

ISSUE BRIEF

Medicare Coverage and Technology Diffusion: Past, Present, and Future

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A discussion featuring

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Medicare Coverage and Technology Diffusion

In 1989 the National Health Policy Forum held a session entitled “Medicare Coverage: Translating Process into Practice.” Now, nine years later, it is holding another meeting looking at the same proposed rule, issued in 1989 by the Health Care Financing Administration (HCFA), on Medicare coverage of services and products and exploring a process that has changed little over the past decade. The issues remain fundamentally the same. Only now the issue of coverage—for Medicare as well as for private plans—has become more complex as the market has fractured into a range of health plans. As Medicare dips its toes into the managed care waters through its Medicare + Choice program, it will have to resolve the dilemma all plans are facing: balancing risk with coverage policy. Under managed care, as more risk is shifted to providers, the coverage issue changes its character. Providers no longer have the clear incentives to adopt new technology they once had under fee-for-service reimbursement. Today, those incentives are more diluted.

Criticisms of the Medicare coverage process include lack of openness, lack of public participation, lack of predictability, lack of precise definitions of key terms and criteria, and lack of an adequate appeals process. In part, these criticisms are a manifestation of the tension Medicare faces in balancing the encouragement of innovation and quality of care against the proliferation of inappropriate services and the escalation of health care costs. The challenge lies in providing Medicare beneficiaries with access to the newest medical technologies whose costs are justified by improvements in health outcomes while limiting access to technologies of lesser or unknown value.

Medicare coverage is critical for successful technology diffusion. Complicating this process, however, is the nonlinear, incremental nature of innovation in medical technology. For example, before a device is deemed effective enough for coverage, it may need to be used by patients and physicians and improved over a period of time as it diffuses into everyday medical practice. On the other hand, successful diffusion may depend on whether or not the device is covered. Thus, coverage determination and technology innovation can become ensnared in a classic catch-22.

Coverage determination does not occur in a vacuum. It is part of a continuum that includes technology assessment, payment determination (for example, method, site,

and level of payment), and the demand for evidence (for example, quality of life data, economic outcomes, and societal costs). Medicare coverage, which involves different levels of decision making, highlights the important role the physician plays in determining medical necessity. This Forum session will look at the Medicare coverage process, examine its strengths and weaknesses, and review options for its improvement.

THE PAST: LEGISLATING AND REGULATING MEDICARE COVERAGE

Congress established the Medicare program in 1965 with the enactment of title XVIII of the Social Security Act. While the law provides for the coverage of broad categories of benefits, such as inpatient hospital care, it does not include a specific list of services actually covered. It was inevitable that, over time, particularly with the development of new technologies, questions would arise requiring individual coverage determinations. Congress anticipated this need and provided the secretary of health and human services with the authority to make these decisions. Section 1862 (a)(1)(A) of the Act states:

Notwithstanding any other provisions of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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The regulations implementing the “reasonable and necessary” section of the law are quite general [42 CFR 405.310 (k)]. Although the criteria that a health care technology must meet in order to be considered reasonable and necessary are specified, precise definitions do not exist. Historically, reasonable and necessary has been largely defined by the local physician community.

Determinations about whether services are reasonable and necessary and, therefore, covered under Medicare have wide-felt repercussions. They have, for example, considerable impact on the shape of the health care marketplace. A negative coverage decision may slow down or even halt the diffusion of a new technology, in turn limiting the services physicians may feel free to use. From the patient’s point of view, he or she may be denied needed services for which technology does exist but coverage—and therefore payment—does not.

On April 29, 1987, HCFA published a notice (52 FR 15560) in the *Federal Register* announcing its process for making coverage decisions. This notice was the result of *Jameson v. Bowen*, a lawsuit in which the plaintiff sued to have HCFA reimburse him for a percutaneous transluminal coronary angioplasty (PTCA) procedure performed before a coverage determination had been made. In addition to reimbursing the plaintiff, HCFA agreed to publish the notice. On January 30, 1989, HCFA published another proposed rule expanding upon this 1987 description of the process. The 1989 proposed rule moved to clarify some of the uncertainty, explaining that

Although the process by which we make Medicare coverage decisions on health care technology has been in place for many years, we believe there are segments of the population that may still benefit from a complete description of the coverage decision making process. We also believe the process should be more open and that the review of breakthrough technologies should be streamlined. It is for these reasons that we are now presenting the coverage decisions process as a public document.

Many experts, however, argued that HCFA’s proposed rule did not go far enough. Further, some of its elements, such as the cost-effectiveness component, were highly controversial. A modest effort to issue the 1989 regulation in final form died in 1996, highlighting again the controversial nature of coverage decision making.

THE PRESENT: THE MEDICARE COVERAGE PROCESS EXPLAINED¹

Coverage involves deciding whether or not to pay for a particular service or product, while *reimbursement*

involves determining the methods and amounts of payment for covered services and products. To be paid by the Medicare program, all services and products must be covered by HCFA, the agency that administers the program. That is, the services or procedures and the products used in them must be deemed to be reasonable and necessary for diagnosing or treating a patient. They must also fit into particular statutory categories, such as hospital services, surgical dressings, durable medical equipment, prosthetics and orthotics, or supplies incident to a physician’s services.

The vast majority of Medicare coverage decisions are made by its contractors, known as fiscal intermediaries for Medicare Part A (inpatient) services and carriers for Medicare Part B (outpatient, physician, clinical laboratory, and medical supplier) services. These contractors are private insurance companies that contract with Medicare to process claims from beneficiaries, providers, and suppliers.

Medicare coverage is carried out at three levels: local, regional, and national. Figure 1 (see page 9) depicts the local and national coverage decision-making process for Medicare.

Local Coverage

In deciding whether to cover a medical service or technology, contractors review applicable manuals for specific product- or procedure-related policies supplied by HCFA or apply general criteria such as the following: Is the product safe and effective? Is it reasonable and necessary? Is it appropriate? Is it experimental or investigational?

Many carriers maintain medical advisory committees comprising local specialists to advise them on new procedures and technologies. These advisory committees, along with medical directors and medical policy staff of the carriers, play an important role in reviewing new technologies and making local coverage decisions. Such decisions are often printed in local carrier bulletins or newsletters.

Local coverage decision making has been viewed as a double-edged sword by many. On the one hand, decisions are not standardized, since each contractor makes separate decisions. What is covered in one locality may not be in another. From a manufacturer, physician, and patient point of view, this process, while sometimes confusing and frustrating, allows for coverage in some circumstances as the new technology diffuses. A national decision, on the other hand, while uniform and standard, can be a death sentence for a

technology if a national noncoverage determination is handed down by HCFA's central office.

Regional Coverage

In 1993 and 1994, Medicare Part B claims processing for certain products was transferred from 34 local carriers to four regional carriers, known as durable medical equipment carriers (DMERCs). These carriers process claims for durable medical equipment, prosthetics, orthotics, surgical dressings, and a wide array of supplies used in the patient's home. Each DMERC has issued a manual with detailed coverage and payment policies on particular product areas, such as infusion pumps, wheelchairs, and orthopedic support devices.

National Coverage

Under certain circumstances, HCFA may decide that a technology requires a national coverage decision—that is, one that applies to all contractors. Such a decision may be warranted, for example, if a device is likely to result in a major increase in Medicare costs or provide important therapeutic benefits.

Manufacturers, health care providers, beneficiaries, HCFA contractors and others may request that HCFA issue a national coverage decision for a technology. HCFA then conducts an initial review to determine whether such a decision should be considered. At this point in the process, HCFA can refer to the Office of Health Technology Assessment (OHTA) within the Agency for Health Care Policy and Research (AHCPR) for a full assessment or inquiry. Alternatively, HCFA's staff can conduct a special study of its own (as was the case with heart transplants). HCFA can issue a national coverage decision without referring to OHTA, or it can decline to make a national coverage decision and leave it to the discretion of its contractors. Beneficiaries, providers, and manufacturers have limited opportunities to appeal HCFA's coverage decision, but they may ask for reconsideration, especially based on new scientific data. HCFA's coverage issues manual contains approximately 200 national coverage decisions. Local contractors must abide by national coverage decisions.

MEDICARE COVERAGE OF EXPERIMENTAL OR INVESTIGATIONAL PRODUCTS

HCFA has historically interpreted "experimental" devices or procedures to be outside the scope of the reasonable and necessary clause. Included in the agency's definition of experimental is whether the

product has been cleared by the Food and Drug Administration (FDA).

In early 1994, the Department of Health and Human Services, Office of Inspector General sent subpoenas to more than 135 hospitals asking for information about products billed to Medicare and Medicaid that had been used in services covered by the program but had not been approved for those purposes by the FDA. By the second half of 1994, HCFA was rigorously enforcing the practice of not paying for services in which medical devices that had not received an FDA premarket approval were used. (This practice is not required by the Medicare statute and is not contained in the HCFA regulatory manual.) The development raised significant questions about the precise role of FDA approval in Medicare coverage determinations, as well as about the use of a product outside the scope of its labeled indications.

The Regulation of Medical Devices: The Role of the FDA

In the United States, the FDA is responsible for regulating medical products for *safety* and *effectiveness*, while HCFA reviews technologies to determine whether they will be available (that is, covered) through the Medicare program for eligible beneficiaries. How Medicare pays for these products is a separate issue and depends upon the item.

While some define technology as all-encompassing—that is drugs, devices, and biologics—the FDA regulates each of these categories differently. The FDA's duties regarding devices fall into two general categories: review of a device before it reaches the market and postmarket control after it has been cleared by the FDA. This description is limited to the premarket process.

Both the type of premarket review and the degree of regulation a medical device undergoes depend, in large measure, upon the potential risk presented to patients. The landmark Medical Device Amendments of 1976 introduced a systematic premarket regulation of medical devices, classifying products into one of three categories:

- *Class I*—products that pose the least risk, such as elastic bandages. Class I devices must meet certain general controls that assure, among other things, that the product is not adulterated or misbranded, that it is properly labeled, that it is manufactured in a manner that meets all specifications, and that the FDA is notified prior to marketing.
- *Class II*—products that pose a moderate degree of risk, such as catheters and hypodermic needles. In

addition to meeting Class I general controls, Class II devices must meet any standards or other special controls developed by the FDA for that type of device.

- *Class III*—products that pose the most significant potential risk, such as replacement heart valves and extended-wear contact lenses. In addition to the Class I and II controls, these devices must undergo detailed and often lengthy premarket evaluation to determine if they are *safe* and *effective*.

The product approval process. With the exception of some custom devices and certain Class I devices, the FDA conducts a premarket review of all medical devices before they can be introduced into the market. This is done either through a detailed premarket review of the device (known as a premarket approval, or PMA) or through a more routine premarket notification, or 510(k).

- *Premarket notification*—A company intending to market a product that is “substantially equivalent” to an earlier, legally marketed device, can submit a premarket notification application, often referred to as a 510(k) application, to the FDA. The idea behind premarket notification is to expedite incremental adjustments in health care technologies through the regulatory process. 510(k)s are typically used for Class I and II devices, and, in some cases, for Class III devices for which the FDA has not required a more detailed PMA submission. With a 510(k), the company must show that the device has the same technological characteristics and the same intended use as the earlier device already in the market. If the device represents different characteristics, the company must show that it is just as safe and effective as the earlier device. Once the company receives clearance from the FDA, it can market the product.
- *Premarket approval*—The FDA conducts a rigorous premarket review for those devices that represent a potentially great risk. These include Class III products, such as implantable devices or those representing potentially significant risk of injury or illness. Class III products also include all products that are not substantially equivalent to an earlier device—that is, they represent a new kind of technology whose risk and reliability are unknown. In this case, the FDA requires a premarket approval, or PMA, application, which involves a wide range of physical, scientific, biological, and engineering testing and information. In order for a company to collect these data on patients, it must obtain approval of an institutional review board.

In addition, a company must also submit a plan to the FDA explaining, among other things, how it will conduct the testing, what types of patients it will use, what results it expects, and what risks and precautions it believes are involved. If the FDA considers the request to be sound, it will grant an investigational device exemption or IDE. The IDE allows for the device to be used in patients for the purpose of gathering data. (An approved IDE is also required for clinical testing of devices that undergo marketing clearance through 510[k]).

Linking Product Safety and Efficacy to Product Coverage and Reimbursement

Payers today have become increasingly sophisticated and are demanding far more information beyond FDA approval, information such as outcomes and cost-effectiveness. The FDA imprimatur alone is not enough to assure commercial success. Overwhelmingly, however, payers look to see whether, at a minimum, a product has received FDA approval or clearance (that is, PMA or 510[k]).

This “FDA stamp of approval” is typically the first criterion applied, because, without it, a product may be considered experimental or investigational. However, these products, under limited conditions, *may* be considered for coverage. “Deciding when an innovative new therapy has moved from experimental to standard treatment is an issue with which insurers, providers, and public policymakers all struggle.”²

Generally, Medicare carriers will not cover experimental or investigational technologies, although much has happened over the past few years, including the recent growing attention to the relationship between a technology’s FDA review status and Medicare coverage determination. Most important was the publication of HCFA’s “Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services” final rule in the September 19, 1995, *Federal Register*. The rule specifically “sets forth the process by which the FDA will assist HCFA in identifying non-experimental investigational devices that are potentially covered under Medicare.”

Medicare coverage of IDEs. The September 19, 1995, rule established in regulations that certain devices involved in trials approved by the FDA under an IDE as well as certain services related to those devices *may* be covered under Medicare. Specifically, the rule outlines the process by which the FDA will assist HCFA in

identifying non-experimental investigational devices that are potentially covered under Medicare.

Historically, the term experimental has been used synonymously with the term investigational. Therefore, a device categorized by the FDA as being investigational served as an indication that it was not reasonable and necessary within the meaning of the Medicare program. The following is noted in the final rule:

There is increasing recognition, however, that there are devices that are refinements of existing technologies or replications of existing technologies by other manufacturers. The FDA places many of these devices within the IDE category as a means of gathering the scientific information necessary to establish the safety and effectiveness of the particular device, even though there is scientific evidence that similar devices can be safe and effective. Arguably, these devices could be viewed as reasonable and necessary under Medicare and recognized for payment if it were possible to identify them in the FDA's process.

The fundamental policy issue addressed by this rule is the need for a mechanism to prevent HCFA from automatically excluding from Medicare coverage all devices that the FDA considers investigational.

IDE categorization. To that end, the rule set out a new categorization system. To assist HCFA in its coverage decision process, the FDA follows a categorization process that differentiates between the clinical assessment of novel, first-of-a-kind devices and newer generations of legally marketed devices. The policy changes in this rule reflect the categorization of investigational devices that are the subject of FDA-approved IDEs.

Under the new categorization process, the FDA assigns each device with an FDA-approved IDE to one of two categories: experimental/investigational (Category A) devices, or non-experimental/investigational (Category B) devices. A Category A device is "an innovative device in Class III for which 'absolute risk' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type can be safe and effective.)" HCFA is, according to the rule, to exclude from Medicare coverage a Category A device.

A Category B device is a

device believed to be in Class I or II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for

example, other manufacturers have obtained FDA approval for that device type.

HCFA will now *consider* covering Category B devices and related services (also spelled out in the rule). Even if an IDE device receives a Category B determination from the FDA, Medicare coverage is not guaranteed or mandated. Rather, HCFA will not automatically exclude the device from Medicare coverage consideration.

Alternative Options for Crossover Technologies

In a Summer 1994 *Health Affairs* Perspectives piece, "How Can Medicare Keep Pace with Cutting-Edge Technology?"—in which she expressed her individual opinion and not her agency's—deputy director of HCFA's Center for Health Plans and Providers Kathleen Buto wrote that

Therapies that are evolving from experimental to standard practice pose some of the most difficult coverage issues for Medicare. . . . The Medicare program could go on as it is, basing coverage decisions on technology assessments and limiting coverage of crossover³ therapies until they become part of standard practice. But HCFA could consider changes that will make promising therapies available earlier and lead to better data on use and patient outcomes. Any changes should provide more options for providers and patients and greater flexibility for the Medicare program to revise coverage policy.

Two alternatives meet these goals: (1) broader use of limited coverage approaches (coverage of a technology or therapy that is limited by certain criteria or conditions) and (2) a clinical research fund or set-aside (similar to the Blue Cross/Blue Shield fund used to support breast cancer clinical trials). The fund could be used to pay for services not otherwise covered and would allow Medicare to support studies of potentially beneficial treatments for the elderly or persons with disabilities.

THE FUTURE: MEDICARE COVERAGE POLICY CHALLENGES—OPTIONS FOR CHANGE

According to a March 1998 white paper, "Medicare Coverage: Time for a Public Policy Dialogue," by the Medical Technology Leadership Forum (MTLF),

The Health Care Financing Administration has experimented with some aspects of coverage policy, primarily on an *ad hoc* basis using informal guidelines and directives. The result is that there are pressing issues of timeliness, flexibility, and accountability in the Medicare coverage process. In addition, major public policy issues about technology and Medicare have not

been addressed explicitly in an open forum. It is time for a serious reevaluation of the Medicare coverage policy.

The MTLF paper lays out four key policy issues:

- *What standard of evidence should be applied to Medicare coverage decisions? What criteria or standards should be applied? Are they appropriate for medical devices and procedures? What methodologies are acceptable to meet the standards? Who defines the elements of that standard, including concepts such as “authoritative evidence,” “demonstrated evidence,” or “relative effectiveness?” Should HCFA defer to the FDA’s finding of safety and effectiveness? Should cost-effectiveness be considered? If so, how should costs and effectiveness be defined? Who should pay for the costs of developing the data?*
- *What is the appropriate balance between national coverage decisions and those of local carriers? How important is uniformity for the program? Are there some decisions that are best left to local decision making? What role should the opinions of medical specialty societies play in Medicare coverage decisions? What role should producers of technology play?*
- *Should Medicare have a responsibility to support and encourage medical innovation? How does this change as Medicare transforms itself from an administrator of health care into a provider of health care through its Medicare + Choice program?*
- *Who should participate in coverage decisions and how can the process be improved? Should it be more open? More flexible? More predictable? Where should the locus of decision making reside? What role, if any, should cost-effectiveness play? When should a technology be assessed? By whom? Are there adequate appeals processes in place?*

Options under Consideration

Several stakeholders have spent a great deal of time analyzing the intricacies of the Medicare coverage process and circulating proposals around Capitol Hill and throughout the various federal agencies, including HCFA, OHTA, AHCP, and the National Institutes of Health. Most of these proposals call for greater predictability, openness, and flexibility in the process.

At the beginning of 1998, the Indiana Medical Device Association challenged HCFA’s Technology Advisory Committee (TAC) as not complying with the

Federal Advisory Commission Act, which calls for an open, public hearing as part of the coverage determination process. As a result of the ruling in this court case as well as a recent GAO finding, the TAC will be restructured to address concerns about due process in assuring openness.

While most agree that the process needs to be more open and public, there is less agreement as to *how* this should be accomplished. The four basic options available to policymakers are

- Constructive informal discussions with HCFA among all concerned parties.
- Notice and comment rulemaking.
- Negotiated rulemaking.
- Legislation.

Forum speakers will consider the benefits and drawbacks of each as they discuss the past, present, and future of Medicare coverage decision making.

THE FORUM SESSION

Donald A. Young, M.D., senior vice president for policy and clinical services at the American Association of Health Plans (AAHP), will open with an overview of how we got to where we are today—a history of the issues and lessons learned and implications for the private sector. Before joining the AAHP, Dr. Young was the executive director of the Prospective Payment Assessment Commission. He also served as deputy director of the Policy Bureau at HCFA, where he was responsible for Medicare and Medicaid eligibility, reimbursement, and coverage policies.

Jeffrey L. Kang, M.D., M.P.H., HCFA’s chief clinical officer and director of the Office of Clinical Standards and Quality, will discuss where HCFA is today vis-à-vis the Medicare coverage process. He will look at the strengths and weaknesses of the current system as well as what changes might occur in coverage decision making as Medicare becomes a provider of health care through its Medicare + Choice program. Dr. Kang’s responsibilities include developing national coverage policies and quality standards for Medicare providers, collecting clinical data to support agency initiatives, overseeing quality improvement activities, and managing Medicare’s peer review program.

Michael B. McCulley, Esq., assistant general counsel of Johnson & Johnson will explain the implications of Medicare decision making on technology

innovation and adoption. His present assignments include work in the areas of general corporate and U.S. and international regulatory law, with a primary regulatory focus on matters relating to the FDA, the European Common Market, and HCFA. Before joining Johnson & Johnson, Mr. McCulley was senior regulatory counsel for the American Hospital Supply Corporation.

A panel of Capitol Hill speakers will continue the discussion. **Allison Giles, J.D.**, professional staff member of the House health subcommittee of the House Ways and Means Committee, will explore concerns of members of Congress, focusing on HCFA's Technology Advisory Committee. For more than two years before joining the health subcommittee, Ms. Giles worked on health care policy issues in the personal office of its chairman, Rep. Bill Thomas (R-Calif.). From 1992 to 1994, she was the assistant chief counsel for health policy in the Office of Advocacy at the U.S. Small Business Administration.

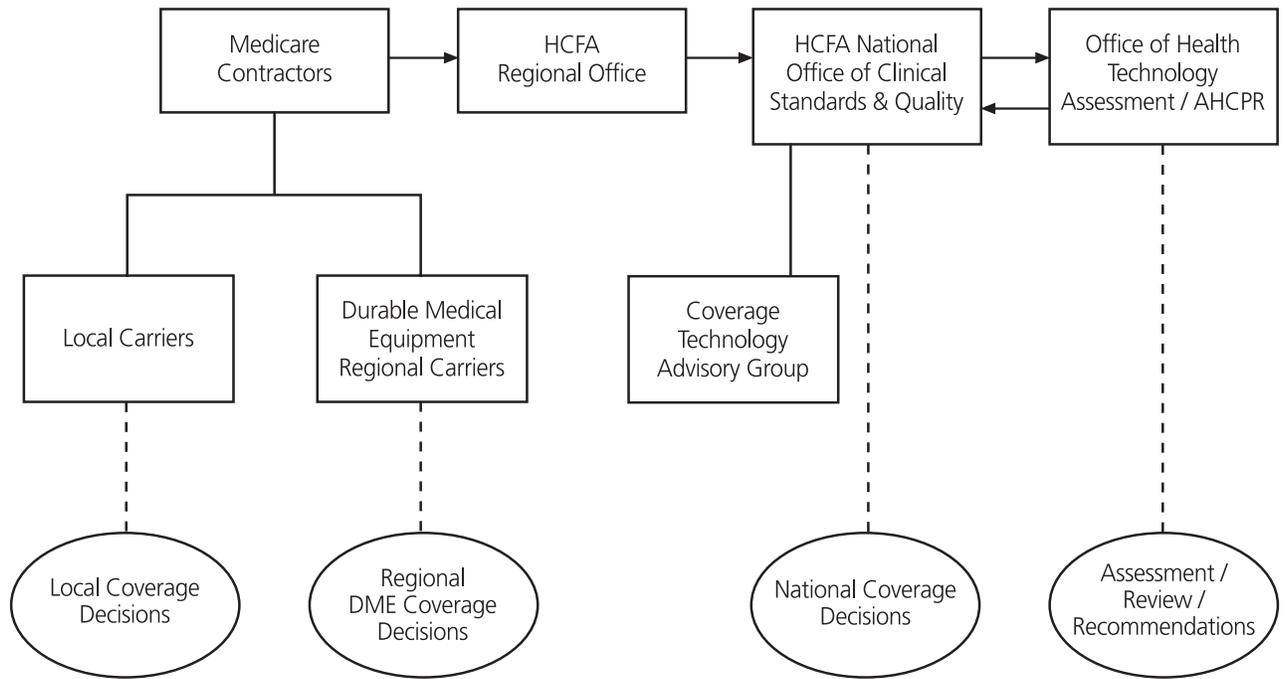
Alexander Vachon, Ph.D., chief social security analyst with the Senate Committee on Finance, will talk about aspects of coverage decision making included in the recent Balanced Budget Act, with a focus on laboratory coverage. In addition, Mr. Vachon will touch upon how the process affects access of care for patients. Dr. Vachon has worked on every major spending bill that has come before the committee since he joined it in 1995, including the Balanced Budget Act of 1995. Previously, he was a legislative aide to Sen. Bob Dole (R-Kans.).

Wrapping up will be **Peter Hasselbacher, M.D.**, Robert Wood Johnson Health Policy Fellow with the Senate Committee on Finance. Dr. Hasselbacher, who has served as medical director of a large multi-specialty group practice and as medical director and vice president for medical affairs of a 135,000-member managed care plan, will discuss implications of government coverage determinations on managed care programs. He will review the origins, implications, and limitations of HCFA's definitions of "safe and effective," "medically necessary and appropriate," and "investigational." He will highlight some intrinsic tensions between manufacturers and payers related to coverage determinations that will not be easy (or perhaps desirable) to resolve.

ENDNOTES

1. Much of this section was taken from the *1995 Reference Guide for the Health Care Technology Industry*, Health Care Technology Institute, Alexandria, Virginia, 22-25.
2. Stanley Joel Reiser, "Criteria for Standard versus Experimental Therapy," *Health Affairs (Medical Innovation: Risks and Rewards)*, Summer 1994, 127.
3. As explained by Stanley Joel Reiser in his Summer 1994 *Health Affairs* article, "Criteria for Standard versus Experimental Therapy," crossover technologies—which are innovations that move between experimental and standard categories—can be defined in the following manner: "Therapies are like trains: They exist in an oscillating motion, shuttling back and forth between standard and experimental stations, and sometimes taking a crossover track to pause at a place in between them." To define this in-between place, Reiser offers the term "crossover therapy."

Figure 1
Medicare Local, Regional, and National Coverage



Source: Gordon B. Schatz of Reed, Smith, Shaw & McClay, Washington, DC, 1994 (updated 1998).