, no new specific genetic CPT codes emerged as the years went by. Therefore, the growth in testing reached payers via provider health insurance claims as millions of claim lines for "DNA amplification" or "Molecular test, other." This level of imprecision was not necessarily much different than for other services – for example, Medicare alone receives over $100 billion dollars of claims for "office visits." But the complete absence of test-specific codes and the apparent ease with which they might have been generated by the CPT authorities irked payers. Further, even "routine" genetic tests, at $100-300, were expensive in comparison to traditional lab tests in the $10 to $20 range. Payors were also disgruntled by the economics of the molecular chemistry coding system – if a test could be performed in either 10 molecular steps or 20, the lab using the latter chemistry and coding properly would be paid twice as much for the same test result. Finally, by 2008-2010, payors were confronted with a growing number of molecular tests with charges in the $2000+ range. Just as payors became concerned about the proliferation of new oncology drugs costing over $40,000, they became concerned that the escalation in the number of more expensive genomic tests was just beginning. And the newer, higher-value tests did not reach the CMS pricing system (on which private insurers could piggyback) because that process is triggered only by the creation of new CPT codes, which was not occurring.

Section 4.
A Rumble on the Mountain: 2009-2011

Based on the publicly available record, the first attempt at providing more coding specificity for genetic tests was the introduction, in 2005, of two-place modifiers which appeared as Appendix "I" of the AMA CPT handbook. This effort envisioned a system that could be revised on a rolling basis and would allow about 260 specifications, a digit (0-9) and a letter (A-Z). For example, modifiers beginning with "2" would be neoplasia/lymphoid (2A, 2B, etc); modifiers beginning with 5 would be neurologic genetic tests; and so on. The system was developed by a

[5] Hillman B and Goldsmith J (2010) The sorcerer's apprentice: how medical imaging is changing healthcare. Oxford University Press.

[6] "Tsunami," Dr. B. Straube, in an NIH presentation, 12/2010. Policy concerns that diagnostic tests are grievously overused can be found in numerous citations dating back to the 1910s and 1920s; additional material available from the author.

CAP-chaired Genetic Testing Workgroup and approved by the CAP-chaired Pathology Coding Caucus before approval by the CPT Editorial Panel.[7]

The two-digit modifiers were never adopted by labs and payors. They represented an interesting policy option, because they had promised more specificity in genetic test communications (as payors requested; "tracking" of genetic test types) *without* triggering any change in the stack-code pricing and payment system (since the underlying procedure CPT codes were unchanged, which may have been satisfactory to some of the stakeholders.)

The lack of adoption of the two-digit modifiers became clear by 2007/2008. According to documentation available from the Association of Molecular Pathologists,[8] a new proposal which would directly create true CPT codes for genetic tests was spearheaded by the Economic Affairs Committee of the AMP and was crafted by committee meetings held in 2008 and 2009. The committee worked to the following constraints:[9]

> The major problems the AMP Economic Affairs Committee identified for resolution within existing constraints included those listed below.
>
> 1. Specificity of clinical (vs. procedural) services provided
> 2. Incorporation of methodologic complexity (laboratory and physician work) into molecular CPT codes
> 3. Issues raised by large numbers of units of service
> 4. Interpretation of complex molecular assays
>
> Constraints included:
> a. Finite number of available CPT codes
> b. Rapidly growing list of analytes and technologies
> c. Dealing with 'multiplex' analyses
> d. Ability to accommodate innovation
>
> *Source: AMP website*

The AMP committee worked independently of the AMA CPT process, but developed a detailed coding system framework which is very similar to that later approved in 2010 by the much larger Molecular Pathology Coding Workgroup that did report through the Pathology Coding Caucus to the AMA. The workgroup proposal involved: (✔) deleting existing "stack" or "process" molecular codes, (✔) creating a large number of gene-specific CPT codes, and (✔) creating a new set of "complexity" codes or "tiered" codes, as we describe later. The committee focused

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[7] CAP Statline, 2/18/2004, CPT Panel Reacts Favorably to Genetic Test Coding Proposal. http://tinyurl.com/CAP2DIGMOD (All footnoted links were active in 20/2011.)

[8] http://tinyurl.com/AMP2009REFORM

[9] Ibid.

on "genetic tests" – genes for hereditary disorders – and major oncogene mutations.[10] The committee, through the end of 2010, did not offer a coding approach to "proprietary" complex or IVDMIA-type molecular tests.

The Molecular Pathology Coding Workgroup (MPCW) was largely composed of members of the College of American Pathologists and the Association for Molecular Pathology. It held public meetings in conjunction with the regular AMA CPT editorial meetings in February, June, and October of 2010 and 2011. The first set of several dozen genetic CPT codes were presented to, and approved by, the CPT editorial committee in October 2010, with several dozen more approved in February 2011.[11] The calendar is important because these 100-plus codes (including the "tiered" codes) that were approved by February 2011 met a cut-off date to be included in the January, 2012 AMA CPT edition. Breaking with tradition, in which new codes are not released until just before the calendar year they are effective, shortly after the February 2011 CPT meeting, in March 2011, the AMA MPCW published a list of the completed-to-date genetic codes and tiering system on the AMA website, as a "Molecular Pathology Code Review and Feedback" request.[12]

By the October 2010 to February 2011 period, several stress lines among stakeholders had appeared. The two most critical ones include (1) the reimbursement of genetic lab tests and (2) the handling of increasingly well-accepted and popular high-value genomic tests, such as the Oncotype DX and Mammaprint tests for prognosis of breast cancer.

(1) Reimbursement of genetic laboratory tests

Through today, genetic tests have all been classified as "clinical laboratory" tests, and paid on a "clinical laboratory" fee schedule. Economic issues were never far from the surface of the new coding process. For example, although the 2009 AMP memorandum presenting its genetic coding proposal states in the preface that the committee "[has] consciously not addressed the many issues associated with appropriate reimbursement," the committee nonetheless opened by stating that there were, in fact, "many issues" regarding reimbursement, and *two of the four* cardinal points to be resolved were economic, involving "incorporation of physician work" into molecular CPT codes and involving "issues raised by large numbers of units of service." (See boxed table earlier). Simply *placing a large number of units of service on a claim form* is not likely the issue, but rather, that by listing a large number of units (say, 110 units) the payer received a request for a high payment (here, about $2200.)

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[10] Often, "genetic" tests refer to germline gene variations that are inherited, and "genomic" tests include somatic mutations like gene deletions in tumors. The two terms may also be used interchangeable by some authors.

[11] As of October 2011, a half-dozen workgroup documents were still available at the AMA CPT website, http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page

[12] http://tinyurl.com/AMAMPCW-March2011

If the new genetic tests remained on the "laboratory" fee schedule, there would be almost no allowance for the work of a physician in interpreting the result of the test. However, if the tests were reclassified to be "physician pathology tests," they would be forwarded to the AMA's relative valuation committee, the RUC, which would assign all the work, time, and materials inputs required by CMS to generate an RVU and a test price. This was done: The tests were passed along to the AMA RUC as "physician" schedule tests. So far as is known publicly, all or nearly all of the new genetic codes, approved by February 2011, were forwarded to the RUC for review and valuation in the spring and summer of 2011. In retrospect, shunting new genomic codes in the direction of RUC assessment was foreseeable, as the only other molecular codes created by the AMA in recent years, those for cytogenetic array analysis, were also sent to the RUC for valuation preliminary to assignment under the physician fee schedule.[13]

However, this switch of fee schedule from "clinical lab" to "physician service" trigger a host of collateral issues which various stakeholders are highly attuned to:

- The assignment of lab test to fee schedule is not whimsical; it follows a body of law and regulation dating back to the 1980s and fee schedule placement is set by CMS staff, not AMA members (discussed below; the pivotal Medicare regulation is found at 42 CFR 415.130).

- Placement of genetic laboratory tests on the Physician Fee Schedule makes them:

    - subject to 20% copays, not found on clinical laboratory tests, and

    - triggers special signature rules not required of clinical laboratory tests,[14] and

    - triggers different Medicare policies regarding physician kickbacks and purchased-test rules different than those for clinical laboratory tests, and

    - pathology tests are paid on a different, and much lower fee schedule, in the Medicare Hospital Outpatient setting, whereas clinical laboratory tests are paid on the same clinical laboratory fee schedule in this setting.[15]

    - Indirect costs would be assigned on the basis of all pathologist indirect costs, including hospital-based pathologists and the mean indirect costs of pathology tests, dominated by the routine preparation of paraffin blocks and slides. These indirect costs likely far undershoot the indirect expense of a molecular diagnostics center, with far more expensive staff, development, and QC costs.

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[13] Codes 88384-86, created for CPT 2006.

[14] 69.175.53.20/federal_register/2011/jun/30/2011-16366. Fed Reg. 76:38342, 6/30/2011.

[15] For example, for molecular test code 88386, the physician fee schedule payment to an independent lab is $552 but the payment to a hospital-based molecular lab is only $56, about 10% as much (APC 0344); other pathology test codes may pay about 50% on the APC system; 75 Fed. Reg. 72431

- Placement on the Physician Fee Schedule triggers RUC-valued, resource-based bottom-up pricing, rather than Clinical Fee Schedule pricing.

The RUC-based pricing is similar to "cost of goods sold" pricing, based on physician time, laboratory technician time, disposable inputs, capital inputs, and a less visible CMS allowance for indirect costs ("practice expense.")[16] [17] According to one policy expert speaking at an industry seminar in July 2011, valuations set by the RUC would convert to RVU prices roughly 40% less than those charged for the same test under the current stack-coding system.[18]

2. Handling of high-value genomic tests.

The 2009 and 2010 workgroups held some discussions regarding the creation of specific codes for "value priced" genomic tests, but no such codes were created. Instead, some 100 specific genetic test CPT codes were chosen almost entirely from the most common human germline or oncogene tests provided by one of the largest national commercial laboratories. The Molecular Pathology Coding Workgroup discussed proprietary tests more explicitly at public meetings in June 2011 (with the San Francisco CPT meeting) and at a special public meeting dedicated to this topic in July 2011 (held in Chicago, with some 50 stakeholders in attendance.) At various points these tests were termed "IVDMIA" tests or "Multi Analyte Assay with Algorithm" (MAAA) tests. CAP has previously distinguished these tests from other laboratory-developed tests.[19] For example, in response to the FDA's 2010 solicitation for guidance on how to regulate laboratory developed tests, CAP recommended FDA regulation as appropriate to one group of tests, high risk tests, and then identified the group of high-risk tests as being IVDMIAs.[20]

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[16] For genetic array code 88386, 251-500 probe chip, the input factor allowances include 95 minutes of MD time ($98), 160 minutes of staff time, a $75 "priming kit", a $339 "Genosensor Array kit," smaller amounts for various chemistry costs. There is also an allowance for capital equipment; for example, a $65,000 hybridization station is used for 133 minutes, with an allowance of $30.22. As opposed to the $98 professional fee, the "test" component of payment is $552. Added linearly, and without overhead, the various RUC expense tally to $74 for technicians, $625 for disposables, and $33 for capital equipment, or $732 for all technical costs, which is almost $200 more than the CMS price of $552. But the $552 is supposed to already include overhead. Assuming, in a large publicly traded lab such as Quest or Labcorp, efficient indirect costs run about 1:1 with direct costs, as a going concern a test activity-costed at $732 requires a price, with a nominal net income margin, that would be closer to $1400, not Medicare's $552. (For research-based devices, from firms such as Medtronics, the ratio of all costs to direct costs is about 4:1, based on public financial data.) AMA data: 88386, RBRVS Data Manager, AMA, 2010 (on CD).

[17] As indicated in the prior footnote, CMS has historically divided physician test services into a professional fee and a technical (test) component – whether pathology or radiology services – allowing MDs and hospitals or labs to receive separate payment, and allowing the "test" itself (a microscope slide or an MRI image) to be produced in one center but interpreted in another one

[18] Webinar, "Weathering the Perfect Storm," July 2011, http://www.xifin.com/resources/xifinwebinarseries

[19] http://tinyurl.com/CAPonIVDMIA

[20] http://www.cap.org/apps/docs/advocacy/comments/comments_fda_oversight_developed_tests.pdf

Nearly without exception, AMA CPT codes do not include product names or brand names. Likely the AMA has enough difficulties dealing with industry, and corrals them by ensuring that code descriptors are brand-name-free. The AMA might be concerned about publication rights for trademarked product names. Highly specific and branded CPT codes might be inflationary: since codes are based on the market expense of inputs, a sole-source manufacturer who raised prices sharply would see "his" proprietary CPT code rise as well, in a lockstep fashion, as his branded device became more expensive. Conversely, at least in principle, if the code is unbranded and workable equipment is multi-source, the provider would aim to buy the least expensive equipment compatible with the service provided, creating market competition rather than monopoly among the corresponding suppliers.

The most common high-value tests (with the exception of complex cystic fibrosis testing) are branded tests, such as Oncotype DX, the HIV diagnostic Trofile, and the BRCAnalysis test. Labs and payors might worry that if the descriptor for such tests was sufficiently general (e.g. "prognostic test for breast cancer, 5 or more genes") then some labs might substitute very thinly validated tests for highly validated ones while receiving payment and coverage under the same CPT code. This problem might be mitigated; payors could write policies that CPT code 8XXXX is payable for diagnostic tests "Brand A" and "Brand B" but not covered for "Brand C" or "other brands." As stated in publicly available meeting minutes, from the July 2011 AMA IVDMIA meeting, the Molecular Pathology Coding Workgroup floated the possibility of a new class of codes, Category IV codes, which would be rapidly created as new proprietary tests rolled out (this is a desire of payers), and which might include brand names. Response to this proposal was tepid but it could probably be implement with minor changes by the AMA, most likely by finalization at the February 2012 AMA CPT meeting and publication in the calendar 2013 AMA CPT handbook.

In general, stakeholders agree that proprietary labs did not directly campaign for or apply for CPT codes in the past few years, but that such CPT codes might be created in this or a coming year by the MPCW. Some community stakeholders held the position that this may be caused by the CPT's own rules, which on their face appear to disallow code applications from sole-source providers. In any case, current Medicare statute and regulations require that new CPT codes for laboratory test enter the CMS pricing process during the summer before the January in which the codes become active. In an unusual event, the many dozens of new genetic CPT codes that will enter the CPT system in January 2012 will not be used by CMS, because it declined to open their pricing issues either in the summer rulemaking for the Physician Fee Schedule (June, 2011), or in the required July meeting for the clinical lab fee schedule (July, 2011). Between late 2011 and May 2012, CMS will likely resolve the interests and arguments of competing stakeholders and place the new genetic tests on one or the other of its two fee schedules. Until July 2012, when CMS will have to choose one pricing method or another, the population of new genetic test codes will be like a ship of castaways shuttling back and forth on an ocean of CMS policy between the two land masses of the physician and clinical lab fee schedules.

As Medicare policy staff are aware, the national pricing process for physician services allows only a modest margin or even creates a negative payment relative to the "cost of goods sold" line-item analysis of the service. As shown in footnote 15, Medicare's pricing of gene array chips literally undershoots the plain value of the RUC inputs by a significant margin ($552 paid by CMS, *versus* $732 actual and direct cost based on the RUC's bottom-up inputs). Since the

RUC value for direct costs resembles the financial term "costs of goods sold," a research-based concern (say, Medtronic) requires market pricing roughly 4-fold the cost of goods sold (here, $732 COGS x 4 = $2928). It would be impossible for such a firm to develop products with extensive clinical trials, risk, FDA and other costs, for only the cost of goods sold or even double that amount. The ratio must be closer to 4X. From the perspective of innovators or investors, even research-based tests that add great value to the healthcare process or even save net costs in healthcare delivery[21] would never be brought into existence with a RUC/CMS valuation that appears to undershoot COGS itself. The distance between the COGS/RUC/PFS price and the actual cost is so large that alternatives to Physician Fee Schedule assumptions would have to be found.[22]

However, as shown in the next section, it seems unlikely that genetic and genomic tests will actually be moved by CMS to the Physician Fee Schedule.

Section 5.
What Will Happen Next

1. Will Genomic Tests Move to the Physician Fee Schedule? No.

2. Will CMS Use the New Genetic Codes in 2012? No.

3. Will the AMA Coding Process Consider IVDMIAs? Very likely.

1. Will Genomic Tests Move to the Physician Fee Schedule? No.

Genomic tests will probably not move to the Physician Fee Schedule. After hostile lawsuits and political policy battles dating to the early 1980s, CMS erected high barriers to the placement of laboratory tests as physician services. While CMS has announced it will definitely not use the new AMA genomic codes in calendar 2012[23], there is a strong chance they will never be placed on the Physician Fee Schedule, even when CMS begins using them.

The history of pathology payment battles actually begins even before the original Medicare legislation passed Congress in 1965. Several attempts to create a national healthcare program, at

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[21] According to a September 13, 2011 press release, seven health economics studies in six countries show the Oncotype DX test to be highly cost effective (e.g. $4000-6000/QALY in Japan; Breast Cancer Res Treatment 127:739, 2011) or actually net cost-saving. www.genomichealth.com

[22] For additional information on the risk, investment costs, and narrow margins in bringing a new diagnostic to market, see Davis JC et al. (2009) The microeconomics of personalized medicine. Nat Rev Drug Disc 8:279-286. See also Quinn B (2010) Personalized diagnostics: the struggle for position. Person. Med. 7:263-73.

[23] CMS, Federal rulemaking, final 2012 Medicare Physician Fee Schedule, released online 11/1/2011, Federal Register publication date in mid November, 2011.

least for the elderly, date back to the late 1950s. The opposition of the AMA to "socialized medicine" or "Medicare" was so acute that proponents focused on hospital insurance alone – what became Medicare Part A. The Anderson-Javits bill of 1962 (H.R. 10606) placed pathologist payments along with what were otherwise hospital-only services. Johnson's Medicare (Part A) bill of April 1965 carried the same provisions.[24] The passage of both Medicare Part B (physicians) and Part A (hospitals) later in 1965 made the carve-off of pathologist services less important. Pathologists were paid partly by the hospital as staff and partly by Part B for individual diagnostic services. This followed rudimentary, but critical, language in the original Medicare act that forbid Part B payment for any service payable in Part A, and defined Part B services as physician services performed and required in the care of individual patients. Physicians (Part B) were paid on the basis of "reasonable charges" and hospitals (Part A) on a basis of "reasonable cost."[25]

By the late 1970s, Medicare had undergone several spasms of amendments aimed at curbing the rise of physician incomes. As Part B charges were constricted, pathologists in some hospitals sought more and more of their income under the rubric of "hospital costs" by claiming salaries that could double year to year, yet remained payable as an uncontrolled pass-through under the heading of "hospital costs."[26] In 1980, CMS responded by a program notice entirely banning pathologist fees for clinical laboratory tests.[27] CAP won an injunction against this regulation in federal court.[28] However, in 1982, Congress gave CMS the specific authority to define what it would and would not allow as "services of a physician" including pathologists.[29] CMS rapidly responded with two regulations, finalized early in 1983, one defining more narrowly "services of a physician" and a second defining stringently what it considered a Part B "services of a pathologist."[30] *There is no similar regulation for any other specialty* (no regulation for services

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[24] Skidmore MJ (1970) Medicare and the American Rhetoric of Reconciliation, Univ Alabama, pp. 93, 94, 114.

[25] Note that one cannot pay physicians on the basis of "reasonable cost" because their inputs – nursing staff, office staff, rent – would add up to "costs" that would not include "salary" or "income" of the physician. In contrast, a charge includes the physician's income.

[26] 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."

[27] 45 Fed. Reg. 15,550 (Mar. 11, 1980).

[28] 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.

[29] 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).

[30] 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,

payable to a surgeon, to an internist, to an endocrinologist.) The payable services to a pathologist are only the following:

> *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[31] 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.

Following the structure of this regulation section by section, first, genetic tests are not option (1), "surgical pathology services." Nor are they option (2). Even if they are defined as a type of "cytopathology, hematology [or] blood banking service" (option 2), genetic tests do not *require* the performance of a physician. 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. These conclusions dispense with options (1) and (2) as mechanisms to classify genetic tests as physician services.

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 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 final payment category is exemplified by code 83912, physician interpretation of genetic test, $20,[32] paid for a test conducted with the molecular chemistry codes, 93890-909.

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.

[31] The general physician regulation at 42 CFR 415.102 requires that all services payable to a physician are *generally performed* by a physician. The pathologist's regulation at 415.130 states that his services *must require performance* by a physician. The rulemaking and ligitation history makes clear that the difference was intentional.

[32] 83912 is valued at 20 minutes of physician time, but there is no recent public record of CAP or AMP introducing new tiers of codes for this interpretation or revaluing this one. For example, in its August 2011 comment letter to

CAP again sued CMS in federal court. CAP challenged the above regulation within months of its issuance; the association lost in federal district court in 1983 and in federal appeals court in 1984 (734 F.2d 859). In its briefs to the court, CAP argued that the above regulation, if implemented as written, would ban pathologist fees for nearly all clinical laboratory tests. In its court filings, CMS agreed that was exactly the case. The 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 to be self-implementing, by using clear terms that could easily be interpreted by future CMS staff and contractors. Stung by the series of lawsuits, CMS succeeded in creating binding public regulations that defined, with little ambiguity, what it would allow as services of a pathologist.

We hedge our statement that the genetic tests will not move to the physician fee schedule with a few caveats.

- A movement to the physician fee schedule would give CMS staff more control over genetic test pricing, for example, to allow prices to drop as the marginal costs of genetic testing continues to fall. Accordingly, CMS staff may seek permissible ways to make the move possible.

- CMS staff may view the introduction of copays to be favorable, and remarkably, occurring *at the request* of physician stakeholders who want the move to the physician schedule.[33]

- CMS may be doubtful that genetic tests always require physician interpretation. For example, a large preponderance of genetic tests, when appropriately ordered (for example, to rule in one of a series of genetic cardiomyopathies), are normal. Ten normal reports in a row do not require detailed, de novo, narrative interpretations requiring twenty minutes each of the pathologist's time (200 minutes or about $200). CMS could also be concerned that some laboratory that some laboratories could report the normal

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CMS, CAP discussed a range of pathology codes but did *not* propose this one as undervalued, nor has it done so in *any* recent year.

[33] This reflects one of the policy splits in the laboratory medicine community, with pathologists favoring copays on genetic/genomic tests, and most laboratory associations opposed. There are other paradoxical sequelae. For example, in 2000, CMS passed regulations requiring only hospitals to bill for pathology tests on their inpatients or outpatients. Pathologists have won an annual legislative reprieve, the "pathology technical component grandfather clause." This legislation passes because it has a very low budget impact score, less than $100M over 10 years. If hundreds of millions of dollars of genomic tests are moved to the physician fee schedule, extension of the pathology grandfather clause will probably be untenable. See CAP, Comment on 2012 Physician Fee Schedule Rulemaking, 8/30/2011.

reference sequence in question for the ten genes, and the patient's sequence, but not "interpret" them, allowing the ordering physician to do so for a $200 fee.[34]

- Some genetic tests are complicated to interpret, occurring in sequences such as CG-rich regions where DNA analysis is problematic; but these are problems of a type that *both* PhD molecular biologists and pathologist MDs are trained to handle, they do not *require* a background in anatomy, CPR, and pharmacology, the background of a physician. CMS's regulations (and the historical preambles to them) clearly used the strong meaning of the word "require" – the test must "require" a physician, as does the reading of a breast cancer biopsy. To reduce the requirement that only an MD can interpret the test, that an MD is "required," CMS could change its regulation (42 CFR 415.130) through rulemaking in summer 2012. However, such new public rulemaking would not be in effect until January 2013, so it might be problematic for CMS to apply it to the June 2012 fee schedule processes.

2. Will CMS Use the New Genetic Codes in 2012? No.

No. CMS chose not to introduce any of the new genetic codes into the Clinical Laboratory pricing process for January 2012, which by regulation had to begin in July 2011. Therefore, the codes will have no CMS pricing in 2012. Some stakeholders raised the possibility that the new genetic codes might be classified or priced by "contractor discretion" in 2012, but we considered this extremely unlikely and it did not occur. CMS announced in the final policy for calendar 2012 that the new genetic codes would be unused by Medicare in 2012, and therefore, code-stacking codes would be the remaining available method again in 2012.[35] In addition to listing the new genetic codes as void for Medicare purposes in calendar 2012, CMS declined to publish the RVU values created by the RUC committees for these codes.[36]

Private payers could use the CPT codes in 2012, because they are part of the AMA CPT code set now. However, use of the CPT codes would disengage them from the automated pricing that occurs now when code-stack codes are used. When the AMA codes are eventually adopted, almost certainly in calendar 2013, it is uncertain to what degree either private payers or Medicare contractors might enforce more strict coverage policies tuned to the much more specifically named tests.

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[34] Here, CMS and CLIA rules differ. CMS rules require that contractors pay any interpreting physician for a diagnostic test interpretation, whereas CLIA rules govern who is qualified to complete the report for any clinical diagnostic test used in patient care.

[35] CMS final rule, published online, 11/1/2011. To appear in Federal Register in mid November 2011.

[36] This was on choice on CMS's part. In other cases, CMS has published the RUC RVU values for certain codes even though they were not used by CMS itself. Over 100 codes unused by CMS have published RUC values in CMS data tables.

3. Will the AMA Coding Process Consider IVDMIAs? Uncertain.

There is considerable pressure from payors to rapidly provide codes for proprietary molecular tests, but it is unclear whether any stakeholder group has enough support to push through such codes against the opposition of other stakeholders, or indeed, what form the codes would take. One key industry consideration, however, is that the assignment of AMA Category I CPT codes triggers the CMS pricing process in the following year.

It seems likely that if stasis occurs on the issue of coding value-based tests at the AMA CPT level, payors will find alternative means of coding and covering molecular diagnostics. One key concern of payors is that the molecular "stack" codes provide no information about what test is performed. Because HIPPA specifies the AMA CPT as the only U.S. code set, payors are not allowed to create their own codes at will. However, they may increasingly discover effective workarounds. The Medicare contractor Palmetto, which manages Medicare Jurisdiction J1, including California, has in September 2010 published guidance on the coding of new molecular diagnostics, and in October 2011, draft LCDs that require special coding and description approaches that will be highly specific to each diagnostic test.[37] On November 2, 2011, Palmetto also announced a CMS-endorsed pilot program for coding molecular diagnostics. Because of their potentially rapid evolution and revision, the Palmetto draft LCDs and the Palmetto pilot program are the topic of a separate white paper in this series.

Other entities have also proposed coding alternatives to the AMA CPT system. McKesson has established an Advanced Diagnostics Management System[38] that will interface between physicians, general and proprietary laboratories, and payors, and transmit test-specific coverage and coding information that is highly granular. Potentially, such a system could be paired with a generic AMA CPT code for "advanced molecular diagnostic" which is unpriced, and payers could hinge coverage and payment information on additional "comment field" information while not violating the use of AMA CPT as a primary code. Whether such a system would obtain widespread use remains to be seen.

Finally, some alternatives to providing genomic testing are emerging that may not involve the traditional coding and pricing system at all. Medco has begun providing pharmacogenetic channels bundled to its pharmacy benefit management services, for example, by making warfarin genetic testing available to warfarin patients within the cost structure of its drug benefit plan.[39] This approach is entirely independent of the coding and fee schedule issues dealt with in this paper and is a promising one. In the near term, however, the majority of genetic and genomic test provided in the U.S. healthcare system will remain managed at a fee for service level in the traditional line-item model of health insurance.

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[37] www.palmettogba.com Website links vary; see "Laboratory and Molecular Services Program" and draft local coverage determinations DL32286 and DL 32288.

[38] http://tinyurl.com/McKADMS

[39] E.g. Allison M (2010) US pharmacies broaden access to pharmacogenetic tests. Nature Biotechnol 28:299-300.

About the Author

Bruce Quinn, MD PhD, is a national expert on Medicare policy, the impact of health reform on innovation, and the crafting of successful business strategies within he US healthcare reimbursement system. Dr. Quinn has worked successfully with both large and small companies in overcoming hurdles to commercialization through negotiation, understanding insightful ways to use the existing system to advantage, and the mechanisms of policy change. Foley Hoag LLP serves cutting edge healthcare diagnostics companies who are forging the new horizon of personalized medicine.

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Dr. Quinn travels nationwide to speak on health reform issues and publishes actively, publishing two peer reviewed policy articles in 2010 on advanced diagnostics. Before joining Foley Hoag LLP, he was the regional Medicare medical director for the California Part B program, with authority for final coverage decisions for approximately 15% of the U.S. Medicare program. Earlier in his career, Dr. Quinn was a physician executive in the Health & Life Sciences division of Accenture, working with the pharma, biotech, and genomics industries. Dr. Quinn is a board-certified pathologist. As a physician-scientist on the faculty of Northwestern University School of Medicine, he led pathology research for Northwestern's NIH-funded Alzheimer Research Center. Earlier, he also held academic positions at New York University School of Medicine and the UCLA Center for Health Sciences and is the author or co-author on 30 scientific publications. He has an MBA from the Kellogg School of Northwestern University. He can be reached at: bquinn@foleyhoag.com .