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Medicare Coverage:
Lessons from the Past,
Questions for the Future

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■
A background paper prepared by
Robin J. Strongin, *Consultant*

Overview—This paper describes the Medicare coverage process for emerging technologies and the ways it has changed over time. Issues addressed include both the national coverage process and local medical review policies, which account for 90 percent of the coverage determinations. The paper also includes a discussion of the relationship between the coverage process and technology assessment, payment systems and the ongoing debate over coverage criteria and levels of evidence.

The complex process that determines whether and when new and emerging technologies become covered under the Medicare program has changed over the years and is still in a state of flux. Its complexity underscores many of the difficult choices that Medicare, as both a payer and a purchaser, must make on behalf of its beneficiaries. The Health Care Financing Administration (HCFA), recently renamed the Centers for Medicare and Medicaid Services (CMS), in the Department of Health and Human Services (DHHS), has long been responsible for making national Medicare coverage determinations. These determinations do not, however, occur in isolation. Rather, they are closely linked to Food and Drug Administration (FDA) safety and effectiveness determinations, to reimbursement and payment policies, and to coding decisions.

FDA approval, the green light for marketing a product, is granted once safety and effectiveness have been established. The FDA imprimatur alone, however, does not guarantee that a product will be covered by Medicare. Because the threshold for efficacy depends upon the type of technology—that is, whether it is (a) a breakthrough product, which requires a rigorous FDA approval process referred to as premarket approval, or PMA, or (b) a product that is “substantially equivalent” to one already on the market, which goes through a more routine premarket notification known as a 510(k) review—clinical data are not required in all instances. Clinical data are, however, required for all Medicare coverage decisions.

Coverage involves deciding whether or not a particular service or product is eligible for payment, while reimbursement involves determining the methods and amounts of payment for covered services and products. For various reasons, payment systems (for example, inpatient prospective payment, physician fee schedules, and outpatient prospective payment) are built upon different coding systems. (The Forum is planning to hold a separate meeting on coding and payment issues.) Various methodologies and formulas have been legislated to determine the actual level of payment various providers

receive for various products and services. Table 1 (see page 3) shows three payment systems and their related coding schemes and payment bases.

These payment systems and their relationship to the coverage process are extremely complex. In fact, at times the coverage and payment processes appear to meld into one. That is, discrete national coverage decisions rendered by CMS and local carrier coverage decisions (both of which are more fully described later in this background paper) represent only two of the ways in which technologies enter the Medicare program.

Another point of entry for technology is through the various payment systems. Both the inpatient prospective payment system (PPS) and the outpatient prospective payment system are based upon bundled payments—diagnosis-related groups, or DRGs, for the inpatient PPS and the newly created ambulatory payment classifications, or APCs, for the outpatient PPS. Based upon certain formulas, providers are reimbursed for the services, including technologies, that are used within a given payment bundle. In this situation, the provider (not the government) is the purchaser and makes both the coverage and the reimbursement decisions. New technologies can therefore obtain reimbursement as long as there is a code and a bundled payment to which they can be attached. Analysts point out, however, that new technologies entering payment systems in this manner are rarely evaluated for efficacy. Such systems also present a challenge when a new technology does not fit well within an established payment bundle. At that point the government gets involved.

BACKGROUND PAPER

National Health Policy Forum

2131 K Street, NW, Suite 500
Washington, DC 20037

202/872-1390

202/862-9837 (fax)

nHPF@gwu.edu (e-mail)

www.nHPF.org (Web site)

Judith Miller Jones, Director
Judith D. Moore, Co-Director
Michele Black, Publications Director

NHPF is a nonpartisan education and information exchange for federal health policymakers.

Table 1
Medicare Reimbursement Payment Systems
with Their Related Coding Schemes and Payment Bases

Payment System	Coding Scheme	Payment Basis
Inpatient Prospective Payment System	ICD-9-CM*	Diagnosis Related Group (DRG)
Physician Fee Schedule	HCPCS,** CPT†	Relative Value Unit (RVU)
Outpatient Prospective Payment System	HCPCS, CPT	Ambulatory Payment Classification (APC)

* *International Classification of Diseases, Ninth Revision, Clinical Modification*

** *HCFA Common Procedural Coding System*

† *Current Procedural Terminology*

In order to evaluate and assess technologies for coverage and payment purposes, payers require data and scientific evidence. This information is key to the coverage process as well. To fully appreciate these processes, it helps to step back and see where coverage fits within the broader picture of technology evaluation.

ASSESSING TECHNOLOGIES

Technology assessment is the foundation upon which regulatory and purchasing decision-making takes place. Wade M. Aubry, M.D. chairman of the Medical Advisory Panel of the Blue Cross Blue Shield Association, summarizes what he sees as the four goals of technology assessment:¹

- Determine the technology's effect on health outcomes, such as length and quality of life (for example, functional status).
- Compare beneficial outcomes to harmful ones.
- Compare alternative technologies for a given set of indications.
- Use the results to make rational decisions related to coverage and medical practice, including physicians and patients choosing among treatment options.

Technology assessment in the United States began in earnest in the early 1970s, when the relationship between medical technology and health care costs came more sharply into focus. The seventies witnessed the birth of revolutionary technologies, such as CT scanning, electronic fetal monitoring, and mammography. The earliest cardiac therapies, such as cardiac catheterization, were making their way into medical practice. These big-ticket technologies paved the way for a national technology assessment agenda.²

Over the years, technology assessment has been transformed from a regulatory model, originally intended to constrain the premature use of technology, into a more clinical approach with a focus on health outcomes and, in the view of many, as a tool to manage costs. The establishment of the Agency for Health Care Policy and Research (now called AHRQ, the Agency for Healthcare Research and Quality), and the concurrent development of practice guidelines put a new spin on assessment protocols, stretching the boundaries of technology assessment. No longer was technology assessment solely concerned with safety, efficacy, and effectiveness. Today, assessors are also interested in the *appropriateness* and *value* of a medical technology.

Technology assessment occurs at every phase of a technology's "life," from idea conception to FDA approval through coverage and payment determinations and ultimately to purchasing decisions. Because of the nature of medical device innovation (which differs greatly from that of prescription drug innovation), manufacturers have expressed concerns over how and when different kinds of device technologies are assessed.

At its core, device innovation is a dynamic, complex, and incremental process. It is marked by uncertainties and unexpected twists, and it rarely moves in a linear, predictable pattern. It spans many different stages and activities—from development of a new idea, to diffusion of a new device, to refinement of an existing product. Among the host of factors influencing device innovation are market forces; federal policies, such as product liability, patents, and funding of research; and patient needs and demands. But perhaps most significantly, device innovation is a process that is rooted in the active day-to-day interchange between device users [physicians] and device manufacturing companies. The relationship that often develops among these parties during the early stages of device innovation can be viewed as the beginning of a long-running dialogue.³

The medical technology industry has voiced concern that premature assessment of a technology may limit or even deny the possibility of discovering new and improved applications of the technology in clinical practice. It is often the rule, rather than the exception, that once physicians or other providers begin to use a product, they discover additional possibilities. These can take the form of (a) technical adjustments or modifications that would allow additional capacity or greater speed or (b) a new use for patients with different conditions. Assessment of technology before it has an opportunity to diffuse precludes new and improved applications for patients, according to device manufacturers. Assessors on the other hand, point out that diffusion of a technology prior to a thorough assessment can preclude the technology from ever being properly evaluated.

Nowhere is the evaluation of medical technology a more heated issue than for those technologies currently assessed by CMS—particularly as CMS continues to craft its Medicare coverage criteria. Some observers are concerned that what is being assessed is not just the technology, but how medicine is practiced (raising, for example, questions such as where this test fits in with the others already being performed). Regulating the practice of medicine, critics assert, oversteps the legal boundaries defining the Medicare coverage process.

STATUTORY AUTHORITY

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* [emphasis added] for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The regulations implementing the “reasonable and necessary” section of the law [42 CFR 405.310 (k)] are quite general. 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.⁴ Historically, reasonable and necessary have been largely defined by the local physician community.

In addition to the reasonable and necessary requirements, products must typically be deemed to be safe and effective. In the United States, the FDA is responsible for regulating medical products for safety and effectiveness, while CMS 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 and the site of service. Furthermore, Medicare is frequently asked to cover “off-label” uses of devices or drugs that have not been approved by the FDA.

Ultimately, 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—national, regional, and local.⁵

NATIONAL COVERAGE DECISION MAKING

Since Medicare began, fewer than 300 national coverage decisions—approximately 10 percent—have been issued. These products typically represent breakthrough technologies, the technologies that have the potential to affect the most people and have the biggest impact on the health care system.

According to CMS, national coverage decisions are defined as “prospective, population-based policies which describe what patients under what clinical circumstances are eligible for what items or services under what conditions.” In a recent presentation, Sean Tunis, M.D., director of CMS’s Coverage and Analysis Group, indicated that the following factors could trigger the national coverage process:

- Inconsistent local coverage policies.
- Significant advances in medical science.
- Substantial disagreement among experts.
- Potential for rapid diffusion or overutilization.
- Program integrity concerns.

Over the years, the coverage process itself has been undergoing a significant evolution. The current Medicare national coverage process is depicted in Figure 1 (see page 6).

Once a request is formally submitted and accepted by CMS (based on its completeness and benefit category), CMS has set a goal of 90 days to issue a coverage decision memorandum. The 90 days can be extended if, for example, the requestor submits additional information. A requestor can be almost anyone, a manufacturer, a physician, a carrier, an advocacy group, a beneficiary, a congressional inquiry or internal CMS staff, for example.

If the request duplicates a pending request, the requests are typically combined. If it duplicates an earlier request where a decision was made (that is, a noncoverage decision), there may or may not be sufficient evidence to reopen the request.

For those requests that are neither duplicates nor reconsiderations, CMS must make a determination from among the following options:

- National noncoverage decision.
- Issue left to contractor discretion.
- National coverage decision with coverage limitations.
- National coverage decision without coverage limitations.

Once a determination is made, CMS announces its decision on its Web site. Based on the decision memo, CMS then issues coverage instructions, within 60 days, that are binding on all Medicare contractors and administrative law judges.

To assist with the decision making, CMS relies on both internal and external resources. Internally, CMS has medical experts on staff who play a vital role in the review process. In addition, CMS staff members meet with stakeholders and conduct literature searches and reviews (using standard abstraction tools).

When external expertise is called for, CMS staff have two options. They can request a technology assessment, a rigorous systematic analysis, from an impartial third party. Often, this involves AHRQ, which contracts the assessment to one of its evidence-based practice centers, or EPCs.

The second option, referring a request to the relatively new entity known as MCAC, the Medicare Coverage Advisory Committee, has garnered the most attention and has become a lightning rod for contro-

versy. This controversy has its roots in the past, when companies and investors criticized the Medicare coverage process for its lack of openness (the proverbial “black box” of coverage decision making), as well as for its lack of predictability, lack of precise definitions and terms, lack of criteria, and lack of an adequate appeals process. Some of these concerns were addressed during the 1970s, 1980s, 1990s, and most recently in 2000, but some still remain.

MCAC: Shining Light inside the Black Box

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 procedure performed before a coverage determination had been made. In addition to reimbursing the plaintiff, HCFA agreed to publish the notice, thereby explaining its coverage process.

On January 30, 1989, HCFA published another proposed rule expanding upon this 1987 notice. The 1989 proposed rule moved to clarify some of the remaining uncertainty, explaining that

Although the process by which we make Medicare coverage determinations 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 decision 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.

In its most recent effort to open the process, clear up the uncertainty, and assuage industry concerns, most notably the concern that the process as it stood did not comply with the Federal Advisory Commission Act,⁶ the secretary of health and human services chartered the Medicare Coverage Advisory Committee on November 24, 1998. MCAC effectively replaced its predecessor known as the TAC (the Technology Advisory Committee), which was perceived by industry to be the inner sanctum of the black box of coverage.

According to the CMS Web site, the Medicare Coverage Advisory Committee

advises [CMS] on whether medical items and services are reasonable and necessary under Medicare law. They perform this task via a careful review and discussion of specific clinical and scientific issues in an open and public forum. The MCAC is advisory in nature, with the final decision on all issues resting with [CMS]. Accordingly, the advice rendered by the MCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations.⁷

MCAC consists of an Executive Committee and six panels: the Medical/Surgical Panel, the Drugs/Biologics/Therapeutics Panel, the Laboratory and Diagnostic Services Panel, the Medical Devices Panel, the Durable Medical Equipment Panel, and the Diagnostic Imaging Panel. The purpose of the Executive Committee is to provide guidance to the panels. For example, the committee drafted guidelines for evaluating clinical effectiveness. These guidelines were modified and adopted in early 2001 and are posted on the CMS Web site. The panels use these guidelines during their deliberations.

Panel meetings are held at different times throughout the year (meeting dates and staff contacts are posted on the CMS Web site) and are open to the public. These meetings have time built in for public comment, and interested parties can present their views orally or submit them in writing. Each panel consists of a chair and a vice-chair, voting members, a nonvoting industry representative, and a consumer representative.

Each MCAC panel “will use certain criteria and procedures to evaluate the adequacy of the evidence and the magnitude of clinical benefit in determining the effectiveness of new medical products and services.”⁸ While most observers agree that recent improvements made by CMS—greater openness, more public input, and clearer procedures—are positive, exactly how CMS (through the MCAC) makes its coverage decisions and exactly what it bases those decisions on continues to be a source of great consternation and controversy.

Some observers have noted that, while the process itself may not be perfectly transparent up-front, once a decision has been made, CMS is under great pressure to prove it did everything absolutely correctly since its decision memos are universally available once they are posted on the Internet. CMS must explain its reasoning and, should an omission of facts or some other mistake be discovered, there is a reconsideration process in place.

Coverage Criteria and Evidence-based Medicine

Shortly before the establishment of MCAC, HCFA held a Medicare coverage town hall meeting on September 25, 1998, the purpose of which was to address several of the concerns raised over the years. At that meeting, a number of new coverage initiatives were unveiled, including the MCAC.

Also discussed was the promise of a new *Federal Register* notice which would rescind the 1989 notice of proposed rulemaking and update the 1987 *Federal Register* notice. On May 16, 2000, HCFA released a “notice of intent” (NOI), specifying proposed criteria for determining what is reasonable and necessary, the statutory basis for coverage determinations. The proposed criteria to be used in considering Medicare coverage for a new technology included “medical benefit” and “added value.”

The NOI laid out its four-step process by which the agency would base its Medicare coverage decisions on the medical benefit of new technologies and their added value compared to existing services. This new proposed coverage algorithm, paraphrased below, took the form of a coverage decision tree with two branches, one focused on medical benefit and three on added value:

1. *Medical benefit*—Is there sufficient evidence to demonstrate that the product or service is medically beneficial for a particular population?

NO – not covered
YES – move to #2

2. *Added value*—Does Medicare already cover a medically beneficial service that is in the same clinical modality for the same condition?

NO – covered
YES – move to #3

3. *Added value*—Is the new product or service substantially more beneficial, substantially less beneficial, or just about as beneficial as the same modality product or service that is already covered?

MORE BENEFICIAL – covered
LESS BENEFICIAL – not covered
ABOUT EQUAL – move to #4

4. *Added value*—Does the new product or service “result in equivalent or lower total costs for the Medicare population than the Medicare-covered alternative?”

NO – not covered
YES – covered

The notion of using cost as a variable in the Medicare coverage process is anathema to those in the device industry. In a March 2000 published list of recommended principles put forward by the Pan Industry Group on Medicare Coverage, which includes key associations such as the Advanced Medical Technology Association (AdvaMed), the Medical Device Manufacturers Association, and the National Electrical Manufacturers Association, among others, the signatories stated that

HCFA has no authority to deny coverage for a treatment because of issues related to cost effectiveness, and as a policy matter, it should not do so. If economic factors are to be considered, it is more appropriate to do so in the context of payment. HCFA should rely on market data in setting (and adjusting) payment levels.

Second only to cost in terms of controversy is the notion of evidence: How much? What kind? Gathered in what way? These nuances are critical because they determine how complex studies must be and how much and what type of data must be gathered. In his speech before the International Society of Technology Assessment in Health Care in June 2001, Sean Tunis, M.D., stated that “the framework for evaluating clinical effectiveness is clinical epidemiology, more recently called evidence-based medicine (EBM).”

The original definition of EBM was developed by the Evidence-Based Medicine Working Group. Their thinking about EBM follows:

A new paradigm for medical practice is emerging. Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and patho-physiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research. EBM requires new skills of the physician, including efficient literature searching and the application of formal rules of evidence evaluating the clinical literature.⁹

Researchers typically refer to the existence of a hierarchy of evidence, such as the following, developed by AHRQ and listed from strongest to weakest:

- Meta-analysis of multiple, well-designed controlled studies.
- At least one well-designed experimental study.
- Well-designed, quasi-experimental studies such as nonrandomized controlled, single group pre-post, cohort, time series, or matched case-controlled studies.
- Well-designed, nonexperimental studies, such as comparative and correlational descriptive and case studies.

- Case reports and clinical examples.¹⁰

While “the gold standard” among researchers is generally considered to be blinded, prospective randomized controlled clinical trials, this is not always feasible. Such a review is particularly problematic for devices. Some experts point to ethical reasons (that is, one could not operate on a person needing a pacemaker and not insert one, for example) as to why these types of studies are sometimes not possible. Others, however, are of the opinion that it is admittedly more difficult and more costly, but not out of the question, to conduct randomized (but not blinded) clinical device trials.

AHRQ administrator John Eisenberg, M.D., weighed in on this difficult question in the November 17, 1999, issue of the *Journal of the American Medical Association*:

Those who conduct technology assessments should be as innovative in their evaluations as the technologies themselves. There is little argument that the randomized clinical trial is an accepted high standard for testing effectiveness under ideal circumstances, but it may not be the best way to evaluate all the interventions and technologies that decisions makers are considering.

Therefore, the question becomes what type of and how much evidence is necessary to make a Medicare coverage decision? In order to answer the evidence question, the coverage criteria must be considered. That is, the criteria require the question, Is there adequate evidence that a technology is clinically effective and for whom?

The scientific evidence, on the other hand, is the yardstick or measuring stick for determining the level of proof necessary to answer the criteria questions. Asking what type of evidence and how much of it is necessary to establish “proof” of a technology is, in many ways, the heart of the coverage matter. In thinking about the evidence, analysts consider the patient’s condition, the availability of alternatives, and the risks associated with a given technology.

While it is difficult to disaggregate the criteria (which are highly politically charged) from the evidence (which is grounded more heavily in science and statistics), it is important to distinguish between the two. The May 2000 NOI mentioned above laid out the coverage criteria. A proposed rule, however, has yet to be published.

In the meantime, while CMS continues to grapple with these very difficult policies, many technologies are finding their way into the Medicare program through the local medical review process.

LOCAL MEDICAL REVIEW POLICY

Although it is the national Medicare coverage decisions that tend to receive a great deal of attention, the vast majority of coverage decisions occur at the local carrier level. In deciding whether or not to cover a medical service or technology, contractors review applicable manuals for specific product- or procedure-related policies supplied by CMS 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 who provide advice 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.

The decisions that constitute local medical review policy have been viewed as a double-edged sword by many. On the one hand, such decisions are not standardized, since each contractor makes separate decisions that apply only to the area in which that contractor serves. Therefore, a technology that 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 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 the CMS central office.¹¹

REGIONAL COVERAGE POLICY

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 issues a manual with detailed coverage and payment policies on particular product areas, such as infusion pumps, wheelchairs, and orthopedic support devices.

POLICY QUESTIONS FROM THE PAST

In 1999, the National Institute for Health Care Management and the Agency for Health Care Policy

and Research held a symposium entitled "Making Coverage Decisions about Emerging Technologies." At that symposium, Eisenberg posed the following questions:

- What will be the rules of evidence for translating information into knowledge?
- How do we take limited resources into consideration when making coverage decisions?
- Should costs enter the decision? If so, how?
- How should old technologies be evaluated? Should they be held to a different standard?
- What mechanisms can serve to enhance technology assessment programs?

QUESTIONS FOR THE FUTURE

In addition to the questions listed above, which are still relevant, additional questions spring to mind when thinking about current and future coverage issues.

- Is CMS the appropriate locus for national Medicare coverage determinations? (Over the years, entities entrusted with the responsibility for making technology assessment determinations and/or coverage decisions, such as the National Center for Health Care Technology and the Congressional Office of Technology Assessment, have tended to become sitting political ducks and eventually to be disbanded.)
- In defining Medicare coverage criteria, is CMS required to initiate the formal rulemaking process? What role, if any, should the MCAC have in defining coverage criteria?
- Where should the issue of cost be dealt with—on the coverage or payment side of the decision-making process? Some argue that if cost were taken out of consideration on the coverage side and dealt with on the payment side, CMS would have no flexibility on the payment formulas. Is this as it should be?
- Should the coverage process come to a screeching halt when FDA has already approved a technology but there is inadequate or no scientific evidence available for the MCAC to review, or should the technology be allowed to diffuse while data are collected and analyzed? What can be learned about the effectiveness of a device while it diffuses?
- To what extent do ethical barriers preclude device clinical trials?

- What are the pros and cons of alternatives to an all or nothing national coverage determination (for example, conditional coverage or limited coverage)?
- Could (or should) a new technology be substituted for an existing treatment at a lower cost to the Medicare population? Who should make that determination?
- How much control over data collection is appropriate for the federal government? What will be the impact of the recent privacy legislation as it relates to the coverage process and scientific evidentiary data?
- Among its many provisions, the Benefits Improvement and Protection Act of 2000 contained language for revising the Medicare coverage process and expanding the process of appealing Medicare policies and denials of claims. DHHS has, however, taken the position that sections 521 and 522, which outline Medicare coverage appeal reforms, should be delayed for one year from the date of effectiveness. What is the implication of this delay?
- What impact could new patients' bill of rights legislation have on the Medicare coverage process, particularly in the area of coverage denials and with regard to distinguishing between medically necessary and experimental?
- On June 7, 2000, President Clinton issued an executive memorandum directing the DHHS secretary to "explicitly authorize [Medicare] payment for routine patient care costs . . . and costs due to medical complications associated with participation in clinical trials." What are the implications for medical devices?¹²
- Among the many challenges to be addressed in considering a Medicare prescription drug benefit is the question of coverage—which drugs will be covered and paid for under a new benefit? For purposes of Medicare coverage, how should therapeutic class be defined? How will coverage determinations be made? By whom? How, if at all, will this be related to the current Medicare coverage process for devices? If the coverage process for prescription drugs is not within the purview of CMS, what does this portend for devices? Will there be two separate entities, with two separate processes making separate coverage decisions, one for drugs and one for devices? How will coverage decisions for combination products (that is, drug-device products) be made? Where do biotech products fit into all this? What role, if any, will local carriers have?

ENDNOTES

1. National Institute for Health Care Management, *Making Coverage Decisions about Emerging Technologies*, proceedings of an interactive symposium sponsored by the National Institute for Health Care Management with support from the Agency for Health Care Policy and Research, Washington, D.C., February 11, 1999, 17.
2. For more detail on technology assessment, see Robin J. Strongin "Outcomes Research: Stretching the Boundaries of Technology Assessment," NHPF Issue Brief No. 570, June 4, 1991.
3. Ron Geigle, "The Dialogue of Device Innovation: An Overview of the Medical Technology Innovation Process," *Health Care Technology Institute Policy Brief*, November 1993.
4. In recent years, the definition of medical necessity and the possibility of legislating medical necessity, particularly within private health plans, has gained a great deal of attention and has sparked a great deal of debate. See Sarah Singer and Linda Berghthold, "Decreasing Variation in Medical Necessity Decision Making," final report to the California Health Care Foundation from the Center for Health Policy, Stanford University, Palo Alto, California, August 1999.
5. Sometimes, Congress gets involved in coverage. Over the years Congress has required that Medicare cover, for example, diabetes glucose monitors and test strips, colorectal and prostate cancer screenings, bone mass measurements, and other preventive measures.
6. At the beginning of 1998, the Indiana Medical Device Association challenged HCFA's Technology Advisory Committee's (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, the TAC was abolished.
7. Centers for Medicare and Medicaid Services, "Medicare Coverage Policy—MCAC"; accessed August 7, 2001, at <http://www.hcfa.gov/coverage/8b1.htm>.
8. Centers for Medicare and Medicaid Services, "Medicare Coverage Advisory Committee Executive Committee Interim Recommendations for Evaluating Effectiveness, March 1, 2000"; accessed April 10, 2001, at <http://www.hcfa.gov/quality/8b1%2Di9.htm>.
9. Evidence-Based Medicine Working Group, "Evidence-Based Medicine," *Journal of the American Medical Association*, 268, no. 17 (November 4, 1992): 2420–2425.
10. Agency for Healthcare Research and Quality, "Clinical Practice Guideline Number 9: Management of Cancer Pain," AHCPR Pub. No. 94-0592, 1994: 225.
11. A manufacturer could, however, submit additional evidence as it becomes available for CMS to reconsider, possibly overturning the noncoverage determination.
12. For more information on this, see <http://www.hcfa.gov/coverage/8d.htm> or contact clinicaltrials@hcfa.gov.