

LABORATORY RULE-MAKING: “WE MUST ALL HANG TOGETHER OR ASSUREDLY WE SHALL ALL HANG SEPARATELY.”

Dinetia M. Newman

Benjamin Franklin’s July 4, 1776 comment to delegates preparing to sign the Declaration of Independence is equally applicable to hospitals and physicians convened in HCFA’s negotiated rule-making committee regarding clinical diagnostic laboratory tests. As with other Medicare payment rules, Medicare’s clinical laboratory payment rules pit hospitals and physicians against each other.

The Conflict Between Hospital and Independent Labs and Physicians

The conflict between physicians and both independent and hospital-operated labs stems from the applicable provisions of Medicare statutes, regulations and manual sections governing coverage and payment for clinical laboratory tests. If a physician performs a clinical laboratory test and requests payment from Medicare, he must include in his request for payment the appropriate diagnosis code or codes for the laboratory test.¹ This requirement may not apply if a physician orders a lab test from a hospital or independent laboratory. In 1997, the Balanced Budget Act (the “BBA”) amended Section 1842 of the Social Security Act to require a physician or other practitioner who orders a lab test furnished by another entity to provide diagnostic or other medical information to the entity performing the service if the Secretary of HHS or an intermediary (through a local medical review policy) requires such provision.² This requirement to provide diagnostic information coupled with Medicare’s general rule that coverage and payment for services to beneficiaries must be reasonable and medically necessary has resulted in a misunderstanding regarding a physician’s obligation to provide diagnostic information to laboratories. This misunderstanding has resulted in claim denials and lost revenue for hospitals and independent labs.

The inherent tension between hospitals and physicians is fueled by HCFA’s and the OIG’s position that the billing laboratory bears responsibility for assuring medical necessity.³ According to the OIG, hospital laboratories billing the Medicare program must ensure that physicians provide sufficient diagnostic information in lab test orders, continue to recontact physicians for additional information or refuse to perform laboratory tests until needed documentation is obtained.⁴ The latter alternative is not an option for hospitals. There is anecdotal information that hospitals routinely write off hundreds of thousands of dollars monthly based upon their unwillingness to hold a laboratory test hostage to documentation requests and their reluctance to risk filing a claim which may not be considered medically necessary.⁵

Legislative and Regulatory Concerns

Congress’ and HCFA’s desire to ensure that our tax dollars pay for medically necessary services only is not unjustifiable, however. At a time when Medicare funding levels are projected to be

significantly reduced with the advent of baby boomers into the beneficiary pool, legislators and regulators have reason to be concerned with the additional program costs resulting from the provision of unnecessary services to program beneficiaries.⁶

HCFA's concern is also generated by differences among its contractors. Contractor claims processing systems vary, as noted by HCFA personnel in recent clinical laboratory negotiated rule-making committee meetings.⁷ HCFA related that certain contractors' systems accepted a default code or blank field for diagnostic information and would continue such behavior until implementation of proposed requirements to implement the administrative simplification provisions in HIPAA through the requirement of the submission of diagnostic information with each and every claim.⁸

Physician and Laboratory Concerns

Discussions at American Medical Association meetings has centered around limiting the requirement that physicians supply laboratories with additional documentation and concern that physicians may commit unintentional fraud as a result of their signature on records or documents not properly reviewed.⁹ Physicians further object to the additional expense of hiring a coding specialist to master the multiple local medical review policies produced by intermediaries and carriers as well as the burden of reviewing local medical review policies prior to placing each lab order. Their fear and concern over enforcement of civil monetary penalty laws is heightened by the ever increasing number of investigations and prosecutions by federal and state agencies strengthened and enlarged by HIPAA funding. Physicians are also wary of HCFA's expressed concern with providers' "allegedly" obtaining advance beneficiary notices ("ABNs") in situations when it was only "likely" that the laboratory tests would not be covered by Medicare.¹⁰

Laboratory organizations (particularly the American Clinical Lab Association) have objected to laboratories' "middle man" status.¹¹ The burden of protecting the integrity of the Medicare program should not be placed on laboratories, the Association has argued. Similarly, pathologists recognize as do hospitals that laboratories may not refuse to perform tests despite their conclusions that the tests may not be medically necessary. Since most reference laboratories have little patient contact, the use of ABNs is virtually eliminated.¹² While it might be possible for a physician to recontact a patient and request signature on the advance beneficiary notice, this route is not feasible.

A final concern for laboratories is the increasing use of frequency limitations on laboratory services.¹³ Since a laboratory has little ability to determine how many times a Medicare beneficiary has been provided a particular service when a laboratory test is ordered due to the fact that patients often receive treatment from different physicians, this is a valid concern. Physicians express frustration concerning their inability to obtain ABNs when frequency limitations result in denial of laboratory claims.¹⁴

OIG Muddies the Waters

The frustration between and among physicians, hospitals and laboratories increased following the OIG's publication of its Compliance Program Guidance for Clinical Laboratories in 1997 (revised in August 1998) ("Compliance Guidance"). In its Compliance Guidance, the OIG stated that laboratories should ensure that the "lab can support tests billed to Medicare with documentation from the physician ordering the test."¹⁵ According to the OIG, laboratories should annually notify physicians of national and local medical review policies for laboratory testing, information required for "custom" profiles and Medicare's requirement that organ disease panels will be paid only when all components are medically necessary.

In other words, the OIG placed the burden for assuring that laboratory tests ordered and billed are medically necessary squarely upon the shoulders of hospital and independent laboratories. Although the OIG recognized that a lab may ask an ordering physician to obtain an ABN, it stated that the lab has responsibility to produce the ABN when required to do so by a HCFA contractor.¹⁶

Negotiated Rule-Making Process

The ongoing rule-making process may resolve the conflict soon. Congress recognized the severity of physicians' and laboratories' concerns by mandating in the BBA that HCFA adopt national coverage and administrative policies for clinical diagnostic laboratory tests through a negotiated rule-making process.¹⁷ Scheduled for completion by January 1, 1999, the rule-making committee meetings concluded with an agreement on a document of concepts on January 27, 1999. Although a draft copy of the proposed rule was scheduled for circulation among committee members by May 15, HCFA postponed the distribution date to July. In an August 30 - 31, 1999 meeting, the rule-making committee will conduct a limited review of any substantive differences between HCFA's proposed rule and the committee's previous consensus reached in January.

Issues on which the committee has reached a consensus with regard to providing diagnostic or other medical information include:

- HCFA will review coverage rules every two years.
- An ordering provider must maintain documentation of medical necessity in the patients' medical records. The entity billing Medicare must maintain information submitted by the ordering provider.
- The entity submitting the claim is responsible for maintaining records documenting the submission of claim information which accurately reflects information received from the ordering provider.
- If a lab or Medicare contractor is required by Medicare to obtain or maintain additional information from the ordering physician to support reasonableness in medical necessity, the request to the ordering provider must focus on information to justify medical necessity of the specific tests, taking into consideration patient confidentiality rules.
- Medicare carriers may not have a frequency screen unless certain information is published as to what is the appropriate frequency for a particular lab test. The screen may not be more restrictive than the terms of the published information.
- Physician signatures will not be required on orders for lab tests.
- Contractors will review all diagnosis codes submitted when no "matching" is furnished between the ICD-9 codes and the CPT codes.
- The "date of service" for all laboratory claims will be the date of collection.
In addition to discussing and proposing rules regarding document requirements, "work groups" assisted the negotiated rule-making committee in adopting 20 national coverage policies for approximately 59 CPT codes and in adopting specific ICD-9 codes considered evidence of medical necessity.¹⁸

Congress' belief that a negotiated rule-making produces rules more technically accurate, more easily enforced and less subject to litigation challenges than traditional rules developed through HCFA's informal rule-making process is a belief that laboratory providers are hopeful will prove true. The success of the negotiated rule-making process lies with the willingness of its members to reach a consensus on HCFA's proposed draft rule and the determination of hospitals, laboratories and physicians to "hang together" for the benefit of all Medicare

providers, beneficiaries and taxpayers. At a time when providers are experiencing the BBA's reimbursement cuts and increased scrutiny from enforcers, including U.S. Attorneys, Medicaid fraud control units and HHS's Office of Inspector General, all providers' goals should be virtually identical: heal the sick, obtain fair payment and reduce inappropriate expenses.

End Notes

¹Social Security Act § 1842; 42 U.S.C. § 1395u(p)(i).

²*Id.* § 1395u(p)(4)(enacted in § 4317(b) of the Balanced Budget Act of 1997). Medicare requires laboratories actually performing the test to bill the program for such tests with limited exceptions. 42 U.S.C. § 13951(h)(5).

³See *Compliance Program Guidance for Clinical Laboratories*, 63 Fed. Reg. 45,076, 45,080 (1998) ("Compliance Guidance") ("We recognize that laboratories do not and cannot treat patients or make medical necessity determinations. However, there are steps that such facilities can take to assure compliance with the applicable statutes, regulations and the requirements of federal, state and private health plans."). Medicare generally pays only for services which are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Social Security Act § 1862, 42 U.S.C. § 1395y. Except in limited circumstances, Medicare does not cover screening tests. See 42 C.F.R. § 411.15(a)(i) (excluding from coverage routine physical checkups performed for a purpose other than treatment of a specific diagnosis or illness, symptom, complaint or injury except for certain enumerated screening tests); but see Medicare Carriers Manual § 14-3-7517.2 (carrier cannot require non-physician provider to submit ICD-9 code; carrier must make provision for narrative description).

⁴*Compliance Guidance* at 45,080.

⁵HCFA does consider some laboratory tests presumptively medically necessary. In a January 1, 1999 Program Memorandum to carriers, HCFA discussed the American Medical Association's 1998 addition of the current procedural terminology which established three new and one revised organ or disease-oriented laboratory panels. HCFA indicated that a general presumption of medical necessity exists for these panels composed of "clinically relevant groupings of automated and multichannel tests." HCFA Program Memorandum, Pub. 60 B, Transmittal No. B-99-1 (January 1, 1999).

⁶Congress reflected its focus on fraud and abusive activities by inclusion in the Health Insurance Portability and Accountability Act of 1996 (the "HIPAA") of a civil monetary penalty for the ordering of a pattern of medical or other items or services if a provider knows or should know that those items or services are not medically necessary. 42 U.S.C. § 1320a-7a(1)(E)(enacted in the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, § 231).

⁷See Negotiated Rule-Making Committee, Ninth Meeting Minutes - January 25 - 27, 1999 ("Rule-Making Committee Minutes") (HCFA's withdrawal of previous concurrence regarding the requirement of the inclusion of diagnostic or other medical information in claims forms due to divergence in contractor systems.)

⁸HIPAA, § 262.

⁹*BNA Medicare Report*, 9 MCR 1265-66 (December 11, 1998).

¹⁰

During negotiated rule-making committee meetings, HCFA also expressed its concern with laboratories claiming waiver of liability, 42 U.S.C. § 1395pp), following claims denials based upon a position that the only expectation of laboratories is to obtain documentation from the ordering physician to support medical necessity. Rule-Making Committee Minutes at 5. In the negotiated rule-making committee meeting, a HCFA representative implied that a provider's claim of waiver of liability might provoke the OIG or Department of Justice to argue that the lab had not taken sufficient steps to obtain information from the physician prior to claim submission. *Id.*

¹¹*Id.* at 1225-26.

¹²*Medicare Carrier's Manual* §§ 7300.4, 7300.5A. An advance notice provided to a Medicare beneficiary and documented on a physician's claim will rebut a presumption that a beneficiary did not nor could reasonably have been expected to know that the items and services he received were not reasonable and necessary. *Id.* At 7300.5.

¹³Rule-Making Committee Minutes at 6.

¹⁴See, e.g., *Medicare Carriers Manual, Part 3* (HCFA Pub. 14-3), Transmittal No. 1637 (April 1, 1999)(certain prostate cancer screening tests subject to frequency limitations, i.e., once every 12 months).

¹⁵*Compliance Guidance* at 45,080.

¹⁶In addition to shifting responsibility for medical necessity determinations to laboratories, the OIG's Compliance Guidance discouraged standing orders and recommended reflex testing only when necessary. *Id.*

¹⁷BBA, § 4554(b)(1). This section's legislative history reflects Congress' realization that there existed numerous variations among carriers in rules for filing laboratory claims. H.R. Rep. No. 105-217, 105th Cong., 1st Session 795-97 (1997).

¹⁸Rule-Making Committee Minutes at 1-14