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Genes, Coding, and Bold Action?

Palmetto GBA Designs a Medicare Genomics Evaluation Program for 2012

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The last decade has seen the creation of complex genomic tests, sometimes as the outcome of tens of millions of dollars of research, designed from ground up to solve a recognized clinical problem. These tests, which range in price from $500 to $3000, are the "poster child" for the potential as well as the challenges when genomics and advanced bioinformatics are brought together and enter the clinic. According to a number of published studies, at least some tests in these categories can be net cost-saving in real-world scenarios, in addition to improving medical decision-making.

In March 2012, the local Medicare contractor for all California-based laboratories plans to launch an elaborate program for genomic test evaluation, coding, and pricing. This essay discusses major features of the program, as they have been released up to November 2011. The program is likely one of the most distinctive strategic policy efforts proposed by a Medicare contractor in the forty-five year history of the Medicare program.

Thirty Years of Genomics in Silicon Valley

In Jerry Brown's tenure as Governor (1976-1984), a new boom period in technology was about to begin. When he entered office, some Silicon Valley companies like Hewlett Packard were already well established. But two landmark events would occur in Silocon Valley while Brown was in office: Steve Jobs founded Apple, and Paul Berg at Stanford won the Nobel Prize for his fundamental and work on DNA. As an aside to these two events, Craig Venter was an unknown NIH postdoc who had just finished his PhD in California at UCSD.

The years from 1984 forward brought revolutionary changes both in computers and in biotechnology. Since the computer technology revolution started earlier, we've already seen it change the processes of daily life, through creations like search engines and instant email and internet storefronts for real goods and the instant globalization of political and social information.

For medical research, policy, and practice, in the fifteen years between 1995 and 2010, for example, it became possible to retrieve nearly any medical or biological journal article online, an enormous advantage to researchers. After 2000, digital technology and biotechnology intersected in the realization of enormous databases of genetic information were online (a process that began for peptides and genes in the 1980s).

Beginning around 2005-2010, genomics has had an increasing direct impact on clinical care, one that many observers believe is poised to increase substantially in the next decade. In 2010 and 2011, articles in the New England Journal of Medicine, JAMA, and Lancet are already early signals to the eventual arrival of next-generation sequencing in clinical care.

Genomics and the Healthcare Payor System

The genomic revolution has sped past the procedural system that healthcare payors are required to use for insurance claims processing. There have been refinements in the technology of electronic claims submission and electronic funds transfer for payments, from the perspective of transmitting rich content information about genomic laboratory tests, almost nothing has happened in twenty years. The process for describing molecular genetics procedures for the health insurance documents that govern the entire flow of funds in healthcare is almost unchanged today from what it was in 1993.[1] The awareness of critical problems in payer handling of genomic information is not new, however. Already by 2003, insurers were asking the AMA CPT system for much more specific coding for genomic tests, a problem that will have no national solution until 2013, *at the earliest*.[2] It took far less time for Steve Jobs to advance from the first, crude iPod

[1] See a previous paper in this series, Tempest in the Melting Pot, available at: www.tinyurl.com/brucequinnfoley

[2] Insurers complained about the 'stack code' system for genetics at least by 2003, with a two-digit modifier plan developed in 2003 and approved by the AMA CPT group in 2004, published in 2005.

to the first iPhone. It took less time for Genentech to develop genetically engineered Herceptin.

This white paper tells the new story of efforts by a Medicare contractor to jumpstart a substantial change in the way genomics are conveyed on claims to insurers, and to institute a new process for its genomic coverage decisions. Some readers will be unfamiliar with what a "Medicare contractor" is. Medicare claims are processed not by national Medicare policy staff, who are based in Baltimore and Washington, but by about a dozen contractors who operate the Medicare program in clusters of states (called "jurisdictions") under five-year federal contracts. Medicare's federal policy staff, operating under a framework of federal laws and regulations, set the outlines of coverage and payment policies nationally. But a great deal of the business of processing hundreds of millions of claims for tens of millions of patients – for any disease and nearly any kind of medical benefit – is not and cannot be specified in written regulation, so countless decisions are made by the local contractors.[3] Blue Cross Blue Shield of South Carolina is the corporate owner of two of the largest Medicare contractors, run independently as Palmetto GBA and Trailblazer Health Enterprises LLC.[4] These two businesses together manage the Medicare program in eleven states under three federal contracts.

With the stage thus set, the rest of this white paper describes the intersection of the Palmbetto GBA Medicare contractor and its policy staff with the rapidly changing and expanding penetration of genomic technologies into clinical decision-making.

Palmetto GBA and its MolDx Program

Because the Palmetto GBA contractor manages Medicare claims in California, Palmetto GBA has a disproportionate share of the national volume of genomics claims for Medicare patients. (This is because laboratories serving Medicare patients bill the contractor where the lab is located, not where the patient lives; the laboratory is the "location of service" under Medicare policy.)

For the Medicare program, then, Palmetto GBA has shouldered the brunt of the very poor existing coding system for genomic tests. Under the current system, human genetic or genomic tests are submitted to insurers with a few relatively trivial process codes, such as "DNA extraction" or "DNA amplification."[5] Some tests are submitted with what are

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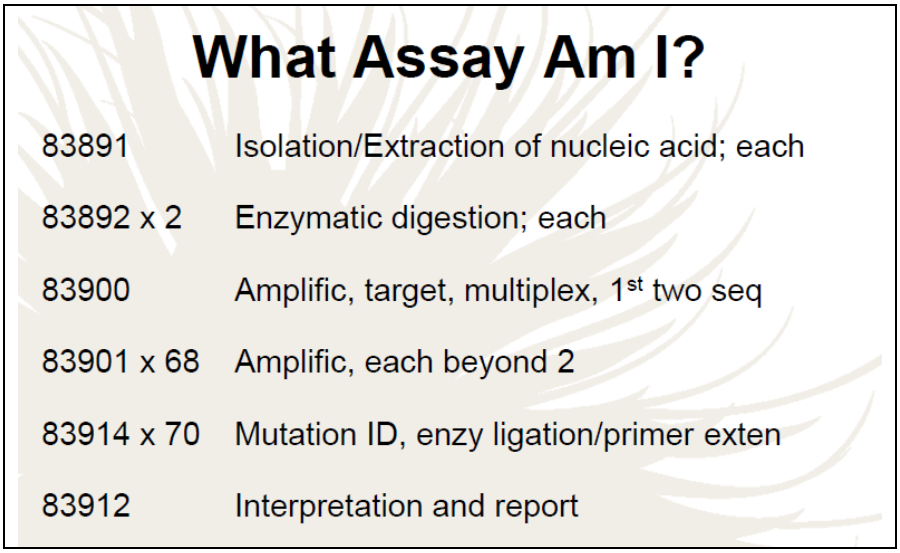
[3] The system of local contractors dates to the beginning of the Medicare program, in 1965, when most contractors operated as local (state based) Blue Cross or Blue Shield plans. This allowed the Medicare program to have a "turn key" start since the Blues' payment and policy systems and relationships with physicians and hospitals were already in place. Two earlier terms, "fiscal intermediary" and 'carrier," have been replaced by the more generic term "Medicare contractor." For more information on the Medicare contractor system see: https://www.cms.gov/medicarecontractingreform/

[4] See ww.Trailblazerhealth.com; www.Palmetto GBAgba.com . Palmetto GBA manages Medicare in four eastern states (NC, SC, WV, VA) and three western states (CA, NV, HI). Trailblazer manages Medicare in four southwestern and mountain states (TX, OK. NM, CO).

[5] By convention, "genetic" tests most often refer to human germline tests, such as for Huntington's disease or cystic fibrosis. "Genomic" tests include tumor mutation genes, levels of RNA expression in tumors, and other DNA or RNA based characteristics beyond the germline genes themselves. However, the terms "genetic" and "genomic" may sometimes be used interchangeably.

called "NOC" codes or "not otherwise classified" codes. These are placeholder codes, such as CPT code 84999 which can be used to represent any not-otherwise-identified "other clinical chemistry test."

In a recent slide deck showing the problem it faces under the current telegraphic coding system, Palmetto GBA medical directors framed the problem this way:



Palmetto GBA processes over $20,000,000 of codes per year in California through this "stack coding" claims system and like other insurers, has little or no knowledge of what genetic tests are actually being performed.

Palmetto GBA has sequentially announced three approaches which are its initiative to deal with the lack of specificity of genetic codes. Although the terminology is not used by Palmetto GBA, for the purpose of this white paper we will describe these as Phases One, Two, and Three.

Phase One was a "Palmetto GBA Laboratory and Molecular Diagnostic Services Program" announced in August 2010. **Phase Two** were two interlocking LCDs that restrict payment on genomic tests not previously reviewed and specifically approved by Palmetto GBA policy staff. These LCDs were released in draft form in October 2011 and will become "live" policies in February, 2012. **Phase Three** is a comprehensive umbrella program for handing the review, coding, and pricing of new genomic tests, which is scheduled to go live in March, 2012. Palmetto GBA has branded this comprehensive umbrella program, "MolDx." Unlike Phase One and Phase Two, MolDx represents a program that has been formalized, and granted additional budget, through an addendum to Medicare's federal "statement of work" for Palmetto GBA. MolDx has its own webpage with Palmetto GBA's domain.[6]

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[6] http://www.Palmetto GBAgba.com/Palmetto GBA/Providers.nsf/docsCat/Providers~Jurisdiction%201%20Part%20B~Articles~MolDx?open

We discuss the key features of each phase of the program below.

Phase One: Palmetto GBA Laboratory and Molecular Diagnostic Services Program

Palmetto GBA released a two-page description of its approach to coverage of genomic tests in late August, 2010, and has since updated the document with editorial revisions. The document, although brief, dealt in sequence with coding, coverage, and pricing issues. In opening the document, Palmetto GBA stated that current diagnostics coding presented it with three major problems:

- *Available code descriptions do not identify the service performed*
- *Methodology-based code descriptions are used in place of the specific test performed*
- *Multiple CPT codes are used to identify a single assay (unbundling)*

In response, Palmetto GBA stated it would require a comment field specifying the name of the test, and some additional coding guidelines. Regarding coverage, Palmetto GBA stated that labs presenting new tests for coverage must provide information following a specific dossier outline, and provided a step-by-step guide to submitted a coverage application. Regarding payment, Palmetto GBA quoted Medicare's existing "cross walk" and "gap fill" coverage rules, which is found in federal regulations:[7]

- *Charges for the test and routine discounts to charges*
- *Resources required to perform the test*
- *Payment amounts determined by other payers*
- *Charges, payment amounts and resources required for other tests that may be comparable*

The separate coverage guidance document required the laboratory to submit information on the test's analytical validity, clinical validity, and clinical utility, with additional guidance for its section.

Phase Two: Palmetto GBA LCDs on Genetics/Genomics

In October 2012, Palmetto GBA released two LCDs (with tracking numbers DL32288 and DL32286). While some parts of the two LCDs overlap, the DL32288 addresses all genetic/genomic tests and the DL32286 LCD addresses an additional specific concern of Palmetto GBA regarding what it saw as unorthodox "genomic panel" tests.

The two LCDs entered a public comment period from 10/14/2011 to 12/5/2011 and careful readers questioned the meaning of some sentences as originally drafted (e.g. use of the word "and" versus the word "or"). However, the general intention behind he policies is clear. The LCD titled "Molecular Diagnostic Tests" creates a policy under which no genomic test is covered until authorized by Palmetto GBA policy staff:

LCD DL 32288

[7] 42 CFR 414.508

This policy confirms 'non-coverage' for all molecular diagnostic tests that are not explicitly covered by a National Coverage Determination (NCD), a Local Coverage Determination (LCD) or coverage article published by Palmetto GBA.

For the purposes of this policy, Palmetto GBA defines MDT as "a single test (often with multiple components) that delivers one result and involves nucleic acids (DNA/RNA), proteins, enzymes and/or other metabolite detection. Most test results rely upon an algorithm or other form of data/evaluation derivation."

In addition to this definition, this non-coverage policy applies to all tests that:
1. Are Non-FDA cleared laboratory developed tests (LDTs, or
2. Are performed or marketed by a sole source, hospital or reference laboratory, or
3. Have not received a specific AMA CPT code, or
4. Have not obtained an NCD or a coverage determination from Palmetto GBA (LCD or article).

The LCD does not review or identify any particular test. The LCD itself does not contain further information on what Palmetto GBA's coverage standards would be or how a dossier should be submitted, but guidance is found in an article linked to the LCD.

The DL32286 LCD is directed toward what Palmetto GBA calls "Non-Standardized Organ or Disease-Oriented Panels." The molecular characteristics of these tests are defined similarly to the test definition shown above. However, Palmetto GBA appears to take a stronger view towards these tests:

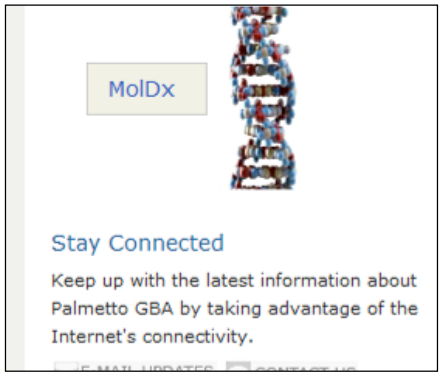
LCD DL 32286
Services reported with multiple codes and a single and/or multiple units of service to represent a single test panel are considered investigational and therefore, not a covered service.
Palmetto GBA will apply the following payment rules:
• Test panels submitted and paid that have NOT been reviewed and approved through the Palmetto GBA mandated process are considered investigational and will be subject to overpayment collection.
• Approved test panels will be effective for dates of service on and after the approval date.
• Dates of service prior to the approval effective date will be subject to denial and overpayment collection.
• Unapproved panels will be subject to denial and overpayment collection.

As an example, Palmetto GBA may be thinking of the following situation. A laboratory offers an oncologist its "Kidney Cancer Diagnostic Panel." The doctor checks the corresponding box on an order form. The laboratory then runs a panel of twenty genes, requiring 120 molecular "steps" (eg PCR x 120) and submits to Medicare a claim for 120 steps x $20 per step or $2400. A few months later, the lab may have expanded the panel to thirty genes, and now submits its claims for 180 x 30 or $3600. Palmetto GBA's draft version of LCD DL3286 reflects their concern that current claim forms to do not have enough clinical and technical information to allow them to confidently autopay the tests billed.

Phase Three: The CMS-funded "MolDx" program

Why was the MolDx program developed? It is reasonable to guess that the contractor's policy staff was concerned about the lack of AMA CPT coding tools to solve the current claims-processing problems of major payors. For example, to the end of 2011, the AMA codebook has not yet even begun to deal with so-called "proprietary" or high-value genomic tests. Even if the AMA were to address proprietary tests in a future year, any such new codes will not take effect until 2013, 2014, or later. In addition, the initial AMA CPT genetic codes, although now published, have been classified as void for Medicare use by CMS during calendar year 2012. They will not be effective for Medicare claims until 2013 at the earliest.[8] Some major private insurers have stated they will not use the new AMA CPT genetic codes in 2012, either.[9]

CMS gave direction to Palmetto GBA by adding the MolDx program to its "Statement of Work" beginning October 1, 2011. On November 2, 2011, Palmetto GBA announced a new comprehensive "MolDx" program expands on its earlier policy article (what I have called "Phase One") and depends for some of its features on the two October LCDs on genomics (what I have called "Phase Two.")



The new MolDx program has been extensively described in documentation on the Palmetto GBA website, released in early November (see footnote 6). Likely, additional details and clarifications will continue to appear. Quite likely, some stakeholders will ask Palmetto GBA or CMS federal staff to halt or alter some features of the program. With those caveats mentioned, the major features of the program are as follows.

Regarding coding, there is no change to established procedures for submitting CPT/HCPCS codes on a claim. However, beginning in March 2012, Palmetto GBA will reject any molecular diagnostics claim that does not have an additional code unique to the molecular test being performed and placed in the "comment" box of the claim form. Palmetto GBA states that it can require special codes in the "comment" box of the claim form because federal law requires that only national, HIPAA-endorsed codes and code sets must be used in the standardized parts of a medical claim between U.S. providers and payors, whether the payor is federal and private.[10] Palmetto GBA has stated that laboratories can get a free "Z" code, a five digit alphanumeric code, representing their tests, from McKesson. McKesson is several years into the development of a

[8] For full details, see Document listed at FN 1.
[9] Q1 Diagnostics and Reimbursement Conference, Cambridge, MA, 11/7/2011.
[10] The HIPAA law is best known for patient privacy protections, but also requires uniformity of insurance code sets. See 42 CFR 160 and 162.

supplemental insurance, physician, and laboratory information exchange platform called the Advanced Diagnostics Management system.[11]

Regarding coverage, Palmetto GBA announced a more specific set of instructions to entities submitting a coverage request. Coverage requests will be submitted online beginning in 2012. Palmetto GBA states it will use subject matter experts from academia and industry to advise it on test evaluation. Palmetto cites the GRADE system[12] for medical evidence evaluation as the model to structure this program. When a coverage request is submitted, Palmetto GBA will confirm whether the request is complete within 30 days. Within 90 days, a coverage decision will be completed for "new" tests (not previous submitted for a coverage decision to Medicare). Providers will have the opportunity to "stay the clock" for up to 180 days to provide additional information. A technology review précis' will be posted for 30 day public comment. Within 30 days after a favorable decision, a coverage determination article with billing/coding guidelines be posted. A negative decision will not be publicly announced. If Palmetto GBA denies coverage for the test as "not medically necessary," it will not review a new dossier until after a moratorium of 180 days. Whereas Palmetto GBA had earlier (Phase I) stated that "white papers" and abstracts would not be considered at all, Palmetto GBA will consider these documents as part of the test's packet, as well as articles accepted (that is, in press) at peer reviewed publications. Palmetto GBA states that it may also require non-published (proprietary) internal data regarding aspects of analytical validity.

Regarding pricing, Palmetto GBA is less specific. In public documents announcing the program, Palmetto GBA builds on, but is consistent with, Medicare program manual guidance for pricing novel technologies at the local contractor level. Pricing factors are at the contractor's discretion but inputs may include crosswalk and gapfill methodologies,[13] value based arguments (e.g. health economic studies), discounted rates, private and government payer rates, and market based information. It has not been announced whether Palmetto GBA will release more detailed templates regarding its pricing benchmarks and processes.

A BRIEF EVALUATION

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[11] http://www.mckesson.com/en_us/McKesson.com/For%2BPayors/Private%2BSector/Advanced%2BDiagnostics%2BManagement/Advanced%2BDiagnostics%2BManagement.html

[12] E.g. Harbour et al. (2001) Brit Med J 323:334-6. See also: Schunemann AJ et al. (2008) Brit Med J 336:1106-10.

[13] "Crosswalk" and "gapfill" are terms of art in laboratory test pricing. Crosswalk means the price of a test is matched to the existing price of one or more similar tests. (For example, Test X could be 3 times Test Y.) "Gapfill" means an interpolated price where no crosswalk is available. CMS formally recommends several benchmarks, including the price of similar tests, resources required to provide the test, and prices of other payors. Regulations require that the crosswalk and gapfill methods be used when the AMA announces a new CPT code that is placed by CMS on the Clinical Laboratory Fee Schedule. CMS provides very little direct guidance as to how to price a service communicated by a nonspecific code (e.g. 84999) although in the absence of other guidance, a contractor could choose to use the gapfill guidance found at 42 CFR 414.508.

MolDx: A framework built from existing parts

Although the Phase Two and Phase Three programs seem dramatic, most of the features they embody are actually latent or possible in prior policy.[14] To illustrate this, here are three examples:

- *Seeking outside input.* Medicare contractors and medical directors have always worked under recommendations by CMS to seek the input of associations, outside technology assessments, stakeholders, and recognized experts.

- *Coverage timeline.* While the Palmetto GBA policy describes a formal 180 moratorium after a negative decision, providers nationwide may be familiar with periods when a medical director simply stops returning further emails, absent any formal notification that a "moratorium" on review has occurred.

- *Inputs to a pricing decision.* The guidelines for pricing "unpriced" products and services are provided by CMS only in sketch form, meaning that much discretion is left to the local contractor. When CMS published its federal regulation on the "gapfill" rules for new laboratory tests, CMS directly noted that pricing may be difficult and that contractors required discretion to assess a range of potential factors in setting a product price for Medicare purposes.[15]

A few policy implications

There are three policy implications of the MolDx framework which will play out in the future. These are (a) the use of special identifier codes, (b) the publication of decisions as articles rather than LCDs, and (c) the impact of the LCDs on the appeal process for providers who disagree with denial and argue their test's medical necessity.

(a) Use of special identifier codes.

Medicare contractors *can* require "all information necessary to appropriately process a claim," under SSA 1833, although there are also *restrictions* against routinely requiring information beyond HIPAA requirements for claim forms. This issue may be more

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[14] I was influenced in this reading of the Palmetto GBA program by a PhD thesis on the evolution of problem, process, and regulation at the FDA (D. Messner, 2008, Fast Track: The practice of drug development and regulatory innovation in the late twentieth century U.S. Univ. Edinburgh.) Messner argues that FDA programs like "Fast Track" and "Accelerated Approval" addressed simmering problems, but that the appearance of formal public regulations often reflected processes already partially put in place *before* the regulation appeared. Thus, aspects of Palmetto GBA's MolDx program (such as consultation with experts) were available and even encouraged by Medicare program policy statements prior to the MolDx documentation, which formalized the process. Examples of national Medicare policy where internal problem analysis and process action preceded and telegraphed later formal regulation include Medicare's lab date of service rule and Medicare's three-year rule for DME.

[15] 71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007

formally debated and resolved. Stakeholders will likely debate whether or not a de facto 'local code" is being created, something is not generally allowed under HIPAA uniformity principles.

As far as the incorporation of McKesson "Z" codes, even if Palmetto GBA did not use the McKesson system of "Z" codes, it could potentially require labs to use some kind of assigned code to achieve its goal of facilitating automated claims processing of specific genomic tests by machine-reading a unique code in the claims form comment field.

(b) Publication of decisions in articles, not LCDs.

Palmetto GBA's would publish the results of its coverage decisions as articles rather than as LCDs. Statute and regulation state that *any coverage decision made by a contractor that is binding throughout its jurisdiction* "is" an LCD. This concept has been tested at law.[16] Admittedly, no one will test a favorable coverage article by complaining about it. However, if a genomics coverage article allows coverage for tumor X but not tumor Y, or for certain ICD-9 codes, but not others, a lab might argue that the document is a de facto LCD (a coverage decision binding throughout a jurisdiction).

(c) Impact of the LCDs on the appeals process.

Medicare regulations give the CMS contractor two privileges. First, it may autodeny claims based on the LCD. Second, if the provider appeals the resulting denials, the cases are more difficult to win because the administrative law judges evaluating CMS appeals must grant "substantial deference" to denials based on an LCD.

- ***Autodenial.*** Regulations state, "CMS may automatically deny a claim [for a laboratory test] without manual review if [an NCD or LCD] specifies the circumstances under which the service is denied."[17] The blanket non-coverage LCDs thus allow Palmetto GBA to put autodenial edits it in place when nonconforming claims arrive.

- ***"Substantial deference."*** If claims denied under these LCDs reach the appeal level of an Administrative Law Judge, it is unclear how much deference they would be provided. Nominally, regulations require that these judges give "substantial deference" to LCDs.[18] Since these are blanket LCDs, they lack argumentation and analysis as to why any *particular* complex genomic test, with a *particular* dossier of research data, would have been denied for a particular

[16]See http://www.hhs.gov/dab/decisions/dab2050.pdf In this case, the then-current California Medicare contractor published in 2004 *an article* stating "non coverage" of an alternative medicine service called "transfer factor" injections. A provider appealed under CMS policy that allows "*an LCD*,"as a whole, to be appealed to an administrative law judge and then further appealed to the Departmental Appeals Board (DAB) of CMS. HHS judges ruled that whether the document in question was called an "article" or called an "LCD," a contractor's document that declared a coverage decision was, de facto, an LCD under current law

[17] 42 CFR 410.32(d)(4)(ii).)

[18] 42 CFR 405.1062(a).

circumstance. As a result, once the autodenied claims reach higher levels of appeal, the deference granted to the original denial may be correspondingly light.

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 the 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 .