

Patent and Trade Office

Second Opinion Genetic Testing

Bruce Quinn MD / for Coalition for 21st Century Medicine

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This submission is a modestly expanded, and footnoted, version of my oral presentation.

My name is Bruce Quinn, and I am here on behalf of the Coalition for 21st Century Medicine,¹ which is a client of the firm I work for, Foley Hoag LLP.²

INTRODUCTION -----

My aim is to discuss **typical insurer policies on second opinion testing**, using the general published rules of the Medicare program as an example. I will briefly provide some examples from other U.S. insurers as well. The U.S. healthcare system is in a fairly rapid state of transition, with new entities and contractual arrangements between doctors, doctors and hospitals, and between all types of providers and insurance organizations. However, my presentation will focus on the basic rules of the traditional Medicare program, which is complex enough.

I had a chance to review documentation on the PTO website from your February 16 and March 9 meetings of last year.³ Section 27 of the America Invents Act provided four questions for the PTO to answer, and the 2012 PTO agenda for those February and March included a much broader and more complex set of 14 questions, some with multiple subparts. The agenda for today's meeting asks the public to comment on the original four Section 27 questions, and my contribution fits within those boundaries.

¹ <http://www.twentyfirstcenturymedicine.org/>

² www.foleyhoag.com

³ Links available under the heading "Genetic Testing" (February 5, 2013) at: http://www.uspto.gov/aia_implementation/aia_studies_reports.jsp#heading-3

Last, year, public statements which addressed insurance policies for second or confirmatory genetic tests included statements of Hans Sauer, of BIO and Kevin Noonan of McDonnell, Boehnen, Hulbert, and Berghoff LLP. Also last year, Prometheus Labs, a member of the 21st Century Coalition, commented that the apparent incidence of repeat measurements in its records was 0.3%.⁴ The gist of these 2012 comments was either that genetic testing requests for second-testing were either very rare and/or not paid by insurers. My submission here provides additional detail and documentation along the same lines of some of your calendar year 2012 comments.

MY BACKGROUND -----

By way of background, I am an MD/PhD, a board certified pathologist, and served on the full time medical faculties of New York University and Northwestern University, in the first half of my career. Since 2001, I have worked as a physician executive at a global consulting firm (Accenture), as a Medicare regional medical director (for the state of California), and as a strategy and policy expert in the law firm, Foley Hoag LLP. By way of qualification, through the Medicare and Foley Hoag positions, I would estimate that I have nine years, or about 18,000 hours, of full time experience with the content and the application of Medicare rules and policies. I suspect that taken as a whole, the policies of the Medicare program may rival in complexity those of the FDA or the PTO.

⁴ Sauer, Noon, Prometheus testimony in transcript form or written submission form, *ibid*.

BACKGROUND ON THE MEDICARE PROGRAM AND ITS WRITTEN POLICIES-----

To assert the conclusion of the written documentation I will be presenting: Medicare’s published policies generally do not provide coverage for repeat testing of diagnostic tests. And, as some commenters stated last year, health insurers distinguish between a “second opinion” of a physician or surgeon (based on his personal meeting with the patient) and a repeated test, so I will clarify that difference with appropriate policy citations.

Let me start by given the reader some general background on the Medicare program. Established in 1965, Medicare primarily provides federal health insurance to U.S. citizens over age 65. (Two other smaller membership categories are those disabled as defined by the Social Security Act and those with permanent kidney failure, e.g. on renal dialysis.) Many kinds of health care institutions (such as private not for profit, private for profit, and public hospitals; nursing homes; hospices) and individual providers (doctors, physical therapists, nurse practitioners) may be compensated for the treatment that they provide for Medicare beneficiaries.

Medicare is a “defined benefit” health plan, and many of the benefits are defined very simply and broadly, such as “hospital services,” “physician services,” “ambulance services,” and so forth. Other benefits are defined very specifically (“annual screening mammography”). One category if benefit is “x-rays and other diagnostics tests” (at Social Security Act 1883(s)(3).) This category, now 50 years old, is broad enough to include laboratory tests, and further, to include genetic tests. So genetic tests are a benefit category of Medicare. The test must be “reasonable and necessary to diagnose or treat disease” so historically screening tests like Pap

smears or mammography, in healthy people, would be excluded unless Congress specially provided for them. (As Congress did, the examples of mammography and Pap smears).

SECOND OPINIONS OF PHYSICIANS (E.g. OFFICE VISITS)-----

Medicare has a publicly available, online Benefit Policy Manual which, in Chapter 15, Section 30, paragraph D, allows payment by Medicare for second opinions before major surgeries or procedures.⁵ These are defined as a second opinion of a physician. This benefit policy allows that the original opinion and the second opinions may diverge, in which case, a third physician may provide a tie-breaker opinion. That is the A to Z of the second opinion benefit.

MEDICARE POLICIES FOR LABORATORY DIAGNOSTIC TESTS-----

All diagnostics tests fall under a regulation at 42 CFR 410.32, stating that each payable diagnostic test for an insured Medicare patient must be ordered by a treating physician and used in patient care.⁶ The wording of this regulation, to my eye, doesn't necessarily allow or exclude duplicate testing, but the next policy that I will cite does do so. Medicare also has a published policy manual about the way it pays for clinical chemistry and other laboratory tests.

⁵ Medicare's online manuals of policies, rules, and benefits can be found online beginning with the website: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>

⁶ Social Security Act 1877(h)(5)(C) provides a special rule for a necessary add-on test ordered by the pathologist or radiologist himself in the process of working up a case; that constitutes an exception to the treating-physician-order rule at 410.32.

This is found at the “Correct Coding” section of the Medicare website.⁷ Here, you get to Chapter 10 of the NATIONAL CORRECT CODING INITIATIVE POLICY MANUAL FOR MEDICARE SERVICES, which is the “correct coding” policy manual for insurance claims from laboratories. This document states in several different places that Medicare pays only once for the laboratory test to determine a particular analyte from a patient. For example, it states that even if an analyte can be measured by two different methods, such as immunohistochemistry and flow cytometry, it will only pay for one of them. Here is one of the statements verbatim:

“Medicare does not pay for duplicate testing. Multiple tests to identify the same analyte, marker, or infectious agent should not be reported separately. For example, it would not be appropriate to report both direct probe and amplified probe technique tests for the same infectious agent.”

There is a logical exception mentioned, which concerns measuring the same analyte in two materially different tissues, like a possible skin cancer on the left arm versus one on the right arm, but that type of exception would not apply to germline genetic tests which would give the same results regardless what part of the body a sample was taken from.

In addition, the Medicare correct coding website has MUE edits, which over the past ten years have been variously called Medically Unbelievable and Medically Unlikely Edits.⁸ These are “edits” or computer-based rules that are applied to all incoming claims in the Medicare system. They enforce “correct coding” – for example, doing an appendectomy and closing a wound would not both be payable, because the procedure called “closing the surgical wound”

⁷ <http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/NCCI-Coding-Edits.html>

⁸ <http://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/MUE.html>

is already considered part of doing an appendectomy. Similarly, these rules would block a “medically unlikely” claim that might be received by Medicare for a hysterectomy performed in a male. The “quantity of test” edits during computer processing block payment for 2nd genetic test under the same CPT code. That is, genetic test codes (like the same test for the cystic fibrosis gene or Huntington’s disease gene) will only be paid in a multiple of “1” unit. These tests should always enter the system of electronic claims identified by the same numeric procedure code, because HIPPA law requires that providers communicate with insurers using a particular and thus uniform national code set, called CPT codes.⁹

Another Medicare policy, called the date of service rule (42 CFR 414.510), sets the date of service as the date of specimen collection, rather than the date of test performance. This rule helps Medicare enforce its rules during the processing of claims. So, if a sample is taken, and if three different labs performed the same test on day 5, and 10, and 15, the date of service is the same and the computer edits would block payment for the 2nd and 3rd test.

In summary, this Medicare policy says that ordering the same germline genetic test twice is “medically unbelievable” or “medically unlikely,” so it is not payable.

DIRECT STATEMENTS REGARDING MULTIPLE TESTS OF THE SAME GENE: MEDICARE

One final barrier would be a typical direct statement in insurance policies. Medicare claims are not processed directly by the federal agency, rather, they contract with about a dozen local contractors which process claims in regions of several states. These companies are

⁹ American Medical Association (2013) Current Procedure Terminology. (Updated annually).

called “Medicare Administrative Contractors” or MACs. They are allowed to publish policies online to inform the public of their claims processing rules. Here is an example company Noridian Administrative Services or “NAS”, its Policy L24308, Genetic Testing.¹⁰ NAS writes: “A specific genetic test may only be performed once in a lifetime per beneficiary for inherited conditions.” [Continuing: “...however, when medically reasonable and necessary, genetic testing may be done on malignancies (including separate malignancies developing at different times)...” to track the cancer’s evolution of mutations.]

DIRECT STATEMENTS REGARDING MULTIPLE TESTS OF THE SAME GENE: PRIVATE INSURANCE

Similar, the largest US private payer, Aetna, has a genetic testing policy, Policy 0140, and states “genetic tests for inherited disease need only be conducted once per lifetime of the member.”¹¹ I found similar language in the insurer Wellcare’s policy HS-021, Capital Blue Cross Policy MP-2.232, BCBS Alabama Policy 136, Humana Policy CLPD-0495-006, and so on. Similarly, fifteen years ago, in a 1997 NIH report on genetic testing, a general remark is made that insurers only pay once for a particular genetic test.¹²

These citations support statements made last year that in general, insurance companies state that they will cover germline genetic tests -- only once.

END OF MY MAIN TESTIMONY ON SECOND OPINION GENETIC TESTING

¹⁰ As of 2/2013, the policy being quoted here can be located by going to this federal searchbox website: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx> and entering document number L24308 and on the next screen, a relevant date of interest, e.g. 01/01/2013.

¹¹ http://www.aetna.com/cpb/medical/data/100_199/0140.html

¹² <http://www.genome.gov/10001733>, Appendix 3

PART TWO: ADDITIONAL PERSONAL REMARKS OF DR. QUINN MADE AT THE CONFERENCE:

I can also comment – on a personal note, and based on my experience working as a consultant to companies in the diagnostics industry - there are quite severe incentive gaps in some areas for diagnostics. I make these comments based on statements by NIH staff earlier, that non-exclusive licenses would be granted for genetic patents in most cases, while exclusive licenses might be granted in certain cases where this was necessary to ensure adequate business investment incentives.

U.S. payers, both at the federal Medicare agency and in the private sector, are frequently stating that diagnostic tests lack enough evidence. See e.g. the following:

J Am Coll Radiol. 2011 8:124-31.

Evidence requirements for innovative imaging devices: from concept to adoption.

Frank RA, Rucker DW, Ferguson MA, Sweeney TJ. doi: 10.1016/j.jacr.2010.06.025

<http://www.ncbi.nlm.nih.gov/pubmed/21292189>

Value in Health. 2012 15:1162-71.

Challenges in the Development and Reimbursement of Personalized Medicine—Payer and Manufacturer Perspectives and Implications for Health Economics and Outcomes Research:
A Report of the ISPOR Personalized Medicine Special Interest Group.

<http://www.ncbi.nlm.nih.gov/pubmed/23244820>

Agency for Healthcare Research and Quality (2011)

Update on Horizon Scan for Genetic Tests Currently Available for Clinical Use in Cancers.

<http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id81TA.pdf>

A typical statement is one like this: “Acceptance of [genomic tests] by clinicians, payers, and patients has been unpredictable and suboptimal. A major limiting factor for the use of [genomic tests] is lack of clear evidence of clinical utility.”¹³ Similarly: “Generating and reviewing evidence that a test works and is clinically useful is challenging...[O]f the roughly 1000 to 1,300 newer and more complex tests, only a minority have demonstrated clinical utility so far. ...[Laboratories] often lack the incentives or resources to conduct the relevant studies....Overall, over three-quarters of physicians are either somewhat or very concerned about the lack of evidence supporting the use of genetic testing.”¹⁴ However, generating such

¹³ Institute of Medicine (National Academies of Science), Workshop on molecular diagnostics, May 24, 2012. See: <http://www.iom.edu/Activities/Research/GenomicBasedResearch/2012-MAY-24.aspx>

¹⁴ UnitedHealth [insurer], 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

evidence is costly, requiring the sheparding of substantial resources either from government grants, foundation grants, or from clinical revenue.

Take the case of the **huge health benefit** for that could be obtained through a better understanding the interactions and impact of **generic drug-metabolism genes** on **generic drugs**. This would be a fantastically important area to develop. Personally, as a business consultant, I have been on calls with boards of companies, with investors, that are trying very hard to dig a spade in and invest substantial amounts of funds (e.g. \$10M and more) in this area, an area that may be protected by no patents, FDA approval, or other IP protection. In this environment, it is very hard to invest due to the difficulty in capturing the results of investment. This would be characteristic of genetic tests put out into use on unlimited and unrestricted “licenses” of an existing patent.

I believe this might be more clear if I bring in an example from another field of diagnostic testing. This is just a “for-example.” Let’s say, as there are, there are basically three major PET scan manufacturers. Any one of the three could invest a large amount of resources, say, \$20 million dollars, to show how accurate its scanner was in the diagnosis of metastatic breast cancer. But once this study was completed and published, even if that one manufacturer had that one claim added to its FDA label, everyone would know that the result applies equally to all three brands of PET scanner, assuming they all have the same performance characteristics. It’s not the *post hoc* free rider problem, but the *ex ante* visibility of the this problem that would tend to discourage investment.

Running a reference lab at the national level is very difficult and raises burdens that an individual working inside the NIH licensing office might be unable to guess at. We have a grand profusion of different insurers in the United States. Consider there is one Medicare program, but a couple dozen Medicare Advantage plans splitting 20% of the nation's Medicare patients. There are 50 state Medicaid plans, but many with several separate HMOs within them. Regarding the Blue Cross Blue Shield alliance, there are 38 Blues plans, and each of the 38 treats labs separately for its beneficiaries (the lab must undertake separate enrollment, follow separate payment rules, etc.) Then there are dozens of small and large commercial insurers. If you try to run a national reference lab, or even a large regional one, your business overhead (whether you are an independent company or a university hospital) includes dealing with all of these and very uncertain payment returns from individual patient's insurers. It's as if you had to enroll with 100 or 200 or 300 credit card companies, all with different rules for what items they'll pay for, rather than a few, to run a retail business.

The standard code book for outpatient procedures, including laboratory tests, in the "Current Procedures" manual of the American Medical Association. As mentioned earlier, this is endorsed by a federal health law, HIPPA, as the code set used for communications about health insurance transactions. As of 2013, there are now 100+ gene codes for genetic tests, many are generic genes. I recently heard one Medicare medical director said, "There's not enough data and we wouldn't cover 90% of these [genetic tests]." Thus, having proprietary and IP-protected tests raising one set of circumstances, while having unprotected and generic tests raises another.

So I would say regarding the discussions we heard on January 10 regarding how NIST and NIH make determinations in allocating rights to patents in which the U.S. is a party: If you stand well outside the field, it could be too easy to under estimate the barriers to entry in genetic testing and the appropriateness of policy remedies. Again, this section of this document represents my personal comments as an experienced business consultant in the field of genetic tests and payor reimbursement.

Limits: 25 pages, 12 point, double spaced.