

Crossing the Three Chasms:

Complex Molecular Testing and Medicare Regulations

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The American health care system is in need of major restructuring. This will not be an easy task, but the potential benefits are great. To cross the divide between today's system and the possibilities of tomorrow, strong leadership and clear direction will be necessary.

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“Crossing the Chasm: A New Health System for the 21st Century” has been cited thousands of times in the effort to bring transformational change to the American healthcare system. Published by the Institute of Medicine in 2001, the report describes a “chasm” between the circumstances of today and the possibilities of the future.

For molecular personalized medicine, not one but three chasms must be crossed. As we describe in detail, these chasms stem from new revisions to Medicare rules for billing jurisdiction, Medicare payment rules, and dilemmas in making coverage decisions for innovative technologies. Personalized medicine – getting the right treatment to the right patient at the right time – is a pillar of efforts to bring increased effectiveness and efficiency to healthcare. Frequently, this goal will be unattainable unless physicians have precise molecular information about the disease being treated. Therefore, it is crucial that the healthcare system facilitates the adoption of new molecular technologies when they are clearly shown to be effective.

In this white paper, we demonstrate that several critical reimbursement barriers, or “chasms,” have emerged to block the progress of diagnostic molecular medicine. Unlike scientific or technological barriers, the three chasms facing molecular diagnostics are regulatory conventions. If not addressed, these conventions could easily present a more severe barrier to progress than do purely scientific challenges.

Two of the chasms (billing – Medicare’s specimen rules and coding – the US system of legacy code formats) are unintended consequences of certain regulations, coding conventions, and statutes. These rules are already in collision with the realities of molecular diagnostics, but the resulting problems could be solved by regulatory change or minor statutory change.¹ The third chasm is the limitations of current approaches to evaluating the value of complex tests in molecular personalized medicine. Payers and providers do not have a standard body of tools for evaluating the effectiveness of new approaches, particularly when the results of a test substantially shift existing treatment pathways.

¹ Regulatory change is a rule revision which can be undertaken directly by a government agency. Statutory change describes the revision of a point of Medicare law by Congress.

We suggest changes which will maintain national goals of paying for efficient, well-researched advances based on insightful medical review, while reducing arbitrary and sometimes very high barriers to these same goals.

THE FIRST CHASM: MEDICARE BILLING RULES

Most laboratory tests are performed on individuals who are not hospital inpatients, and Medicare pays for the tests on an itemized basis². However, the rules governing these outpatient lab test payments have become excessively complex and often produce baffling results. Billing for tests using specimens obtained in different settings (for example, a hospital outpatient visit, a physician office visit, an ambulatory surgical center, a hospital surgicenter, etc) is treated differently, even though the testing is performed in a single location by a national referral laboratory and Medicare regulations specify itemized payment for the test. The luck of the draw – here, a blood draw and its location – shunts the specimen and the lab providing the test into a hodgepodge of coding, coverage, and reimbursement pathways.

From a functional perspective, such complexity is unnecessary. Until 2007, when the Centers for Medicare & Medicaid Services (CMS) modified its interpretation of the existing statute,³ reference laboratories performing complex molecular testing (of either hospital outpatient or non-hospital-patient origin) billed Medicare Part B directly. In other respects, Medicare's statutory instructions facilitate efficiency in the laboratory industry, and a host of other Medicare regulations (including national rulemaking for laboratory National Coverage Decisions (NCDs) and rules that allow multi-state laboratories to bill Medicare via one carrier) worked well to reduce paperwork and increase the efficiency and uniformity of test coverage. The referral laboratory billed Medicare once under national guidelines.

As of 2008, however, a reference laboratory performing a unique and complex test in one specialized location must establish a separate contract with each hospital in the United States, large or small, receive the specimen, invoice the hospital, and collect separately from each hospital. More importantly,

² All inpatient services, including laboratory tests, are bundled by Medicare into a single payment covering all of that patient's tests and treatments during one hospital stay. This is called the Diagnosis Related Group (DRG) payment system. We propose no changes to these rules. Where appropriate, the current system allows CMS to issue new technology payments to supplement the existing block payments for DRGs.

³ See discussion of previous legislation at 63 FR 47554-47555 (1998). CMS explicitly stated in 2000 that outpatient lab tests did not need to be "bundled" the hospital payment channels (64 FR 59408), a position flipped in 2001 in a quite subtly phrased remark that evoked no public comment at all (65 FR 55285) .

every Medicare jurisdiction was – essentially overnight – required to develop its own coverage, coding, and reimbursement system for tests performed by such national laboratories. Moreover, each individual hospital must now establish separate billing procedures for extremely complex molecular tests, performed far away, that internal hospital billing staff are unable to understand. And each hospital must negotiate individually with its fiscal intermediary for coverage and payment.

Because it takes many years for tests to receive a laboratory CPT code,⁴ the result is a logistical nightmare for laboratories, hospitals and the fiscal intermediary. It is clear that CMS regulators did not anticipate this outcome.⁵ Further, the new “system” produces disparate coverage and payment policies across the United States for exactly the same product, performed for exactly the same type of Medicare patient, and for exactly the same condition – a result that Congress has elsewhere tried to avoid.⁶ The 2008 process is unnecessarily time consuming, clumsy, and makes little sense.

THE SECOND CHASM: CODING/REIMBURSEMENT RULES

Currently, Medicare pays for laboratory tests using a fixed fee schedule, on which prices have been locked for many years. Laboratory tests are described by 1100 procedure codes (e.g., 85014, “hematocrit”). Very few codes are added each year, and the new-code process takes several years.⁷ This

⁴ Current Procedural Terminology (CPT) codes are managed by the AMA and only limited revisions are possible, on a two-to-three year timeframe. All entities billing insurers for lab services are required to use one or more published CPT codes to describe the work performed. The next section describes coding rules in more detail. Here, the point is that the lack of specific codes aggravates the per-hospital billing nightmare for complex molecular tests. See also note 7.

⁵ 71 FR 69706, regulatory impact discussion at 69773; there is no evidence the burden or complexity for CMS contractors, as well as hospitals and laboratories, was considered with regard to the regulatory notices regarding administration and paperwork.

⁶ MMA 731 directly encouraged CMS to develop mechanisms for uniform coverage across contractors. Both BBA 531 and MMA 942 required CMS to develop appropriate methods for pricing innovative laboratory technologies. See 71 FR 69703. Prior legislation also initiated “negotiated rulemaking” for uniform claims processing and medical review standards (e.g. 42 CFR 410.32(d)) and some two dozen NCDs for conventional (commodity) laboratory tests to promote national uniformity of coverage standards. Legislation also requires the performing laboratory to bill for tests and allowed a multi-state laboratory to bill Medicare from one center, using referents to local fee schedules where the rendering lab was locating. MMA 942 established a council on technology and innovation at CMS to streamline and coordinate processes for coverage, coding, and payment of innovative technologies (<http://www.cms.hhs.gov/CouncilonTechInnov/>)

⁷ While the minimum lead time for a new code is about 18 months, the test must have FDA approval and rules require the service be “widely used” before consideration by the CPT committee, which could take an additional two years. Repeat submission of initially rejected codes is common. Thus, the lead time for a

coding system only makes sense under a paradigm where laboratory tests are commodities with fixed parameters, and innovation is only used to reduce cost or improve precision of existing, historically defined tests. Under these circumstances, new codes are not required, and continued payment at historical rates encourages efficiency.

Unfortunately, this approach has perverse implications for new molecular tests. The payment and coding structure presumes that these tests are made up of a handful of predefined, generic steps which are priced at about \$10-20 each.⁸ Innovative steps, such as quantitative PCR, go many years without a code at all.

Precise, new-generation molecular tests that establish important, unforeseen molecular characterizations of a patient's tumor or illness crack the assumptions under which the current system works. That is, complex molecular laboratory tests are not pre-defined commodities. The new generation of laboratory tests is being developed based on innovative research, and is opening a new technological era in diagnostic testing. The development of these tests involves astute investment, risk, intellectual property, substantial clinical trial costs, and mandates a workable return on tests that can revolutionize treatment decisions. These tests are designed to change the paradigms of clinical decision-making, not just to tweak the cost or precision of an existing predefined test. And crucially, unlike old tests, which required only accuracy and reliability at the benchtop, complex new tests require clinical trials, just as drugs do. The prospect of facing fixed historical prices that ignore investment, patents, and clinical trials can stifle innovation even prior to the investment stage.⁹ That is, current payment

CPT code, after market introduction, could be 2 years before submission, and one to two 12-18 month cycles thereafter. In sharp contrast to, for example, NDC codes for drugs, the system requires several years and there is a strong barrier to issuance of a new code.

⁸ 83890, nucleic acid isolation or extraction, \$5.60. 83902, reverse transcription, \$19.83.

⁹ Where a fixed, historical price like \$18 cannot be applied, CMS has explicit regulations to price the test at the lowest marginal cost (42 CFR 414.514)(b)(ii)), which by definition is blind to risk, development cost, clinic trials, and other necessary costs of actually creating and providing the test. See discussion of 408.514 at 71 FR 49064. Despite locking in marginal-cost pricing, which is blind to development cost, CMS stated directly that "In addition to providing payments, Medicare's clinical laboratory fee schedule for both new and existing tests should foster the provision of quality care and the prevention of avoidable health care costs." Loc cit.

For example, imagine a pancreatic cancer molecular test which takes \$10M to develop and commercialize. There are about 30,000 new cases of pancreatic cancer per year in the US. Allow that the test has a five year payback period at a 10% discount rate, and market penetration of 25%. The overhead which amortizes R&D alone is \$325 per test, without considering actual lab costs (say, \$300), marketing, consideration of a priori development risk, or profit. If the test measures ten genes, Medicare reimbursement may be approximately \$300. Even using simplistic, back-of-envelope assumptions, the break-even cost exceeds \$800, a multifold shortfall over the fee schedule price of \$300.

rules operate to heavily obstruct innovation in an area of healthcare that should be booming, moving healthcare toward the goals of efficiency and effectiveness promised by molecular personalized medicine.

THE THIRD CHASM: COVERAGE FOR INNOVATIVE TECHNOLOGIES

From the perspectives of both effectiveness and efficiency, all stakeholders invested in the struggle to improve America's costly healthcare system agree on the importance of basing medical decision-making on high-quality evidence.

Evidence-based medicine deals with the long-standing adage that the art (of medicine) is long; time is short, experience treacherous. At base, evidence based medicine is a scientific evaluation of whether a treatment works. Technology assessments serve to frame existing evidence, taking into account patient variables, meta-analyses, and other data sources. Comparative effectiveness studies use head-to-head or meta-analytic metrics to weigh either similar (two drugs) or diverse (drug vs. surgery) therapies.

Too often, good intentions – which look for large, randomized, prospective clinical trials to verify every claimed value – run afoul of practical realities. For instance, a new molecular test for prostate cancer, developed through \$10M of preclinical and clinical research, confirms that for a given patient, his chance of prostate cancer recurrence is 2% or below. As a result, he will not be given radiation therapy or chemotherapy because the risks of the therapy are greater than his negligible risk of tumor recurrence. Assume that development trials assure us that the risk of recurrence is indeed 2% or less. An insurer may thus take that stance that while the data is promising, “there is many a slip twixt the cup and the lip” and therefore, the insurer cannot accept the test as “proven” valuable until after the completion of a prospective, randomized controlled trial.

Surprisingly, the insurmountable problem here is not the duration of the trial, the cost of the trial, or the time required to analyze and publicize the results. Rather, the randomized trial cannot be conducted at all, because no institution will take patients with a 2% risk of recurrence and randomize half of them to radiation and chemotherapy. That is, the trial cannot be

The key principle is that where conventional tests must meet only accuracy standards (low direct development costs), new-generation molecular testing requires substantial clinical validation and mapping of clinical utility, more akin to the cost of medical device or drug trials. Neither medical devices nor drugs could exist if reimbursement was locked to marginal cost of the metal and wires of the device, or the chemical formula of the drug. The marginal-cost rule is inconsistent with clear Congressional intent behind repeated instructions to CMS to provide appropriate reimbursement for innovative tests (BIPA 531, MMA 942).

randomized because clinical equipoise between the two treatments cannot be assumed. Many new complex tests, by their nature designed to powerfully impact clinical paradigms of decision-making, will negate clinical equipoise and thus block randomized trials before such trials can be undertaken.¹⁰ There will be circumstances where payer coverage, withheld until after randomized trials are undertaken, will permanently block test availability. In short, there is a net loss of social benefit.

Although important, the point we make is not new. Thought leadership in the area of evidence-based medicine recognizes that a clearly established impact on medical decision-making is the platform for coverage decisions for diagnostics.¹¹ The problem described here, that the accuracy and clinical validity of new tests often make prospective randomized trials unethical, is well-recognized in the evidence-based medicine literature. Practical experience suggests that these concepts may be very poorly recognized at the level of insurer coverage.¹² New paradigms must be implemented judiciously at the level of actual coverage decisions that recognize this paradox and provide a reasoned, clinically sound approach to determining when coverage is appropriate and raises the effectiveness and efficiency of treatments.

RECOMMENDATIONS

The goals of the following recommendations are to achieve efficient billing and reimbursement mechanisms, avoid rules which lead to impossible outcomes (e.g. the reimbursement is 10% of the actual test cost of an efficient, medically necessary test), and promote accurate but timely coverage decisions.

1. **Amend Medicare rules on billing for diagnostic testing (regulatory change).** CMS should clarify whether rules reflect merely date of service conventions, are driven by hospital bundling issues, and/or are based on the impact of the service on care delivered during the hospital

¹⁰ The general point, that strong but not definitive data may make randomized trials unethical, has been made before, e.g. Ioannidis J et al. (2001) JAMA 286:821-30.

¹¹ E.g. Straus SE et al. (2005) Evidence Based Medicine, 3rd Ed., Churchill-Livingstone. Jenicek M (2003) Foundations of Evidence Based Medicine. Informa. Riegelman RK (2004) Studying a Study, Testing a Test. Williams & Wilkins. Khoury et al. (2007) The continuum of translation research in genomic medicine. Genetics in Medicine 7:665-74. Ramsey SD et al. (2007) Toward evidence-based assessment for coverage and reimbursement of laboratory-based diagnostic and genetic tests. Am J Managed Care 12:197-202. Lewin Group/Advamed (2005) The value of diagnostics innovation, adoption, and diffusion into health care.

¹² Institute of Medicine (2008) Knowing What Works in Healthcare: A Roadmap. US must still “develop a common language and standards” for evidence assessment and decision-making.

encounter. Current explanations are inconsistent. Revisions should be designed to standardize the handling and payment of tests and reduce unnecessary burdens on laboratories by choosing efficient billing rules and processes. While these billing rules could be revised at the discretion of CMS, if the agency does not do so, legislation could be used to trigger change. If CMS's primary concern is to prevent separate billing of lab tests during inpatient care, or double-billing of lab tests originating in outpatient tissue samples, then the least burdensome path to this goal should be developed.

2. Modify coding conventions and reimbursement methodology (options for regulatory and statutory change)

a. CODING.

Problem: Current rules channel code development through the CPT panel, which can take 3-5 years after market launch (note 7). This greatly raises administrative costs throughout the reimbursement system.

- i. Increase use of Category III (temporary) CPT codes. We cite this option for completeness, because it addresses the issue of long delays before Category I codes are issued. Category III codes are issued on a semiannual basis and CPT rules do not place barriers as high as those for Category I codes. However, we do not recommend this approach because Category III codes are designated merely as "tracking" codes for new procedures, including experimental ones, and by definition, the codes are temporary.
- ii. Use CMS-assigned HCPCS codes rather than Category I CPT codes. CMS has the discretion to create HCPCS codes semi-annually. However, CMS unilaterally creates HCPCS codes in response to "programmatic need" such as a code required to implement a specific regulation or NCD. CMS has made no indication it would view this approach favorably. CMS has generally left code creation for tests and services to the CPT committee whenever possible.
- iii. Create a novel test-coding system, perhaps similar to NDC codes for drugs or UPC codes for other commercial products. (This would require some regulatory change,

because of HIPAA rules which lock payers to the current CPT system for laboratory codes.) This option, although rarely suggested to date, has the virtue of accelerating timeframes and separates issuance of a test code from time-consuming and indeterminate “need and necessity” decisions at the coding committee. This would be a poor option for other codes like surgical procedures, where there is a high degree of interaction amongst codes and how they parse medical services, and a poor option for historic lab tests, which appropriately describe commodities. One approach, within the five-place coding system, would be to issue novel personalized medicine test codes in a format such as LBXXX, where XXX represents letters. This would allow some 17,000 codes.

- iv. We have not proposed a change of the CPT system itself. The barriers described for complex laboratory test codes are found across the entire the Category I CPT coding system for all physician services, and the rules actually function well for many medical/surgical services. If a substantial change in the AMA/CPT system were undertaken, for other reasons, then such change could incorporate revisions which remove obstacles to coding for personalized medicine tests.

b. REIMBURSEMENT

- i. Develop coding conventions that allow for rapid, accurate identification of novel tests (section 2(a)). This is required in addition to revising reimbursement.
- ii. CMS has twice been encouraged by Congress to develop procedures which price innovative laboratory tests fairly (see footnote 6). Nonetheless, current price-setting guidance focuses on measures of marginal cost alone, which is incompatible with the risk and intrinsic development costs in diagnostic molecular tests which also require clinical research. (When the primary rules for setting marginal cost by reference to legacy fee schedules cannot be applied [for example, no code exists] then current rules jump abruptly to radically different valuation like median of invoice prices; footnote 9.) To date, CMS uses a range of pricing schemes for different kinds of healthcare services, none of which directly

appraise the clinical value of the service provided¹³. However, CMS has clearly emphasized the need to shift to value-based purchasing¹⁴. A statutory demonstration program has been proposed to establish fair pricing of innovative tests through a new committee dedicated to valuation of innovative laboratory tests¹⁵.

3. Ensure acceptance of appropriate frameworks for coverage decisions.

Develop white papers and peer-reviewed publications to clearly describe the problems with current evaluation of the value of new complex molecular tests in the actual world of payer decisions, including Medicare, and provide a framework for effective decisions. Evaluation of novel molecular tests may require a distinct framework from the kinds of analysis focused on changes in clinical decision-making. (For example, the “poster child” dilemma occurs when initial clinical data may be so clear that randomized trials are unethical, but some payers may insist that coverage follows completion of such a randomized trial.) No formal change of existing CMS codes and laws is required. As noted in the body of this paper, these frameworks exist in the public policy, public health, evidence-based medicine literature. The need addressed here is to ensure that this thought capital is readily available to payers, including Medicare contractors. For example, creation of an explicit Medicare guidance document or

¹³ Medicare uses a diversity of pricing methods. Laboratory tests are priced based on historical values or new estimates of marginal costs alone. Drugs, in contrast, are paid at 106% of the average national sales price. Durable medical equipment is priced based on market surveys. Physician prices are based on formal estimates of work effort multiplied by dollar conversion factors. Reimbursement for hospital outpatient services is based on cost surveys, conservatively construed by regulations and adjustments. Competitive bidding pilot programs have been undertaken for DME equipment and conventional laboratory tests, but this model would be of low value when many services had sole-source providers. A new methodology for pricing of novel complex laboratory tests would likely refer to existing price-setting frameworks accepted in one or another part of the Medicare pricing system. It would need, at a minimum, to depart from pure marginal pricing in order to allow for development costs, while providing CMS with controls reining reimbursement to value.

¹⁴ Speech of Acting Administrator Weems to the JP Morgan Healthcare Conference, San Francisco, January 2008. <http://www.cms.hhs.gov/apps/media/speeches.asp>

¹⁵ Senate bill 2404 (Schumer), introduced December 2007. This legislative proposal would require CMS to establish a special multi-stakeholder committee to issue new HCPCS codes quarterly and determine fair pricing. The bill proposes a four-year demonstration project. The committee would assign tests to pricing bands (similar to the APC system) reflecting "typical resources required to perform the test." The amortization or recoupment of intrinsic development costs, as opposed to per-test resource consumption of the final test, is not specified. However, stated goal of the legislation is to provide pricing which is "appropriate" and "equitable."

inclusion of guidance in Medicare's contractor program manual would be very helpful.

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Dr. Quinn is a national leader in the areas of Medicare coverage and payment, claims and billing, and Medicare contractor reform processes. He works with companies, providers and venture capital investors to develop strategies for Medicare payment for new technologies. A large part of this work is on local and national coverage decisions. He focuses, in particular, in the emerging field of molecular diagnostics and personalized medicine. He also advises clients on Medicare Administrative Contractor (MAC) reform and its effect on payment policy.

Before serving in the Medicare Part B program, Dr. Quinn was a physician executive in the Health & Life Sciences division of Accenture and was a clinician-scientist at Northwestern University School of Medicine, leading pathology research for Northwestern's NIH-funded Alzheimer Research Center. He also held academic positions at New York University School of Medicine and UCLA Center for Health Sciences.

