

GAO

Report to the Chairman, Subcommittee
on Health, Committee on Ways and
Means, House of Representatives

April 2003

MEDICARE

Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities



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Highlights

Highlights of [GAO-03-175](#), a report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

Critical choices on whether new technology will be covered for Medicare's 40 million beneficiaries are made nationally by the Centers for Medicare & Medicaid Services (CMS)—the agency that administers Medicare—or locally by contractors that process and pay claims.

GAO was asked to review the degree to which new procedures and devices are incorporated into Medicare, the effect of Medicare coverage policy-making processes on beneficiaries, and to what extent CMS has addressed concerns about its national coverage process.

What GAO Recommends

GAO recommends that CMS eliminate development of new local Medicare coverage policies for procedures and devices that have been assigned codes; evaluate all current local policies on procedures and devices with established codes to determine if the policies should be incorporated into national policies or be rescinded; and establish a new, centrally managed process that is more open, understandable, and timely to develop national coverage policies, using expertise from other sources. HHS disagreed with our recommendations to eliminate local coverage policy development for certain procedures and devices and to develop a new national process. It also disagreed with the intent of our recommendation to evaluate its existing local policies.

www.gao.gov/cgi-bin/getrpt?GAO-03-175.

To view the full report, including the scope and methodology, click on the link above. For more information, contact Leslie G. Aronovitz at (312) 220-7600.

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What GAO Found

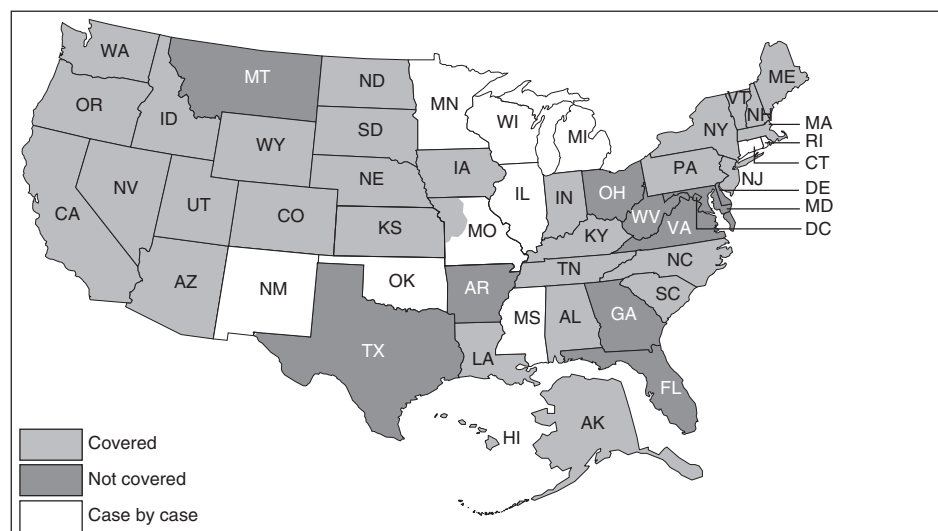
Medicare Covered Most New Procedures and Devices

Medicare covered about 99 percent of the procedures and devices that were assigned codes by an American Medical Association panel or a committee of insurers in 2001. About a quarter were introduced into the program without coverage policies that describe the circumstances for Medicare coverage or place restrictions on their use. Another quarter were affected by national coverage policies and the rest were affected only by local coverage policies.

Variations in Local Coverage Led to Inequities

Because contractors can determine coverage for beneficiaries being treated in their jurisdictions, coverage inequities for beneficiaries with similar medical conditions have resulted. For example, until recently, coverage for a new treatment for debilitating tremors, called bilateral deep brain stimulation (DBS), had been allowed only for beneficiaries treated in some states. On April 1, 2003, CMS implemented a consistent national coverage policy on DBS, but coverage variation continues for other procedures.

Medicare Coverage for Bilateral DBS by State, as of July 31, 2002



Source: GAO survey of carriers.

National Coverage Development Process Raises Concerns

While CMS creates national coverage policies that apply equally to all Medicare beneficiaries, criticisms of its slow pace and its closed policy development process prompted CMS to take steps to make its process more understandable, open, and timely. Nevertheless, the national process remains flawed because it lacks clear coverage criteria, remains closed in fundamental ways to physician and beneficiary input, and has not consistently met timeliness goals.

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Abbreviations

AMA	American Medical Association
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CAG	Coverage and Analysis Group
CMM	Center for Medicare Management
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
DBS	deep brain stimulation
DME	durable medical equipment
FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
MCAC	Medicare Coverage Advisory Committee
NHIC	National Heritage Insurance Company
OIG	Office of Inspector General
SCHIP	State Children's Health Insurance Program

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United States General Accounting Office
Washington, DC 20548

April 11, 2003

The Honorable Nancy L. Johnson
Chairman
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Madam Chairman:

As health care technology evolves, beneficiaries, their families, physicians, and medical device manufacturers are interested in having the Medicare program cover new procedures¹ and devices that could improve individuals' clinical outcomes. Such new procedures and devices are most commonly incremental improvements upon those currently available, but can also represent significant medical breakthroughs. Policies explaining whether, and under what circumstances, new procedures or devices will be covered can be made nationally by the Centers for Medicare & Medicaid Services (CMS)—the agency that administers Medicare—or locally by Medicare claims administration contractors in their service areas. These include 19 carriers, which pay part B claims for most physician, laboratory, and certain other services and items,² and 27 fiscal

¹"Procedure" is used in this report to define all medical actions taken to prevent, diagnose, treat, or manage diseases, injuries, and impairments. This definition includes services such as counseling, evaluation, management of patients, surgery, and laboratory and other tests.

²Part B services include physician and outpatient hospital services, diagnostic tests, mental health services, outpatient physical and occupational therapy, ambulance services, some home health services, durable medical equipment (DME), prosthetics, orthotics, and medical supplies.

intermediaries, which pay part A claims for inpatient hospital and related post-hospital services and part B claims submitted by part A providers.^{3,4}

Procedures and devices are identified by codes that are assigned to them by two committees outside of the Medicare program. When new procedures and devices are assigned codes, CMS decides whether they are among the types of health care benefits described in the Medicare statute and are reasonable and necessary for a beneficiary's treatment, and, therefore, eligible for Medicare payment. CMS notifies contractors whether each new code can be covered, and, based on this information, Medicare's automated claims processing systems pay or deny claims submitted with one of these codes.

CMS or its claims administration contractors sometimes create coverage policies to specify or limit when payment for a particular procedure or device will be made, such as by allowing coverage of a procedure only for certain specified diagnoses. CMS develops national coverage policies that apply to all beneficiaries across the country. Claims administration contractors issue local coverage policies that apply only to beneficiaries treated in their service areas or to providers they service.

Physicians and beneficiary advocates have raised concerns about whether local coverage policies that apply only in a contractor's service area lead to variations that result in inequitable coverage for beneficiaries. In addition, CMS has been criticized for the slow pace by which new procedures and devices are introduced into the program and for the lack of openness and understandability in the process it uses to make national coverage policies.

³Related post-hospital services include some care provided by skilled nursing facilities and home health agencies.

⁴In this report, we refer to carriers, DME regional carriers, and fiscal intermediaries as "claims administration contractors." Unless otherwise specified, the term "carrier" refers to a Medicare claims administration contractor that pays part B claims. The 19 carriers include 4 that also process DME claims and, in this role, are referred to as "DME regional carriers." Under part B, carriers pay claims for treatments provided to beneficiaries in their service areas, which can be portions of states, individual states, or multiple states. Under part A, hospitals and other providers have a choice of which fiscal intermediary to use, and, as a result, more than one fiscal intermediary may pay claims for services provided in any particular geographic area.

In light of these concerns, you asked us to examine:

1. To what extent are new procedures and devices incorporated into the Medicare program?
2. What has been the effect of the local coverage process on beneficiaries, carrier and fiscal intermediary efficiency, and stakeholders, including device manufacturers and physicians?
3. What has been the effect of the national coverage process on beneficiaries, physicians, and other providers, and to what degree has CMS addressed concerns about the process?

In preparing this report, we focused on new procedures and devices that are provided by physicians (and allied professionals under their supervision) or other providers and that could be billed under part B, including anesthesia and laboratory tests. We also included devices that could be used by beneficiaries in their homes. Claims for covered procedures and devices in our study are generally processed by carriers. We included some procedures that physicians would perform in an inpatient hospital setting—such as surgeries—that could also have related claims by hospitals under part A that would be processed by fiscal intermediaries. To determine the extent to which new procedures and devices are incorporated into Medicare, we selected 320 codes for procedures and devices that were new in 2001, analyzed information about these codes, and reviewed national and local policies that affected them. To evaluate the effects of the local and national coverage processes and concerns about the national coverage process, we (1) reviewed CMS, carrier, and fiscal intermediary coverage policies, including analyzing national coverage policies that CMS made from February 1999 through July 2002, and (2) interviewed CMS regional and headquarters officials; Food and Drug Administration (FDA) officials; Medicare staff at four carriers,⁵ which included one DME regional carrier⁶ and one that also served as a fiscal intermediary;⁷ and advocates representing physicians,

⁵We conducted Medicare carrier site visits at National Heritage Insurance Company, Blue Cross Blue Shield of Rhode Island, Noridian Administrative Services, and CIGNA HealthCare Medicare Administration.

⁶CIGNA also serves as one of four DME regional carriers that process all Medicare claims for DME, prosthetics, orthotics, and supplies.

⁷Blue Cross Blue Shield of Rhode Island serves as both the carrier and a fiscal intermediary in that state.

suppliers, and beneficiaries. Appendix I contains more detail on our scope and methodology. Our work was conducted from October 2001 through March 2003 in accordance with generally accepted government auditing standards.

Results in Brief

Medicare covered most—about 99 percent—of procedures and devices assigned codes in 2001. For procedures and devices with established codes, Medicare contractors' automated claims processing systems generally accept—and pay—claims, unless coverage policies define or restrict when Medicare will pay for their provision. About one quarter of the new codes for procedures and devices were introduced into Medicare without any coverage policies that affected their use. About one quarter of the new codes had associated national coverage policies, while the rest were affected only by local coverage policies developed by at least one claims administration contractor. More than half of the codes affected by national coverage policy were also affected by one or more local coverage policies.

Dividing authority to develop coverage policies has led to coverage inequities for Medicare beneficiaries with similar medical conditions based on the location where they receive treatment and to inefficiencies in program administration. For example, in July 2002, carriers provided coverage for a new treatment for Parkinson's disease for certain beneficiaries with debilitating tremors treated in Kansas, but not in Florida. On April 1, 2003, CMS implemented a national coverage policy for this treatment. Coverage varies by state for certain tests to diagnose or monitor an individual's response to treatment for cancer. One test is covered by carriers in Rhode Island and Pennsylvania, but is not covered in Florida and New Jersey. In addition to coverage inequities, having each carrier and fiscal intermediary separately develop policies for the same procedure or device results in duplication of efforts and program inefficiencies. For example, eight carriers have separately followed the extensive, required steps to develop local policies for a method of identifying a possible risk of sudden cardiac death. Despite these problems, some groups, including device manufacturers' representatives and physician groups, argue that local coverage policies have benefits. For example, they state that local policies can be developed more rapidly than national coverage policies and that the local coverage process is open to physician and public input.

Because CMS's national policies apply to all Medicare beneficiaries regardless of their treatment location, these policies promote coverage

consistency for beneficiaries, physicians, and other providers. However, CMS's national coverage process had been criticized for being slow, not clear, and not open to public input. To address these concerns, CMS recently took steps to strengthen its national coverage process. In 1999, for example, the agency made the process more understandable by publishing the steps it takes to develop national coverage policies. Nevertheless, some problems persist. For example, CMS does not publish its draft national coverage policies for public comment. In addition, CMS does not always consult with experts outside the agency when it develops coverage policies.

Because of inequities and inefficiencies resulting from divided authority to develop coverage policy among CMS, carriers, and fiscal intermediaries, we are recommending that CMS eliminate claims administration contractors' development of new local coverage policies for procedures and devices that have established codes. We are also recommending that CMS establish a new process for making national coverage policy.

In commenting on a draft of this report, the Department of Health and Human Services (HHS) generally disagreed with our recommendations and expressed concerns about the effects of these proposed changes on the Medicare program and the resources that would be required to implement them. We believe our recommendations would lead to more consistent coverage policies for Medicare beneficiaries and would increase program efficiency through redirecting the resources that are currently devoted to duplicative policy making.

Background

Medicare is the federal health insurance program that serves 40 million beneficiaries who are aged 65 years and older, certain disabled people under 65 years of age, and individuals with end-stage renal disease. The program is administered by CMS—formerly the Health Care Financing Administration (HCFA)⁸—an agency within HHS. Most beneficiaries receive their care on a fee-for-service basis, with providers submitting claims for payment for each service provided. CMS contracts with claims administrators—health insurers—to process claims from nearly 1 million hospitals, physicians, and other health care providers. In fiscal year 2000,

⁸This report will refer to HCFA in discussing actions taken before the agency's name was officially changed on July 1, 2001.

carriers processed about 740 million claims and fiscal intermediaries processed about 151 million claims.

Medicare Payment for Claims Relies on Codes for Billing

Medicare's payment systems for claims are highly automated and rely on codes to identify medical procedures and devices used in beneficiaries' diagnoses and treatments. Contractors identify specific procedures and devices billed on behalf of a beneficiary by Healthcare Common Procedure Coding System (HCPCS) codes, a series of five digits used by Medicare and other health insurance programs. The HCPCS also contains miscellaneous codes that can be used to bill for procedures and devices for which there are no established codes.⁹ The HCPCS contains three sets of codes—Levels I, II, and III. Level I consists of Current Procedural Terminology (CPT) codes used primarily to identify medical services and procedures furnished by physicians and other health care professionals. Level II codes represent products, supplies, and services not included in CPT codes, such as ambulance services and DME used in a beneficiary's home. Level III codes are "local" codes that have been developed by Medicare carriers and fiscal intermediaries, Medicaid state agencies, and private insurers for use only in their specific jurisdictions. Local codes are scheduled to be eliminated in December 2003.¹⁰

A request for a new HCPCS code may be made by physicians or medical device manufacturers for procedures and devices that may be clinically different from existing treatment options—generally to better delineate a new procedure from a similar one or when the cost of a new procedure or device necessitates a different payment amount.

Two different entities are responsible for assigning new codes. The American Medical Association's (AMA) CPT Editorial Panel¹¹ annually

⁹Physicians and suppliers must provide additional documentation when submitting Medicare claims using a miscellaneous code. Contractors manually review these claims to determine what procedure or device is being billed, whether it should be covered, and the amount that should be paid. In 2001, miscellaneous codes accounted for less than one quarter of 1 percent of part B payments.

¹⁰Local codes are scheduled to be eliminated as part of the establishment of standards and requirements for the transmission of health information under the Health Insurance Portability and Accountability Act of 1996. Pub. L. No. 106-191, § 262, 110 Stat. 1936, 2021.

¹¹The CPT Editorial Panel is predominantly comprised of AMA-appointed physicians, but also includes physicians nominated by CMS, the Blue Cross/Blue Shield Association, the American Hospital Association, the Health Insurance Association of America, and a nonvoting representative from the American Health Information Management Association.

updates codes for procedures and other physician services—CPT codes. The HCPCS National Panel, which is composed of CMS and insurer representatives,¹² annually updates codes for medical devices and other products—HCPCS Level II codes. Because the code sets maintained by the AMA CPT Editorial Panel and HCPCS National Panel are designed to serve multiple health insurers, not all of the codes are for services or items covered by Medicare.¹³ It usually takes at least 15 months from the date a new code is requested for a new code to be assigned and put into use.

Medicare’s Statute Sets Out Broad Categories of Covered Services and Items

To be eligible for coverage under Medicare, specific health care services must fit into 1 of about 55 categories of benefits described in statute. The Secretary of HHS has been delegated legal authority to specify which procedures, devices, and services are covered in the broad benefit categories and under what conditions. The Secretary delegates this responsibility to CMS, which, in turn, delegates some of this responsibility to its claims administration contractors.

The law states that Medicare cannot pay for any items or services that are not “reasonable and necessary” for the diagnosis and treatment of an illness or injury or to improve functioning of a malformed body part.¹⁴ The law excludes some services and items from coverage, such as routine physical checkups, most immunizations, cosmetic surgeries, hearing aids, eyeglasses, routine foot care, and routine dental care.¹⁵ Medicare law has been amended several times to add new coverage—including certain preventative health care services such as immunizations for pneumonia and influenza; mammogram, pap smear, and pelvic exam screenings; and tests for prostate and colorectal cancer.¹⁶

¹²The HCPCS National Panel is comprised of representatives from CMS, the Blue Cross/Blue Shield Association, and the Health Insurance Association of America.

¹³For additional information about codes, see U.S. General Accounting Office, *HIPAA Standards: Dual Code Sets Are Acceptable for Reporting Medical Procedures*, [GAO-02-796](#) (Washington, D.C.: Aug. 9, 2002).

¹⁴42 U.S.C. § 1395y(a)(1)(A) (2000).

¹⁵Medicare does not cover outpatient, self-administered drugs. However, it does cover physician-administered drugs and drugs used in immunosuppressive therapy (for organ transplant recipients) and anticancer chemotherapy. 42 U.S.C. § 1395x(s)(2)(J) and (Q) (2000).

¹⁶See U.S. General Accounting Office, *Medicare: Beneficiary Use of Clinical Preventive Services*, [GAO-02-422](#) (Washington, D.C.: Apr. 12, 2002).

Each year, CMS reviews new CPT codes and HCPCS Level II codes for procedures and devices to determine if these codes fit into a Medicare benefit category and can be covered because they are deemed reasonable and necessary for a beneficiary's diagnosis or treatment. Following its review, CMS provides information on new codes to claims administration contractors, including coverage, billing, and payment instructions. (See app. II for more detail on the coding assignment process.)

CMS and Claims Administration Contractors May Develop Policies Defining When New Procedures and Devices Are Covered

Even when CMS determines that Medicare may cover a procedure or device, CMS or its claims administration contractors may develop policies that delineate the circumstances under which its use is considered reasonable and necessary, and thus covered. Using a process that began in 1999, CMS's Coverage and Analysis Group (CAG), which is located in the Office of Clinical Standards and Quality, develops national coverage policies, which are binding on Medicare contractors and apply to all beneficiaries. The agency has also compiled a body of national policy on Medicare coverage that is included in manuals and other written materials for claims administration contractors. In addition, claims administration contractors develop local coverage policies, which apply to beneficiaries being treated in their jurisdictions.

CAG begins the national coverage process when it receives a formal request from an outside party—a device manufacturer, for instance—or when CAG internally identifies the need to consider coverage.¹⁷ CAG internally identifies the need for national coverage policies under several circumstances—for example, when a procedure or device is seemingly being used inappropriately, controversy exists about its clinical benefit, or new evidence of clinical effectiveness is available. Once CAG accepts a request to consider a national coverage policy, it may complete an analysis in-house or seek outside scientific help by requesting a technical assessment, referring the issue to an advisory committee, or both. After conducting its own analysis and reviewing any external input, CAG may arrive at several possible courses of action. (See app. III for more information on the process CMS uses to develop national coverage policies.) These include a national noncoverage policy, which precludes claims administration contractors from making Medicare payment; a coverage policy with specific restrictions; a policy that allows claims

¹⁷In 2001, CMS received 10 external requests for national coverage policies, and CMS staff internally decided to consider 8 additional national coverage policies.

administration contractors to use their discretion when deciding whether to cover the procedure or device in their service areas;¹⁸ or a coverage policy with no national restrictions. By statute, CMS can issue policies on national coverage without using the notice and comment rulemaking procedures required for substantive changes.¹⁹

In addition to CMS's national policies, carriers and fiscal intermediaries may develop coverage policies that apply to the claims they process, as long as their policies do not conflict with national coverage policy. Each contractor has at least one physician who serves as a medical director to help develop local coverage policies. Medicare claims administration contractors' role in determining coverage dates back to 1965, when the Medicare program was first authorized. At that time, the Congress arranged for many Medicare operations to be placed in the hands of private insurers to allow the program to be implemented rapidly by organizations already processing claims for hospitals and physicians. Nevertheless, claims administration contractors did not begin to develop written policies until the late 1970s.

Claims administration contractors develop local coverage policies for a number of reasons. Local policies specify conditions to automatically deny inappropriate claims through Medicare's automated claims processing systems.²⁰ In addition, contractors may develop local policies to address their concerns about inappropriate utilization and improper billing for a particular procedure or device.²¹ Local coverage policies may specify acceptable diagnoses, guidelines on use, and documentation requirements. (See app. IV for more information on the process carriers and fiscal intermediaries use to develop local policies.)

¹⁸Some national policies specifically state that CMS is allowing carriers to use their own discretion when determining coverage. For example, a coverage memorandum regarding speech generating devices stated that "carriers. . . will make coverage decisions for claims for any [of these] devices on either a case-by-case basis or through a local policy."

¹⁹42 U.S.C. § 1395hh(a)(2) (2000).

²⁰Even if the contractor has developed a policy that limits coverage, its medical director may make an individual coverage decision for a beneficiary with a rare condition or when a beneficiary has no other treatment options.

²¹Carriers have also developed local policy at the direction of CMS. For example, CMS program memorandum AB-01-129, dated September 15, 2001, directed carriers to develop local medical policies for Doppler flow studies, a test that monitors a patient's blood flow and can be used during kidney dialysis.

Unlike other carriers and fiscal intermediaries that are allowed to develop their own local coverage policies, the four DME regional carriers are required to jointly develop and utilize one set of policies. Therefore, DME regional carriers' policies outlining beneficiaries' coverage for DME, prosthetics, orthotics, and supplies are identical across the nation. While DME regional carriers develop coverage policy that has national applicability, they follow a policy development process that is similar to that employed by carriers and fiscal intermediaries, as outlined in appendix IV.

Medicare Covered Most Procedures and Devices Assigned Codes in 2001, Often Without National or Local Coverage Policy

Overall, Medicare covered most procedures and devices that had been assigned a code for 2001. Medicare's automated payment systems generally accept, and pay claims for, procedures and devices that have established codes, unless coverage policies have been developed to define or restrict when Medicare will pay for their provision. There were no coverage policies for about one quarter of procedures and devices we studied that were assigned codes in 2001. The remaining codes were affected by national or local coverage policies or both.

We selected for our study 320 codes for procedures and devices issued in 2001.²² Of these 320 codes, CMS identified 316 as coverable, and identified only 4—or about 1 percent—as noncoverable.²³ The four noncoverable services and devices were a vision screening test, a type of rehabilitative physical exercise for arterial disease that is supervised by a nurse or an exercise physiologist, smoking cessation counseling, and a supportive garment. CMS determined that these services and devices were not allowable according to Medicare statute.

²²A total of 1,146 new codes were added to the HCPCS list for 2001. There were 826 new codes not included within the scope of our study, including 640 codes added to identify items to which special Medicare hospital outpatient payment rates apply; 113 codes developed for private health insurers or Medicaid; and 73 for other services, such as ambulance services, drugs, and blood-related services.

²³In October 2000, CMS identified 11 of the 320 new codes as noncoverable. Subsequently, CMS deemed 7 of these 11 codes as coverable. Specifically, in a national coverage policy that became effective in April 2001, CMS outlined conditions under which contractors could cover 4 of these codes used to bill for intestinal transplantation procedures. CMS also issued instructions that 3 codes for medical nutrition therapy could be covered after the Congress specified such therapy in statute as a Medicare benefit, effective January 2002. Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, app. F, § 105, 114 Stat. 2761, 2763A-471.

We found that, as of May 2002, there were no coverage policies for 25 percent of the 316 coverable new codes for procedures and devices, and 26 percent were affected by a national coverage policy. For example, national policy permitted a new battery-powered piece of inhalation therapy equipment to be covered only for patients with severely impaired breathing ability. To implement national coverage policies, contractors sometimes develop local coverage policies to provide more detailed billing requirements.²⁴ As table 1 shows, 16 percent of the 2001 codes for procedures and devices that were affected by national policy also had local policy developed by claims administration contractors.

Table 1: Number and Percent of the New Coverable Procedure and Device Codes for 2001 That Were Affected by National or Local Coverage Policy

Type of coverage policy	Number of codes affected	Percent of codes affected
National only	33	10
Both national and local	50	16
Local only	154	49
No policy	79	25
Total	316	100

Source: GAO analysis.

In the absence of a national coverage policy, contractors have broad discretion to develop local coverage policies that can define or restrict coverage for new procedures and devices. About 65 percent of the 316 new codes for procedures and devices were included in at least one local coverage policy that had been created by at least one claims administration contractor.²⁵ For example, in the absence of a national coverage policy, as of December 2002, three carriers and two fiscal intermediaries had developed local coverage policies to define or restrict coverage for a new, minimally invasive surgery for abdominal aortic aneurysms.

²⁴For example, when a national policy indicates a procedure is covered, claims administration contractors can supplement the policy by adding conditions that must be met, the only acceptable diagnoses for billing, or the frequency with which the procedure can be provided as a covered service.

²⁵We conducted this analysis in August 2002 by searching for the codes on LMRP.net. If a contractor revised its policies to update them with new codes and published the revisions on its local Web site, but neglected to update LMRP.net, such revisions would not appear in our analysis.

While local coverage policies affected about 65 percent of the new codes for procedures and devices, each individual contractor's policies generally affected only a small number of the new codes. For example, we found that—on average—individual carriers had policies that affected 8 percent of the 316 procedure and device codes. Further, some of the new codes were incorporated into local policy by only one single-state carrier. For example, Blue Cross Blue Shield of Montana was the only carrier to develop a local policy that outlined how to bill for a new code for venous access catheters, which affected coverage only for beneficiaries in Montana. Similarly, HGSAdministrators was the only carrier to establish a local policy that outlined coverage for new codes involving certain cochlear implantation procedures, which affected coverage only for beneficiaries in Pennsylvania.

Variations in Local Coverage Policies Lead to Program Inequities and Inefficiencies

Allowing carriers and fiscal intermediaries to make local coverage policies leads to different treatment for beneficiaries in different locations and to inefficiencies due to duplication in contractors' policy-making efforts. Because the authority to make local coverage policies is divided among carriers and fiscal intermediaries, Medicare can cover a procedure for a beneficiary receiving care in one locality and not cover that procedure for a beneficiary with a similar medical condition being treated in another location. Further, because more than one fiscal intermediary can pay part A claims for hospitals in a given area, Medicare can cover a procedure for a specific diagnosis in one hospital, but not in another hospital in the same local area. Local policy development is also inefficient because carriers and fiscal intermediaries duplicate many of the steps—such as identifying and assessing the medical literature to determine if the procedure or device has clinical benefit—taken by other carriers or fiscal intermediaries that have developed policies on the same procedures and devices. Despite these problems, some groups still support coverage policy developed at the local level.

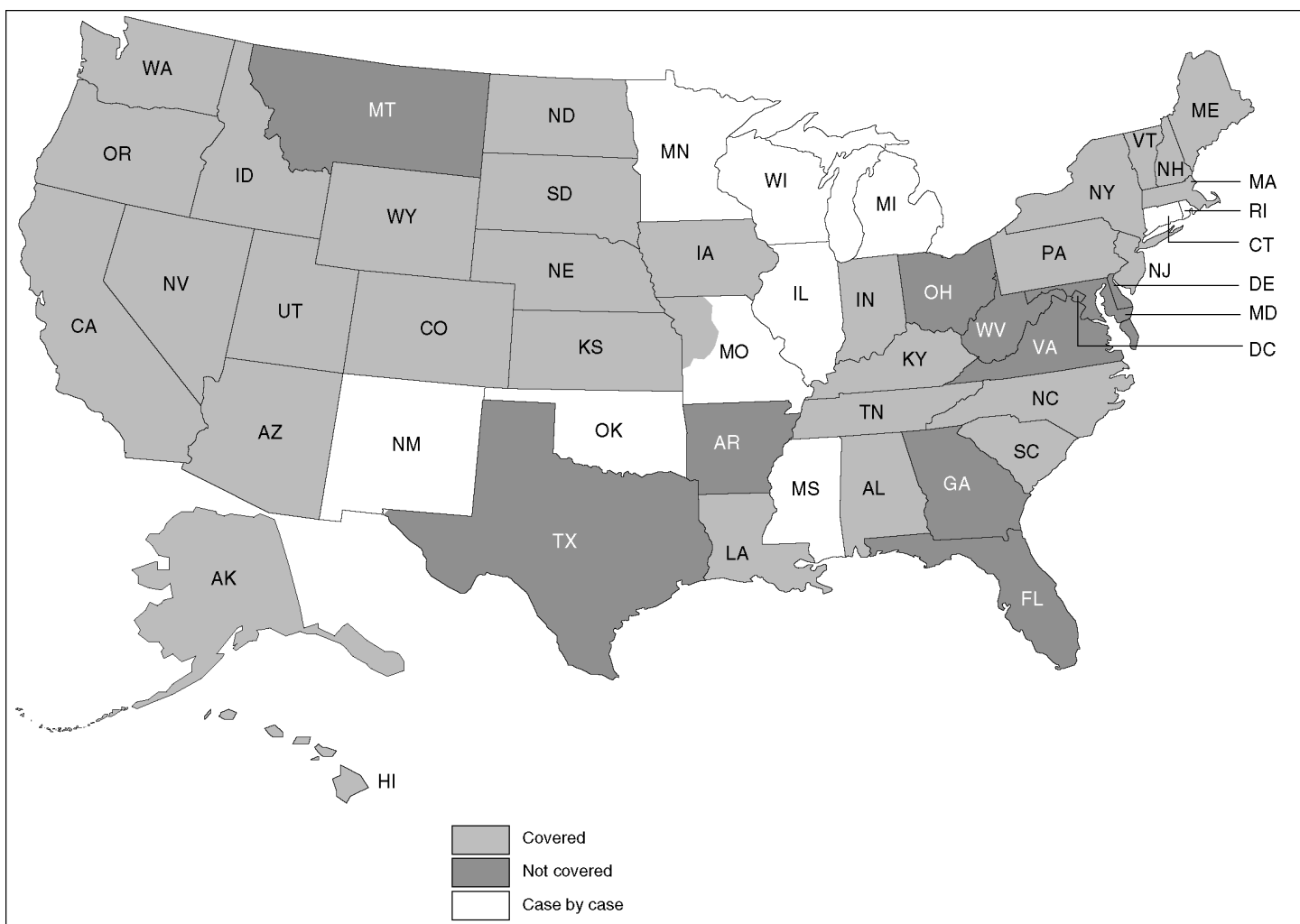
Local Coverage Policy Leads to Coverage Variations that Can Affect Beneficiaries' Access to Treatment

Because CMS gives claims administration contractors discretion to determine coverage and develop local coverage policy, beneficiaries' coverage for specific procedures and devices varies nationwide. One recent example of the impact on beneficiaries involves a surgical treatment—called deep brain stimulation (DBS)—for tremors associated with the two most common neurological disorders.²⁶ DBS may produce significant improvement in physical functioning for people suffering from severe, debilitating tremors that can no longer be controlled by medication.²⁷ There are two kinds of DBS—unilateral brain stimulation of the thalamus and bilateral stimulation of other brain structures. Bilateral DBS can help reduce the typically more debilitating symptoms of Parkinson's disease, including stiffness and slowness. According to a survey of carriers we conducted, Medicare coverage of bilateral DBS varied considerably. (See fig. 1.) As of July 31, 2002, carriers serving 30 states and part of another covered bilateral DBS, while carriers did not cover this procedure in 10 states and the District of Columbia. In 9 states and part of another, carriers indicated that they might approve the procedure on a case-by-case basis. For example, in Missouri, where two carriers serve different parts of the state, bilateral DBS was covered in the western part of the state and was covered on a case-by-case basis in the eastern part.

²⁶Essential tremor and Parkinson's disease are the two most common neurological disorders. Essential tremor affects about 1.5 million Americans; Parkinson's disease affects about 1 million. Tremor is a common symptom of both, but Parkinson's disease also causes rigidity, slowness of movement, and poor balance.

²⁷One device manufacturer estimated that about 85,000 individuals with Parkinson's disease and 5,000 individuals with essential tremor are candidates for treatment with DBS.

Figure 1: Carrier Coverage for Bilateral DBS by State, as of July 31, 2002



Source: GAO survey of carriers.

In October 2001, a beneficiary with Parkinson's disease requested that CMS issue a national coverage policy on bilateral DBS. At the time of his request, the beneficiary was not covered for bilateral DBS because he lived in Texas, where the carrier did not cover this surgery.²⁸ On April 1,

²⁸The carrier began to cover this surgery on August 12, 2002.

2003, CMS implemented a national policy that covered DBS for all beneficiaries who meet certain coverage criteria.

While a national coverage policy will help ensure consistent bilateral DBS coverage, variations in coverage continue to be a concern for beneficiaries needing other procedures. For example, carriers vary in their coverage for tumor assay tests that are used to diagnose or monitor the response to treatment of cancer and were assigned codes in 2001. Carriers in Florida and New Jersey have local policies that clearly prohibit coverage for one of these tests because they do not consider its clinical benefits to be proven. In contrast, carriers in other states—such as Rhode Island and Pennsylvania—cover this test for physicians to monitor the course of disease in patients with established diagnoses of certain types of cancers. In 2001, Medicare paid over \$382,000 for this tumor assay test in 38 states.²⁹

We also found that part B coverage for treatment options can differ even for beneficiaries who are treated in the same state and are served by the same carrier. One reason that policies may vary within a carrier's service area is that, since 1990, more than 40 percent of Medicare carriers have left the program. As of October 2002, 11 of the remaining carriers have assumed responsibilities for administering their claims. For example, prior to December 1, 2000, National Heritage Insurance Company (NHIC) served northern California and another carrier served southern California. After NHIC assumed responsibility for claims administration in southern California, NHIC staff assessed local policies in its jurisdiction to understand the extent to which its policies varied. Our analysis of NHIC's data found that 38 percent of southern California's policies were not shared by northern California in September 2001. (See table 2.)³⁰ We found that northern and southern California still had varying local coverage policies as of October 2002, including the examples in table 2.

²⁹Based on claims analysis from part B summary data for 2001 claims extracted as of June 5, 2002.

³⁰Until recently, beneficiaries in northern and southern California suffering from essential tremor and Parkinson's disease were covered differently for DBS. In June 2002, NHIC consolidated local policies in northern and southern California to cover bilateral stimulation.

Table 2: Variations in Local Coverage Policies in Northern and Southern California

Region	Total local coverage policies	Number of local coverage policies limited to one region	Percent of local coverage policies limited to one region	Examples of local coverage policies limited to one region
Northern California	80	22	28	• Whole body bone and/or joint imaging • Extracapsular cataract removal
Southern California	145	55	38	• Audiology testing • Pap smear, diagnostic • Vagus nerve stimulation for epilepsy

Source: GAO analysis.

Coverage policies for part A services can also vary within each state because hospitals and other part A providers can choose their fiscal intermediary. As a result, different fiscal intermediaries may serve providers in the same state, or even in the same city. This can result in differential coverage of a procedure, if two fiscal intermediaries in the same state have differing policies. For example, the two fiscal intermediaries who pay hospital claims in Kansas each have local coverage policies on a specific type of cataract surgery. However, these policies are not identical. One fiscal intermediary's policy lists covered diagnoses that are not listed as covered in the other fiscal intermediary's policy, which leads to differences in claims payment.

Further, CMS does not require carriers and fiscal intermediaries that pay claims for services and items in the same geographic area to develop similar local coverage policies, even for the same treatments. This can lead to differences in coverage depending on location of service, such as whether a procedure is performed in a doctor's office and paid by the carrier, or performed in a hospital outpatient department and paid by the fiscal intermediary responsible for that hospital's claims.

Duplicative Efforts to Develop Local Policies by Carriers and Fiscal Intermediaries Result in Program Inefficiencies

Allowing individual carriers and fiscal intermediaries to develop their own policies results not only in instances of inequitable coverage, but also is inefficient as each contractor takes parallel steps to develop policies on similar topics. For example, eight carriers have developed local coverage policies for a method of measuring changes in heartbeats on an electrocardiogram, which are a possible harbinger of sudden cardiac death. Further, two fiscal intermediaries have developed local coverage policies for a new, minimally invasive treatment for abdominal aortic aneurysms, and four fiscal intermediaries have developed policies for upper gastrointestinal endoscopy, which is a procedure using a lighted tube to visualize the esophagus, stomach, and part of the small intestine.

We identified duplicative efforts to develop policies for procedures and devices assigned codes in 2001 among the four carriers that we visited. As table 3 shows, we found that for six procedures, two carriers independently developed or revised their own coverage policies. For example, two carriers each developed new local coverage policies for a procedure to graft tissue-cultured skin, called bilaminate skin substitute.

Table 3: Local Coverage Policies for Procedures with New Codes Developed or Revised by Four Carriers in Four States

Procedure addressed by local coverage policy	Carrier/state			
	National Heritage Insurance Company	Blue Cross Blue Shield of Rhode Island	Noridian Administrative Services	CIGNA HealthCare Medicare Administration
	Massachusetts	Rhode Island	Nevada	Tennessee
Bilaminate skin substitute	X			X
Percutaneous vertroplasty	X			X
Endoscopic ultrasonography, upper gastrointestinal tract	X		X	
Ocular photodynamic therapy	X		X	
Magnetic resonance angiography		X		X
Immunoassay for tumor antigen		X		X

Source: GAO analysis.

Although the carriers we visited attempt to build on the work of others or adapt policies developed by individual or groups of carrier medical directors, they still often duplicate research efforts. Each carrier ultimately has to arrive at, and justify, its own coverage policy, which means that the carrier medical director and other staff must review the evidence and other related policies. Each carrier also takes parallel steps to complete the process required to adopt the policy, such as consulting with experts, holding public and carrier advisory committee meetings,

responding to input received, and posting draft local coverage policies on the carrier's Web site.³¹

Each contractor that develops policy must devote staff time to this activity. One multistate carrier we visited developed or revised 21 policies in fiscal year 2002, which was a full-time task for a registered nurse, with help from one of the carrier's medical directors and support staff. This carrier reported that its medical directors generally commit 10 to 30 percent of their time to policy development. Medical directors at other carriers also reported committing significant amounts of their time to developing policy. One carrier medical director told us that, because his resources for evidence gathering are limited, he often relies on physicians and suppliers for evidence even though he knows this could bias the selection of information to be considered.

Lack of information and communication from CMS regarding the development of national coverage policies has resulted in wasted local policy development efforts. Two medical directors stated that there are no designated points of contact at CMS headquarters and no established channel of communication between them and CMS staff who make national coverage policies. According to one carrier medical director, in the absence of detailed information on the status of CMS's efforts to develop a national policy on ocular photodynamic therapy, which is a new procedure that uses a laser-activated drug to treat macular degeneration, the carrier developed its own policy. Overall, to clarify their coverage, eight carriers developed local coverage policies for this treatment, which could have affected beneficiaries in 23 states and a portion of another state. While these carriers were obtaining comments on their draft policies, in November 2000 HCFA issued a national coverage policy on this therapy for beneficiaries with certain types of eye lesions.

Some Groups Contend that Local Coverage Policy has Benefits

While critics view variations in local coverage policy as inequitable treatment of beneficiaries, device manufacturers' representatives, some physicians and physician groups, and claims administration contractors stated that the local coverage process has benefits. For example, supporters indicated that the local process results in coverage policy being

³¹DraftLMRP.net, a CMS-sponsored Web site, allows the public to view draft local policies of carriers, DME regional carriers, and fiscal intermediaries posted to their Web sites during the required comment period.

made more rapidly than in the national process. However, comparative timeliness information is difficult to generate because claims administration contractors and CMS track different key dates for their processes. For example, CMS reports the date when a national coverage policy is requested and the agency's review is initiated. In contrast, contractors report the date that a draft local policy is released for comment—a point further along in the process than the initial request date tracked in the national process. Nevertheless, certain features of the local process may allow it to respond quickly in expanding coverage. For example, claims administration contractors can follow an expedited process when they expand coverage, such as when they add new diagnoses as coverable in an existing policy.

Supporters of local coverage policy have also argued that the steps Medicare claims administration contractors take to consult with physicians and the DME industry are a positive characteristic of the local process. As appendix IV shows, when contractors propose a new or more restrictive local coverage policy, carriers' and DME regional carriers' advisory committees³² routinely review and comment on draft local policies³³ and contractors hold public hearings about proposed policies. Further, all contractors post draft policies on their Web sites and on a centralized Web site, draftLMRP.net, and inform the public of how to comment on draft policies and the closing dates for comments.³⁴ Carrier medical directors, who regularly consult with practicing physicians on draft policies, told us that such consultations help them avoid unintended consequences, which might be obvious to practicing physicians or others, and could be beneficial for CMS.

³² Carriers' advisory committees are composed of physicians, a beneficiary representative, and representatives from other medical organizations. DME regional carriers' advisory work groups consist of physicians, other clinicians, beneficiaries, suppliers, and manufacturers.

³³ Fiscal intermediaries may have advisory committees, but CMS does not require them to do so.

³⁴ Claims administration contractors can expand coverage without such consultation—for example, they can add additional diagnoses for which a treatment would be considered medically necessary.

National Coverage Policy Adds Consistency, But Current Policy Development Process Could Be Strengthened

Developing national policy creates more consistent coverage for beneficiaries because it applies to all beneficiaries regardless of their treatment location. Further, because national coverage policy does not vary depending on location, it can be communicated more easily to physicians, other providers, suppliers, and the general public. However, concerns have been expressed about the openness, understandability, and slow pace of the national coverage process, and CMS has attempted to improve it—for example, by publishing the steps it takes to make national coverage policies³⁵ and issuing coverage memorandums that outline the evidence considered to arrive at its policies. Nevertheless, some problems persist, such as the lack of consistent public, expert, or practitioner input on proposed coverage changes.

National Coverage Policy Promotes Programmatic Consistency

Developing coverage policy with national applicability promotes coverage consistency because it applies to all beneficiaries regardless of where they receive treatment. Across the country, beneficiaries, physicians, other providers, and suppliers already have consistent coverage policies for DME, prosthetics, orthotics, and medical supplies because DME regional carriers develop identical policies. Companies providing DME in multiple states can do so knowing that one set of coverage rules applies. In addition, coverage for many laboratory services is subject to more consistent policies. The Balanced Budget Act of 1997 mandated that HCFA establish national coverage policies for laboratory tests³⁶ and, as of November 2002, over 40 percent of laboratory services currently billed to carriers were subject to national coverage policies.

Having national coverage policy simplifies coverage for providers who serve beneficiaries in multiple states. In its report on Medicare laboratory payment policy, the Institute of Medicine noted that Medicare's current administration of laboratory claims through its carriers and fiscal intermediaries created inconsistency in the interpretation of policy and procedures and led to variable interpretations of medical necessity for the same tests given under the same circumstances in different locations. These inconsistencies created particular problems for laboratories that performed tests on specimens drawn from beneficiaries in many different

³⁵64 *Fed. Reg.* 22,619 (Apr. 27, 1999).

³⁶Pub. L. No. 105-33, § 4554(b), 111 Stat. 251, 461.

states, because the laboratories had to deal with differing policies and procedures for similar claims.³⁷

Although national coverage policy could lead to greater programmatic consistency, Medicare still allows local variations in the application of its national policies. For example, HCFA issued a memorandum on national coverage of a noninvasive diagnostic test to measure heart function in 1998.³⁸ The national coverage policy stated that Medicare would cover the test for beneficiaries with suspected or known cardiovascular disease. Some carriers chose to clarify this broad coverage description in order to automate claims denial by specifying the appropriate diagnoses and the diagnostic codes that would indicate medical necessity for performing this test, while other carriers did not. As a result, a beneficiary in Tennessee diagnosed with “shortness of breath” could have the test covered by Medicare, whereas a beneficiary with the same diagnosis in Michigan would not have the test covered.

We and others have recommended that CMS work toward a more consistent coverage approach. In 1996, we reported that carriers differed in their policies for six groups of medical procedures that could be inappropriately used.³⁹ As a result, we recommended that the agency analyze expensive and inappropriately used services, identify local coverage policies for these services, and work with claims administration contractors to develop more consistent policies for them. Since then, the agency has encouraged claims administration contractors to develop policies to address expensive and inappropriately used services. More recently, the Medicare Payment Advisory Commission recommended that the local coverage policy-making process be abolished in favor of a single national process in order to develop more consistency in the program.⁴⁰ The commission noted that eliminating local coverage policies would reduce the current complexity, inconsistency, and uncertainty in the

³⁷Institute of Medicine, National Academy of Sciences, *Medicare Laboratory Payment Policy: Now and in the Future* (Washington, D.C.: 2000).

³⁸HCFA issued its coverage memorandum on this test—cardiac output monitoring by electrical bioimpedance—on September 22, 1998, with coverage effective for services performed on or after July 1, 1999.

³⁹U.S. General Accounting Office, *Medicare: Millions Can Be Saved by Screening Claims for Overused Services*, [GAO/HEHS-96-49](#) (Washington, D.C.: Jan. 30, 1996).

⁴⁰Medicare Payment Advisory Commission, *Reducing Medicare Complexity and Regulatory Burden* (Washington, DC: December 2001).

Medicare program, along with the associated burden on providers and beneficiaries.

Concerns Remain about the Openness, Understandability, and Timeliness of CMS's National Coverage Process

Over the years, the agency's national coverage process has been criticized for its lack of openness, lack of understandability, and slow pace. Critics have stated that the national coverage process was not open because meetings of scientific experts and clinicians advising the agency were not open to the public. Further, they have charged that the process was not understandable because the steps that the agency followed were not clear. In the late 1990s, the agency acknowledged that its advisory committee structure had flaws, its process was not always clear and understandable to outside parties, and its progress in developing policies was not easy to follow. To address these problems, the agency began developing a new coverage process. However, we found that the new national process 1) does not routinely provide for consultation with experts or allow the public to comment on draft policies, 2) is conducted without clear criteria to guide policy making and make it more understandable to interested parties, and 3) generally does not meet agency-set time frames.

CMS Developed Its New National Coverage Process to Address Concerns about Openness and Understandability

One of the first steps the agency took to make its national coverage process more open was to establish a new advisory committee. In 1993, HCFA had created the Technology Advisory Committee to provide it with expert advice concerning whether Medicare should cover specific technologies on a national basis.⁴¹ This panel included officials from HCFA, employees from other agencies within HHS, and carrier medical directors. However, under the Federal Advisory Committee Act, committees that include members who are not government employees and provide expert advice to the federal government are required to do so through open public meetings.⁴² Because the Technology Advisory Committee included carrier medical directors employed by private sector companies, the committee did not fall within the exception in the act for advisory committees made up wholly of government employees. In 1998, we found that, because meetings of the committee had been closed, the

⁴¹The Technology Advisory Committee was formed by merging two earlier advisory groups, the Physicians Panel, which HCFA established in 1980, and the Coverage/Payment Technical Advisory Group, which HCFA established in 1983.

⁴²5 U.S.C. App. 5, § 10(a) (2000).

Technology Advisory Committee was in violation of the Federal Advisory Committee Act.⁴³

To make its advisory process more open and understandable, in 1998 HCFA established a new group—MCAC. When CMS chooses to ask MCAC for assistance, MCAC conducts open, public meetings to assess the scientific and clinical evidence of the effectiveness and appropriateness of services and items, such as DME, which are covered or eligible for coverage under Medicare.⁴⁴ The committee—with up to 120 members divided into specialty panels—includes experts in a broad range of medical, scientific, and other professional disciplines, as well as consumer and industry representatives as nonvoting members. MCAC does not advise CMS as to whether Medicare should cover a service or item. Instead, it discusses medical literature, technical assessments, and other information on the clinical effectiveness of medical services and items, and advises CMS on whether there is sufficient evidence to show that a service or item leads to an appropriate health outcome. When CMS uses MCAC assistance, interested parties have access to public meetings and transcripts, which can help make CMS's final coverage policy more understandable to them.

To further enhance openness and understandability, CMS routinely publishes technical assessment reports on procedures and devices that it is considering for coverage. Technical assessment reports are written evaluations of the clinical usefulness of medical interventions, based on a systematic review of the literature and a synthesis of the data from multiple studies. In December 1999, CMS instituted an agreement with HHS's Agency for Healthcare Research and Quality to obtain, as needed, technical assessment reports. The Agency for Healthcare Research and Quality generally contracts for technical assessments to be conducted by academic or research centers that specialize in evaluating medical evidence. CMS decides, on a case-by-case basis, which issues will be

⁴³U.S. General Accounting Office, Office of the General Counsel, B-278940 (Washington, D.C.: Jan. 13, 1998).

⁴⁴The first meeting of MCAC took place in September 1999. MCAC meets on a varying schedule, depending on requests for coverage policies.

referred to MCAC, to the Agency for Healthcare Research and Quality for an outside technical assessment report, or to both.⁴⁵

CMS took other steps to make its national coverage process more open and understandable. In January 1999, the agency created a Web site that provides information on pending and final national coverage policies—including a tracking sheet that indicates the dates key actions were taken, such as referral to MCAC for a review of clinical evidence, and coverage memorandums that explain CMS’s rationale in making a particular policy.⁴⁶ In addition, in April 1999, to help the public understand its new process, the agency published a notice in the *Federal Register* outlining the procedural steps it would take in developing a national coverage policy.⁴⁷ CMS also noted that it would reconsider coverage policies based on new scientific and medical information. This has allowed individuals to challenge earlier coverage policies. Such challenges have been the most common reason for external requestors to seek a national coverage policy. In fiscal years 2000 and 2001, there were 12 external requests for CMS to review a previously adopted policy, compared to 5 external requests to create a policy for a new item or service.

National Coverage Process Not Always Open to Experts and the Public

CMS has taken significant steps to improve its policy making through its new national coverage process. Nevertheless, the national process is not always open to outside scientific experts, practicing clinicians, beneficiaries, and others. CMS does not publish its draft national coverage policies, and it does not always consult with MCAC, specialty or practicing physician groups, and other experts when developing national coverage policies.

While CMS has recently taken steps to obtain comments on national policies as they are being developed, CMS does not post draft national coverage policies on its Web site or use other means to obtain and incorporate relevant input on draft policies before making them final. Beginning in October 2001, CMS was required by law to ensure that the

⁴⁵The agency is currently developing guiding principles that will help it determine when referrals for technical assessment reports, MCAC assistance, or both should be made.

⁴⁶In December 2002, CMS launched a Medicare coverage database, which allows users to search for national coverage policies, documents related to national coverage policies, and local coverage policies. The database may be accessed at <http://www.cms.hhs.gov/coverage/>.

⁴⁷64 *Fed. Reg.* 22,619 (Apr. 27, 1999).

public is afforded notice and opportunity to comment prior to implementation of a national coverage policy.⁴⁸ CMS has not published a *Federal Register* notice revising its procedural steps to indicate how this notice and opportunity to comment will be provided. An agency official noted that the public may check on the status of national coverage policies that are being developed on the agency's Web site and may submit comments to CMS at any point in the policy development process. CMS noted on its Web site that, for each national coverage policy requested since April 2002, a 30-day comment period would occur starting from the date of the request. However, because the agency does not publish its draft national coverage policies, this comment process does not afford the public the opportunity to review them. Furthermore, the comment process does not require CMS to address in the public record any comments it has received before contractors implement the final policy.

Furthermore, CMS does not always openly consult with outside experts when developing national coverage policies. While MCAC provides a vehicle for CMS to obtain advisory opinions in an open forum, CMS has used the MCAC for less than one-sixth of its national coverage policies. CMS indicated that it calls upon the MCAC when CMS deems the evidence to be more difficult to assess or when the coverage issue is controversial or has potential to have a major impact on the Medicare program. Since MCAC was established, CMS has requested its input for 9 of the 55 completed policies on national coverage—about 16 percent.⁴⁹ When CMS chooses not to ask for MCAC's views, there is no other provision for an open public discussion. And, when MCAC is not used, it is also not clear to the public how CMS is evaluating clinical evidence until the agency publishes a coverage memorandum explaining the rationale for the final policy.

Finally, while CMS sometimes contracts with the Agency for Healthcare Research and Quality for technical assessment reports, it does not routinely obtain input from other HHS agencies that could provide

⁴⁸BIPA § 522(b) and (c), 114 Stat. 2763A-546.

⁴⁹MCAC was established on December 14, 1998. As of July 31, 2002, CMS had published 55 national coverage memorandums pertaining to requests after January 1, 1999.

expertise, such as FDA.⁵⁰ Because FDA considers evidence on safety and effectiveness before approving medical devices and drugs for marketing, routinely consulting with FDA officials who are familiar with such evidence could provide additional insight on coverage issues for CMS. However, when we began this review, FDA officials we interviewed reported little contact with CMS staff working on coverage matters. CMS officials responsible for coverage matters also reported having limited contact with FDA. However, during our review, CMS and FDA officials met to discuss how to coordinate more effectively, while allowing FDA to protect proprietary information that companies have provided to it during the course of its review.

CMS and FDA officials agreed that closer communication with FDA about its reviews of particular devices and drugs could prove beneficial to—and lack of coordination could hinder—CMS coverage policy making. For example, in October 2001, CMS announced that it intended to cover ocular photodynamic therapy, a laser procedure that requires a light-sensitive drug, for patients with a certain type of age-related macular degeneration—a disease that can cause blindness. However, FDA had not added treatment for this type of macular degeneration as a labeled use of the drug. After its October 2001 announcement, CMS developed concerns about the underlying data from the clinical trial upon which the policy was

⁵⁰ Medicare generally will not cover new medical devices or drugs, or procedures that depend on new devices or drugs, until after FDA has approved the devices and drugs for marketing. However, FDA approval does not guarantee Medicare coverage because the Medicare statute requires that services and items fit into one of Medicare's benefit categories and be reasonable and necessary for beneficiaries' care in order to be covered.

based. After reconsideration, CMS rescinded its memorandum on coverage for beneficiaries with this type of the disease.⁵¹

Recognizing the importance of having CMS work effectively with FDA, in November 2002 the HHS Secretary's Advisory Committee on Regulatory Reform⁵² issued a report that included five recommendations for improving interagency coordination, collaboration, and communication relating to new medical device technologies.⁵³ One of the recommendations was to establish a process, with input from affected stakeholders, to enable early coordination between FDA and CMS. Further, the Advisory Committee recommended that, when appropriate, FDA and CMS should have parallel reviews, thereby promoting more timely patient access to innovative therapies. Such a parallel review could have CMS consult with device manufacturers during the design of a clinical trial developed under FDA auspices, so that the clinical trial could address issues of concern for both CMS and FDA.

⁵¹Ocular photodynamic therapy is a new treatment that uses a light-sensitive drug to guide a laser. On November 8, 2000, HCFA issued a memorandum announcing its intent to cover this therapy for patients with predominantly classic lesions in the eye. In May 2001, The Vitreous Society formally requested that HCFA also cover this treatment for patients with nonclassic lesions. On October 17, 2001, CMS issued a memorandum describing its intent to cover ocular photodynamic therapy for patients with nonclassic lesions, based on the results published in a clinical trial. FDA had not approved this use of the drug as a labeled use in the procedure for patients with nonclassic lesions. Because the drug had been found to be safe and effective for patients with classic lesions, physicians could still use the drug "off-label" for patients without classic lesions. Soon after CMS issued its October 2001 memorandum indicating that it intended to cover this therapy for patients with nonclassic lesions, the agency decided to reconsider its stance. On March 28, 2002, CMS issued a new memorandum that rescinded the October 2001 memorandum on covering patients with nonclassic lesions, but maintained the coverage granted in November 2000 for those with classic lesions.

⁵²On June 8, 2001, the HHS Secretary announced a departmentwide initiative to reduce regulatory burdens in health care and respond faster to the concerns of health care providers, state and local governments, and individuals who are affected by HHS rules. As part of this initiative, HHS established the Secretary's Advisory Committee on Regulatory Reform to provide findings and recommendations regarding potential regulatory changes that would enable its programs to reduce burdens and costs associated with the department's regulations, while at the same time maintaining or enhancing effectiveness, efficiency, impact, and accessibility.

⁵³Department of Health and Human Services, *Bringing Common Sense to Health Care Regulation: Report of the Secretary's Advisory Committee on Regulatory Reform* (Nov. 21, 2001).

Lack of Clear Criteria Raises Concerns about Understandability of National Coverage Process

Critics of the national coverage process have also been concerned that the basis for CMS's policies was not understandable, and this continues to be a problem. The fundamental question in determining whether Medicare should cover a new procedure or device is whether it is "reasonable and necessary" for Medicare beneficiaries. However, the agency has not published the criteria that it uses in the national process to determine whether a service or item is reasonable and necessary, nor has it provided information that outlines the evidence needed to demonstrate that a procedure or device is clinically beneficial.⁵⁴

In May 2000, HCFA published a notice of intent to develop a regulation addressing the criteria for making coverage policies.⁵⁵ This was not the agency's first attempt to develop such a regulation. In 1989, HCFA had proposed a regulation that would better define when a service or item was "reasonable and necessary."⁵⁶ The agency tried to include cost-effectiveness as part of the criteria, but this issue generated controversy and the proposed rule was never finalized. HCFA's approach in its May 2000 notice of intent was to solicit public input before the agency began developing a proposed rule. In addition to medical benefit, this notice proposed that an item or service would be covered only if it demonstrated "added value"—which meant that it substantially improved health outcomes; provided access to a beneficial, but different treatment option (for example, treating with a covered drug instead of surgery); or could substitute for an existing item or service at an equal or lower cost to the Medicare population. Proposing the "added value" criterion led to resistance, due to concerns that the agency was planning to use cost considerations as a basis for its coverage policies. CMS has not taken further regulatory action to define what criteria it would apply to determine whether a service or item was reasonable and necessary.

In response to questions we raised about the criteria it uses in its national coverage process, CMS officials did not cite specific criteria that are used. Instead, they stated that a set of case law criteria was evolving through the national policies they had made, and suggested the criteria could be

⁵⁴In contrast to CMS, FDA has established definitions for the "safety" and "effectiveness" criteria that manufacturers must meet in order to receive FDA approval for a device. FDA has also established standards for the evidence it considers to be valid when deciding whether to approve a device for marketing. 21 C.F.R. § 860.7 (2002).

⁵⁵65 *Fed. Reg.* 31,124 (May 16, 2000).

⁵⁶54 *Fed. Reg.* 4,302 (Jan. 30, 1989).

inferred from reading the coverage memorandums on the CMS Web site. However, having beneficiaries, physicians, and device manufacturers infer criteria that may apply to coverage policies from coverage memorandums does not substitute for specifying, and making public, clear criteria. Interested parties may not be able to infer the criteria from CMS's coverage memorandums or may differ in their interpretations. In contrast, the agency has published guidance on criteria in a manual for claims administration contractors to use in developing their coverage policies. These criteria help contractors to determine when a procedure or device that fits into Medicare's benefit categories and is not excluded from coverage by statute may be covered because it is considered reasonable and necessary. (See app. V.)

In addition to not publishing the criteria for its national process, CMS has not published guidance on how it will consider evidence in making national coverage policies. Officials said that they are in the process of preparing guidance to help the public better understand the types of evidence used in making national policies. Agency officials stated that they employ an evidence-based approach in the national coverage process. Using this approach, clinical research results based on a strong methodology are given more weight than other types of evidence. The MCAC advisory input and technical assessments that CMS sometimes obtains are part of its evidence-based approach.

Issues of Timeliness Conflict with Need for Public Input

The timeliness of the agency's coverage policy making has been a long-standing issue. We reported in 1994 that, when complicated clinical issues were involved, it could take HCFA several years to develop national coverage policies.⁵⁷ Device manufacturers raised the issue of timeliness of the national coverage process again during a hearing before the House Ways and Means Committee in 1999.⁵⁸ HCFA responded to concerns about timeliness by setting time frames for developing national coverage policies in its April 1999 *Federal Register* notice about its coverage procedures. In this notice, HCFA stated that it intended to respond in writing to requesters of national coverage policies within 90 calendar days of

⁵⁷U.S. General Accounting Office, *Medicare: Technology Assessment and Medical Coverage Decisions*, [GAO/HEHS-94-195FS](#) (Washington, D.C.: July 20, 1994).

⁵⁸Medicare Coverage Decisions and Beneficiary Appeals: Hearing Before the Subcommittee on Health of the House Committee on Ways and Means, 106th Cong. 80-81 (1999) (statement of Walter M. Rosebrough, Jr., on behalf of the Health Industry Manufacturers Association).

receiving the request.⁵⁹ The agency noted that it generally expected to meet this 90-day time frame and would likely be able to respond in less time if the coverage issue was supported by clear medical and scientific evidence and was not complex or controversial. However, the notice further stated that the time frame could be longer if, for example, at a later time, the requester submitted subsequent medical and scientific information for consideration or if the coverage issue was referred to MCAC or required an outside technical assessment.

In practice, CMS has generally taken considerably longer than the 90-day goal established in 1999. Our analysis of 55 national coverage policies showed that only 10 met the 90-day goal.⁶⁰ Our analysis showed timeliness differences based on whether the coverage policy requester was an outside party or within CMS and whether the issue was referred to MCAC or for a technical assessment. Overall, the agency took an average of about 7½ months to issue a coverage memorandum for the 55 national coverage policies, with 12 taking a year or more.⁶¹ Policies responding to requests

⁵⁹64 *Fed. Reg.* 22,619, 22,622 (Apr. 27, 1999). The notice also indicated that the agency would follow the same procedures and time frames when coverage policy questions were generated internally. After this notice was issued, BIPA established a new process for beneficiaries to directly appeal coverage policies. As part of this new coverage policy appeals process, BIPA also imposed timeliness requirements on the Secretary of HHS for responding to requests from beneficiaries that he develop coverage policies for an item or service they need. Specifically, BIPA requires that one of four actions be taken within 90 days: 1) issue a national coverage policy, 2) issue a national noncoverage policy, 3) determine that no national coverage or noncoverage policy is appropriate, or 4) issue a notice stating that the review is not complete, identifying the remaining review steps to be taken, and establishing a deadline by which the review will be completed. On August 22, 2002, CMS issued proposed regulations on BIPA's new coverage policy appeals process. 67 *Fed. Reg.* 54,534.

⁶⁰We analyzed the 55 national coverage policies that were requested after January 1, 1999, and had a coverage memorandum issued by July 31, 2002. Timeliness data are based on information posted on CMS's Web site that indicates the date of request for a national coverage policy and the date the coverage memorandum was issued. Publishing the coverage memorandum is the first step to implementing the policy. It has taken up to 9 additional months after publishing a coverage memorandum for CMS to issue the national instructions that constitute the coverage policy and for the claims administration contractors to implement necessary payment changes.

⁶¹In June 2002, CMS issued a report to the Congress on 10 national coverage policies that were published and implemented in fiscal year 2001. See Department of Health and Human Services, *Report to Congress on National Coverage Determinations* (Washington, D.C.: June 2002). The report showed that the average time to implement 4 policies without a technical assessment or MCAC input was 96 days (not including 2 emergency policies related to coverage of liver transplants) and the average time to implement 4 policies that had a technical assessment or MCAC input was almost 280 days.

that were generated within the agency took longer than those that were requested by an outside party—such as a device manufacturer or a provider association. There were 28 internal requests, which took an average of about 251 days, and 27 external requests, which averaged about 188 days for CMS to issue a coverage memorandum.⁶²

Referring a coverage issue to MCAC or requesting a technical assessment report added months to the national coverage process. The agency requested technical assessments for most issues referred to MCAC to help that committee assess the evidence.⁶³ While the 39 policies that were processed without outside advice took an average of about 152 days, the 16 policies that were referred for MCAC advice, a technical assessment, or both averaged about 411 days—or over 8 months longer.

Conclusions

As a national program affecting 40 million beneficiaries, Medicare needs consistent coverage policies. Giving contractors broad discretion to make local coverage policies for procedures and devices has led to inequitable variations in coverage for beneficiaries depending on where they are treated. In addition, dividing the authority for making coverage policy among local contractors has resulted in program inefficiencies. While developing policy through a national process offers the advantages of consistency and efficiency, concerns remain about the openness and timeliness of CMS's national coverage process. Further, concerns have been expressed about the process because the agency has not published clear criteria for judging if a particular procedure or device is reasonable and necessary for Medicare beneficiaries.

We believe that a more equitable and efficient way to develop coverage policy would be to eliminate development of local policy for procedures and devices that have established codes. Instead, Medicare coverage policies should be made through a new, single process that develops consistent, national coverage policies for procedures and devices. Such a

⁶²Two of the 27 external requests had coverage memorandums dated on the same day they were formally requested. Both of these involved temporary coverage of liver transplants in nonapproved hospitals during a flooding emergency in Houston, Tex.. When these two national coverage policies were excluded from our analysis, the average time frame to issue a coverage memorandum for the remaining 25 external requests increased to about 203 days.

⁶³As of July 31, 2002, all but two national coverage policies that had been reviewed by MCAC also had technical assessments.

process could also examine current local coverage policies on procedures and devices to determine whether these policies should be consolidated into national coverage policies that would be consistent for all beneficiaries or be eliminated.

Developing a new national coverage process would require careful design and implementation. The new process should address areas of long-standing concern about openness, timeliness, and clarity of policy making. Key aspects of a new process would include routinely consulting with the public, clinicians, and other experts before finalizing coverage policies; leveraging the expertise of others within HHS, such as those within FDA; and closely adhering to established time frames to improve timeliness of policy issuance. We also believe that CMS needs to develop clear criteria for its national process to make its coverage policies more understandable to others.

Recommendations for Executive Action

To ensure that all Medicare beneficiaries are treated equitably, we recommend that the Administrator of CMS

- eliminate the ability of claims administration contractors to develop new coverage policies for procedures and devices that have established codes;
- develop and implement a plan to evaluate the merits of all existing local coverage policies that affect procedures and devices with established codes, with the intent of incorporating appropriate aspects of local policies into national coverage policies and eliminating the remainder;
- establish a new process for making national coverage policies that requires public input on draft policies, adheres to time frames, and provides for routine consultation with key HHS and external stakeholders with scientific, clinical, and programmatic expertise; and
- promulgate written criteria for assessing whether a service or item is reasonable and necessary.

Agency Comments and Our Evaluation

In its written comments, HHS generally disagreed with our recommendations and stated that our draft report did not provide an adequate analytic basis for our recommendations. (See app. VI for HHS's comments.) Specifically, HHS said that we did not demonstrate how developing coverage policy nationally would eliminate inequities related to differing coverage in different parts of the country and did not fully explore the weakness of developing consistent national policy for procedures and devices with established codes or the benefits of developing differing local policies.

Our report's findings and recommendations are based on considerable analytic work. For example, as we noted in our draft report, we assessed national and local policies that related to procedures and devices assigned 320 new codes in 2001; conducted site visits to four Medicare contractors that provided a basis for our analysis of the processes they followed to develop policy and the policies they chose to develop; analyzed the timeliness and process followed to develop 55 national coverage policies; and conducted numerous interviews with, and analyzed documents provided by, CMS and FDA officials, carrier medical directors, experts on evidence-based medicine, and representatives of beneficiaries, physicians, and device manufacturers and suppliers. We believe that the evidence demonstrates that allowing coverage policies to be developed by different contractors leads to differing policies and inconsistent coverage for beneficiaries. Such inequities would be addressed by developing all policies nationally for procedures and devices with established codes. The draft report acknowledges both the weaknesses in the current national process and the strengths of the local processes.

In its comments on our specific recommendations, HHS disagreed with our first recommendation—that CMS eliminate claims administration contractors' ability to develop new coverage policies for procedures and devices that have established codes. The department argued that developing consistent policy nationally for procedures and devices with established codes would drastically alter the intended design of the Medicare program as a regionalized program, remove the Secretary's discretion to make coverage policies, and prevent Medicare from testing new, experimental treatments before enough clinical evidence is available to warrant national coverage. HHS also stated that CMS did not have the resources to develop sufficient national policies, so that the recommendation would increase Medicare payments in future years because contractors would not be able to prevent overuse of certain services and items.

In our opinion, developing consistent coverage policies nationally for procedures and devices with established codes would help modernize Medicare and is an appropriate role for CMS. As our draft report indicates, Medicare has already evolved into a program with a decreasing number of contractors who often serve multiple states and develop policies that are not specific to one locality's needs. Implementing our first recommendation would not remove the Secretary's discretion over coverage policies, although it would require greater commitment to fulfilling this responsibility. Following implementation of our recommendation, contractors would still be able to develop local policies

for new procedures and devices entering the market and billed under miscellaneous codes. These coverage policies would allow for experimentation and could provide a basis for national policy making once the procedures or devices have codes assigned.

Removing the inefficient, duplicative policy making currently conducted by 19 carriers and 27 fiscal intermediaries could allow CMS to focus the \$19.5 million allocated to local policy development and additional funds allocated to national policy development to achieve a more strategic approach to coverage policy. In addition, because similar types of improper or abusive billing practices may be taking place in several localities or may migrate from one locality to another, having consistent national coverage policies to prevent improper billing or overuse of services could result in program savings. It is also more equitable for both providers and beneficiaries. Contractors that have concerns about specific utilization problems would still have the opportunity to propose new policies to be adopted nationally. Such national policies would benefit other contractors that may experience similar utilization problems.

Regarding our second recommendation—which calls for CMS to develop and implement a plan to evaluate existing local coverage policies, with the intent of incorporating aspects of them into national policies or retiring them—HHS agreed that local coverage policies should be evaluated on a regular basis. It noted that CMS currently requires its contractors to separately evaluate their own policies. However, HHS did not respond to the intent of our recommendation, namely that one entity should review all policies for each procedure and device so that the best policy can be developed nationwide.

HHS disagreed with our third recommendation, that CMS develop a new process for making national coverage policies. The department indicated that, instead, a *Federal Register* notice will soon be published that incorporates process improvements and steps that have already been taken to streamline the MCAC process. HHS also indicated that it routinely communicates with FDA on coverage matters and has extensive contacts with experts at the National Institutes of Health.

As we recognized in our draft report, CMS has made improvements in its current national process. Because information on its newest planned process improvements has not been published, we cannot comment on whether these changes will fully address long-standing concerns about the openness, understandability, and timeliness of its policy making. CMS has made progress by streamlining the MCAC decision process and is working

to improve its coordination with FDA. We believe that communication with FDA should be an integral part of the development of each Medicare coverage policy that involves drugs and devices, or procedures that rely on drugs and devices.

HHS disagreed with our fourth recommendation, which would require CMS to publish written criteria it would use to assess whether a service or item is reasonable and necessary. The department said it relies on publishing the rationale for each coverage policy: that is, it uses a case law approach and does not presently plan to engage in rule making on this subject. HHS is considering other options that might be helpful, but is not planning to issue guidance that would serve as written criteria. As a national program of great significance, we believe Medicare should be transparent in the criteria it uses for interpreting whether a service or item is reasonable and necessary and can be covered.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of HHS, the Administrators of CMS and FDA, appropriate congressional committees, and other interested parties. We will also make copies available to others on request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please call me at (312) 220-7600 or Sheila K. Avruch at (202) 512-7277. Other key contributors to this report are listed in appendix VII.

Sincerely yours,



Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues

Appendix I: Scope and Methodology

To assess the extent that new procedures and devices are incorporated into the Medicare program, we analyzed new Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) Level II codes from the HCPCS tape sent to contractors in October 2000. This tape included the codes adopted by the American Medical Association's CPT Editorial Panel and the codes adopted by the HCPCS National Panel. Most of these new codes became effective on January 1, 2001. We selected the codes that represented procedures and devices used in a physician's or allied health professional's office, or by beneficiaries in the home, as well as anesthesia and laboratory services. We excluded codes that represented drugs, blood work, ambulance-related services, and devices used only in the inpatient hospital setting. We did not include codes added to identify items to which special Medicare hospital outpatient payment rates apply or codes that the Panel had adopted for other insurers, but not Medicare. We also did not analyze the extent to which Medicare covered new procedures and devices that were not assigned new codes in 2001. For the list of 320 codes in our scope, we reviewed the coverage status the Centers for Medicare & Medicaid Services (CMS) had given to each code, and we determined whether either national or local coverage policies existed in 2002 for these codes. As part of our research on local policies, we assessed coverage policies by carrier and fiscal intermediary. We analyzed payment data from the Medicare part B extract and summary system for the new codes. To determine the percentage of Medicare part B payments billed under miscellaneous codes, we also analyzed payment data from the Medicare part B extract and summary system for HCPCS Level I and II miscellaneous codes and all HCPCS codes billed.

To determine the effect of the local coverage process on beneficiaries, carrier and fiscal intermediary efficiency, and stakeholders, including device manufacturers and physicians, we interviewed key CMS officials and staff and reviewed documents. We conducted site visits at four carriers: Blue Cross Blue Shield of Rhode Island, CIGNA HealthCare Medicare Administration, National Heritage Insurance Company, and Noridian Administrative Services. CIGNA also serves as a durable medical equipment (DME) regional carrier and Blue Cross Blue Shield of Rhode Island also serves as a fiscal intermediary. We chose these carriers in order to include both multistate and single-state carriers and to include one carrier that was also a DME regional carrier and one that was also a fiscal intermediary. At these site visits, we used a structured protocol to interview contractor medical directors and other staff to assess their local policy development processes and to document policies developed in fiscal years 2000 and 2001. We also analyzed data on local coverage

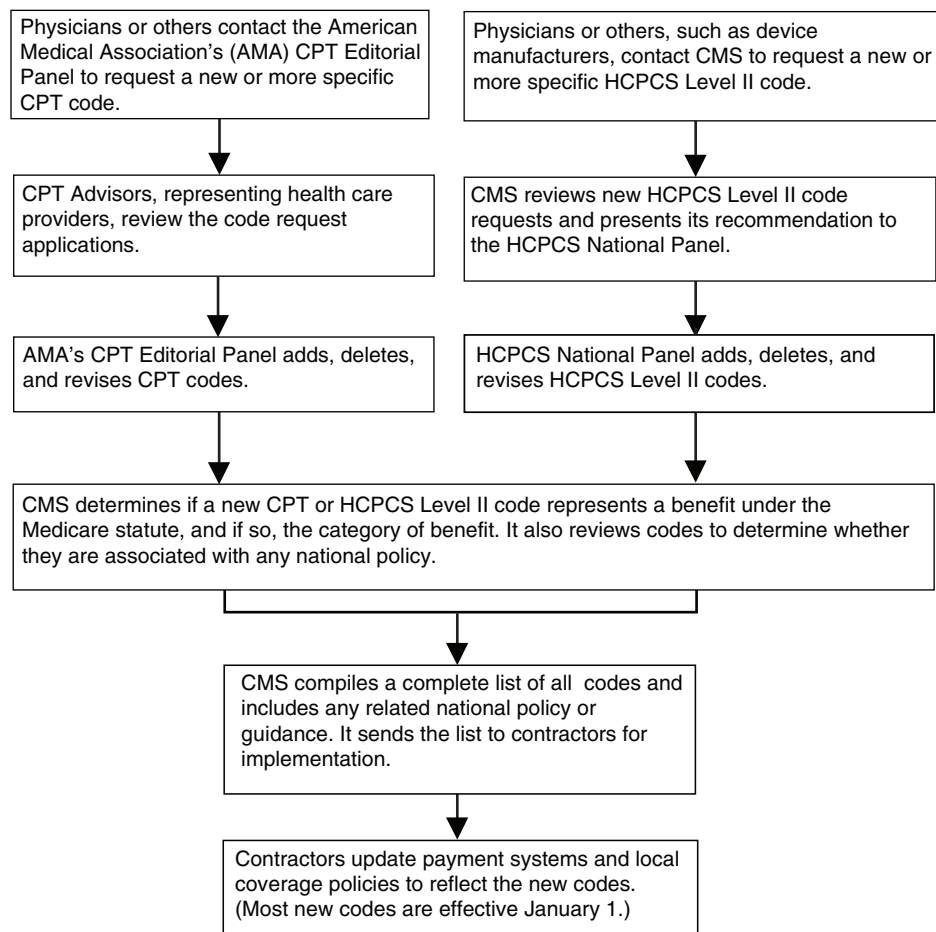
policies on LMRP.net, a CMS-sponsored Web site listing local policies by carrier, DME regional carrier, and fiscal intermediary, and surveyed carrier medical directors to determine whether deep brain stimulation, a surgical procedure to treat tremors associated with Parkinson's disease, was covered under part B for physicians' services in each state. This procedure was selected for study due to variation in its coverage at the time we did our work.

To evaluate the effects of the national coverage process on beneficiaries and other stakeholders and to identify concerns about it, we analyzed the national process in terms of its steps, time frames, criteria and evidence used, coordination with claims administration contractors, and coordination with the Food and Drug Administration (FDA) approval processes. We interviewed experts on evidence-based medicine, CMS and FDA officials, Medicare Coverage Advisory Committee (MCAC) executive committee members and MCAC panel members, and representatives of beneficiaries, physicians, and device manufacturers and suppliers, including the Center for Medicare Advocacy, AdvaMed, the AARP Foundation, the Medical Group Management Association, the National Institute for Health Care Management, the American College of Physicians-American Society of Internal Medicine, the American College of Cardiology, the American College of Chest Physicians, the Marshfield Clinic, and the American Academy of Family Physicians. We obtained their views on issues related to the national coverage process, such as the effectiveness of the national process and the implications of the process for beneficiaries and others. We also observed meetings of the MCAC executive committee, the MCAC medical and surgical procedures panel, and the MCAC diagnostic imaging panel, to understand their roles in the coverage policy-making process, and reviewed MCAC minutes from selected meetings held in 1999 through 2002, as well as selected meeting transcripts. We analyzed 55 national coverage policies, which were requested by external requestors or internally by CMS after January 1, 1999, and had a CMS coverage memorandum issued by July 31, 2002, in order to determine the amount of time needed and the process used to make each policy. We also analyzed the support and rationale used to make some of these policies.

Appendix II: Coding Assignment Process

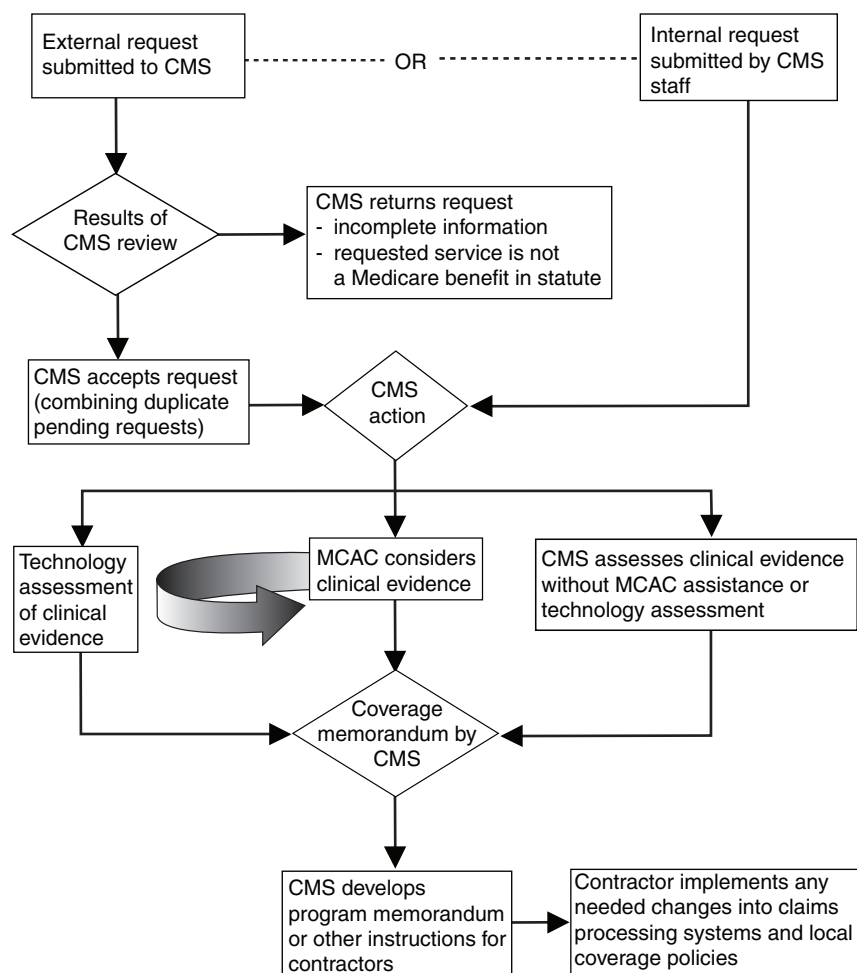
Figure 2 shows the steps that occur for codes to be added for use in the Medicare program. Common Procedure Terminology (CPT) codes are used for medical services and procedures furnished by physicians and other health care professionals and Healthcare Common Procedure Coding System (HCPCS) Level II codes are used for other services, products, and supplies. When new codes are added, old codes may need to be deleted or revised so that the use of each code is clear.

Figure 2: Process for Adding, Deleting, and Revising CPT and HCPCS Level II Codes for Use in the Medicare Program



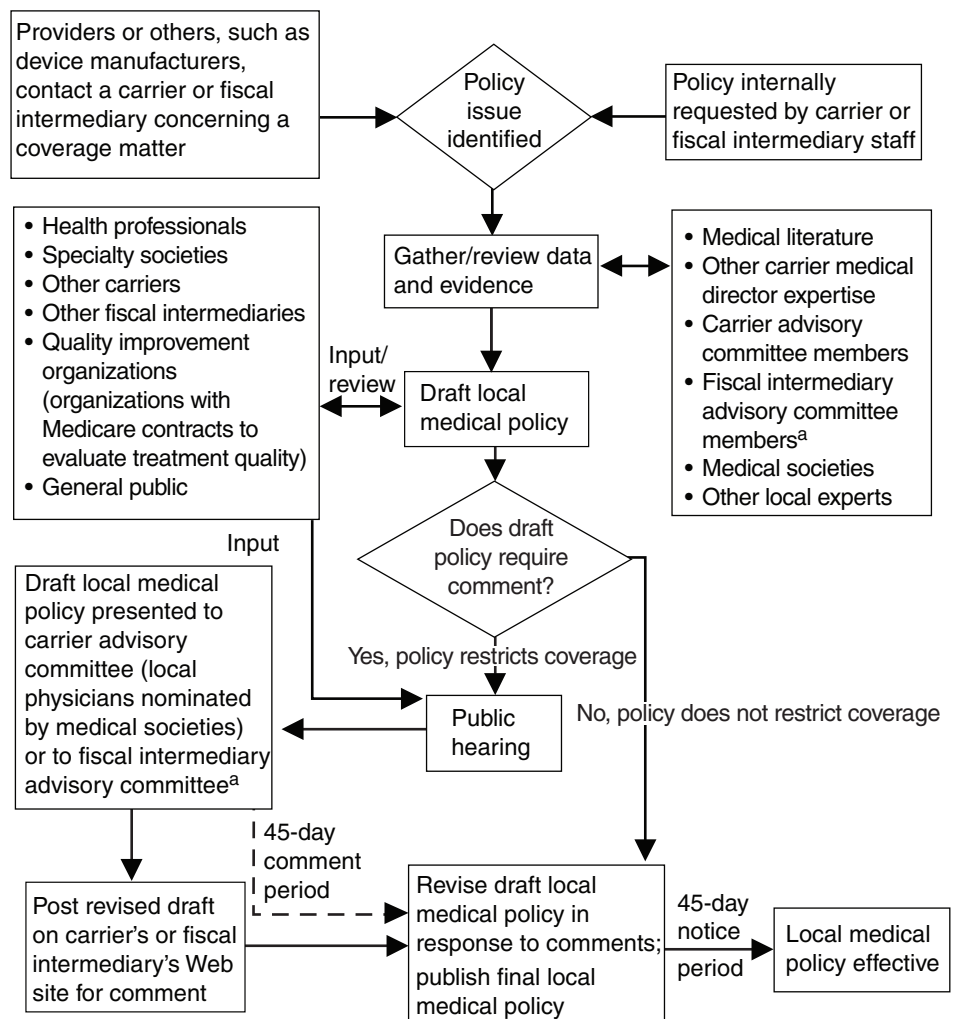
Source: GAO.

Appendix III: Process That CMS Follows to Develop National Coverage Policies



Source: GAO.

Appendix IV: Process That Carriers and Fiscal Intermediaries Follow to Develop Local Coverage Policies



Source: GAO.

^aFiscal intermediaries may have advisory committees, but CMS does not require them to do so.

Appendix V: Coverage Criteria for Medicare Claims Administration Contractors

Figure 3 shows the coverage criteria published for Medicare claims administration contractors to help them determine whether a procedure or device is reasonable and necessary. Criteria focus on whether services are appropriate and clinically beneficial. Contractor guidance also describes the different types of evidence that are used to determine whether a procedure is reasonable and necessary and an assessment of the relative quality of different types of evidence.

Figure 3: Criteria for Claims Administration Contractors to Use to Determine Whether a Procedure or Device Is Reasonable and Necessary

As long as a procedure or device fits into Medicare's benefit categories and is not excluded from coverage, it would be considered reasonable and necessary if it is:

- safe and effective;
- not experimental or investigational—with certain exceptions;^a
- appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
 - furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member—or, for certain specified services, to prevent or screen for illness or to palliate or manage terminal illness;
 - furnished in a setting appropriate to the patient's medical needs and condition;
 - ordered or furnished by qualified personnel;
 - one that meets, but does not exceed, the patient's medical need; and
 - at least as beneficial as an existing and available medically appropriate alternative.

Source: GAO.

^aServices provided in routine clinical trials on or after September 19, 2000, and which meet the requirements of the Clinical Trials National Coverage Determination are considered reasonable and necessary. See *Medicare Coverage Issues Manual, 30-1, Routine Costs of Clinical Trials* (Sept. 19, 2000).

Appendix VI: Comments from the Department of Health and Human Services

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Office of Inspector General
		Washington, D.C. 20201
Ms. Leslie G. Aronovitz Director, Health Care – Program Administration and Integrity Issues United States General Accounting Office Washington, D.C. 20548	MAR 24 2003	
Dear Ms. Aronovitz:		
Enclosed are the department's comments on your draft report entitled, "Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities." The comments represent the tentative position of the department and are subject to reevaluation when the final version of this report is received.		
The department appreciates the opportunity to comment on this draft report before its publication.		
	Sincerely,	
		
	Dennis J. Duquette Acting Principal Deputy Inspector General	
Enclosure		
The Office of Inspector General (OIG) is transmitting the department's response to this draft report in our capacity as the department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.		

Comments of the Department of Health and Human Services on the General Accounting Office's (GAO) Draft Report, "MEDICARE: Divided Authority for Policies on Coverage of Procedures and Devices Results in Inequities" (GAO-03-175)

The Department of Health and Human Services (department) appreciates the opportunity to comment on this draft report.

This report responds to a request from the Chairman of the Subcommittee on Health, House Committee on Ways and Means. The GAO was asked to review the extent to which new procedures and devices are incorporated into Medicare, the effect of Medicare coverage policy-making processes on beneficiaries, and the degree to which the Centers for Medicare and Medicaid Services (CMS) has addressed concerns about its national coverage process.

Medicare is committed to having an open, understandable and predictable coverage process for benefits provided by the program. Medicare law provides for broad coverage of many medical and health care services, including care provided by hospitals, skilled-nursing facilities, home-health agencies and physicians. The law does not provide an all-inclusive list of services covered by Medicare and generally does not specify which medical devices, surgical procedures, or diagnostic services should be included or excluded from coverage. The Congress gave the Secretary of the Department of Health and Human Services the authority to decide which specific items and services Medicare can cover within these categories. The law states that Medicare cannot pay for any items or services that are not "reasonable and necessary" for the diagnosis and treatment of illness or injury. For more than 30 years, the Medicare program has exercised this authority to determine whether specific services that meet one of the broadly defined benefit categories are covered under the program. Most Medicare coverage and policy decisions are made locally by Medicare contractors -- the private companies that by law process and pay Medicare claims. The CMS also has authority to make coverage policies that apply nationwide. In the absence of national decisions for particular services, contractors have discretion to issue local Medicare coverage policies.

It is worth noting that the Medicare structure of coverage decisions at both the national and local level is not unique. Within the Federal Employees Health Benefits Program, in the Blue Cross and Blue Shield Service Benefit Plan (Plan), the Blue Cross Blue Shield Association's Technology Evaluation Center uses evidence based on technology to make national policy determinations on treatments or tests as to experimental/investigational and medical necessity. Absent such a determination, coverage may be adjudicated to reflect an individual Plan's local policy.

General Comments

The GAO draft report does not provide an adequate analytic basis for the recommendations it proposes. It advocates developing a centralized national coverage policy without fully exploring the weaknesses of such an approach or recognizing possible benefits of the local coverage process. While GAO properly emphasizes the importance of consistent and equitable coverage for all beneficiaries, it does not demonstrate how a centralized national coverage policy will eliminate alleged inequities or link current inequities to the local coverage process. Moreover, the GAO report does not consider inequities that might arise in a centralized, national system and only briefly acknowledges some of the benefits to Medicare beneficiaries inherent in a coverage system with both local and national decision-making. In summary, the report does not adequately address and justify how establishment of a new, centralized process for making national coverage policies would result in more timely and equitable coverage decisions than continued evaluation and implementation of on-going improvements to the process currently in place. The report also does not note the enormous resource implications of such a centralized process.

Although the department is highly respectful of GAO's work in this case, we feel strongly that GAO is incorrect, and that these changes would lead to a far more cumbersome and unwieldy Medicare program for beneficiaries, providers and suppliers. The department is anxious to debate this before Congress and will strongly work to discourage these changes.

With regard to GAO's specific recommendations:

GAO Recommendation for Executive Action

The GAO recommends that the Administrator of CMS eliminate the ability of claims administration contractors to develop new coverage policies for procedures and devices that have established codes.

Department Response

The department disagrees with this recommendation. It is important to note that Medicare was designed as a regionalized program that could accommodate local variations in treatment, utilization of care, and the needs of unique beneficiary populations. The GAO's recommendations would drastically alter the intended design of the program.

A system based on the GAO's recommendations would, in essence, remove the discretion for coverage determinations granted to the Secretary by Congress in section 1861(a)(1)(A) of the Social Security Act. It de facto delegates the CMS coverage process to the American Medical Association Current Procedural Technology (CPT) Editorial Panel because the volume of codes would prevent CMS from making coverage decisions on most items or services. There are 200 new CPT codes added every year and 8,000

existing codes. If contractors (including Durable Medical Equipment Regional Carriers) cannot make coverage decisions for established codes, then the only coverage policy will be National Coverage Decisions (NCDs). The CMS does not have the resources to make more than 20-30 NCDs per year. Therefore, if Congress accepted this recommendation, we would be making unrestricted payment nationally for every new procedure regardless of whether it is medically reasonable and necessary; or indeed, safe for the Medicare population. This would be a very shortsighted result.

Although the report does describe some of the advantages of having local coverage policies (namely, that the process is faster and more open to comment from providers and manufacturers), it does not mention that allowing contractors to develop local coverage policies gives Medicare the opportunity to test new, experimental treatments before enough clinical evidence is available to warrant national coverage.

In addition, there are Healthcare Common Procedure Coding System (HCPCS) level 2 codes that we specifically create in order to allow payment but not to imply coverage. Providing these level 2 codes allow us to be responsive to new technology but not to waive our right to make coverage decisions. It may be more difficult to grant these level 2 codes for new technology without the ability for our contractors to restrict coverage in those instances where evidence shows a new technology is not reasonable and necessary.

The implications of the elimination of local coverage decisions for total program expenditures would be significant. There would be significant distributional effects between services within payment systems (e.g., outpatient prospective payment system, physician fee schedule) due to unrestricted payment for certain services. There would also be increased aggregate payments for certain items and services (e.g., drugs, durable medical equipment). We specifically note that there is significant potential for aggregate payments under the physician fee schedule to increase thereby causing negative updates in future years to adjust for the additional payments. In addition, because all other payment systems (e.g., inpatient/outpatient prospective payment system) do not have a volume adjustment, total Medicare spending would also increase significantly.

We believe that the local medical review policies (LMRPs), developed by Medicare contractors allow for timely, accurate, and effective regional reaction to changes in the practice of medicine. By allowing contractors the discretion to develop LMRPs, the Medicare program is afforded flexibility to address needs that are not national in scope. This flexibility would be lost if all policy development were centralized nationally.

The LMRPs also allow contractors to quickly react to localized utilization variances. Often, abusive billing manifests itself differently in different geographic regions. An item or service abused in one region may be ordered appropriately in another region. The LMRPs allow the contractor in the affected area to develop policy to address the abusive billing while other providers remain unaffected.

Additionally, LMRPs are often used to provide additional educational guidance to the provider community. Without the LMRP process, it would not be possible to consider the unique needs of local providers and beneficiaries.

Finally, elimination of local coverage decisions would have a negative impact on the timeliness of claims processing. If a national policy process, such as that proposed by GAO, failed to result in a substantial number of policies (either coverage or non-coverage), contractors would need to individually review every claim for every service. This added workload would delay the decision-making process. As the report noted, the ability to automate coverage and non-coverage decisions significantly improved contractors' ability to process claims within statutorily defined timeframes. On all accounts, this change would stifle Medicare's responsiveness to our beneficiaries.

Recommendation for Executive Action

The GAO recommends that the Administrator of CMS develop and implement a plan to evaluate the merits of all existing local coverage policies that affect procedures and devices with established codes, with the intent of incorporating appropriate aspects of local policies into national coverage policies and eliminating the remainder.

Department Response

The department agrees that LMRPs should be evaluated on a regular basis, and that greater consistency among LMRPs should be fostered. The CMS is aggressively pursuing these through far more contractor and contractor medical officer coordination. Currently, all contractors are required to review all LMRPs at least annually to identify those policies that are obsolete, those that would benefit from nationalization, and those that would require revision.

Recommendation for Executive Action

The GAO recommends that the Administrator of CMS establish a new process for making national coverage policies that requires public input on draft policies, adheres to timeframes, and provides for routine consultation with key HHS and external stakeholders with scientific, clinical, and programmatic expertise.

Department Response

The department disagrees with this recommendation. We are sensitive to GAO's observations and acknowledge the benefits of timely policy making with input from both public and private sector stakeholders. We have made significant strides in these areas (as GAO notes) through implementation of the national coverage determination process announced in the April 17, 1999, *Federal Register*. In order to increase the opportunities for public participation in making national coverage determinations and to streamline the decision-making process, continued enhancement to the current process is warranted rather than establishment of a new process as GAO recommends. Such enhancements are

on the threshold of implementation in a soon-to-be published *Federal Register* Notice incorporating process improvements. Also, a recent change to the Charter of the Medicare Coverage Advisory Committee (MCAC) will further streamline the process by virtue of eliminating the need for Executive Committee ratification of MCAC panel recommendations. This single change alone will save an average of 2-3 months from the national coverage determination process when MCAC consultation is invoked. We believe the CMS process has improved substantially in the past two years. The process is more open and transparent. Most of these “changes” seek to benefit manufacturers who already aggressively approach the agency – not patients. The process serves patients well, and exposing the agency to even more structured pressure from special interests will be counter productive.

Finally, we routinely communicate with the Food and Drug Administration on coverage matters and are working to improving coordination. We also have extensive contacts with experts in the National Institutes of Health.

Recommendation for Executive Action

The GAO recommends that the Administrator of CMS promulgate written criteria for assessing whether a service or item is reasonable and necessary.

Department Response

The department disagrees with this recommendation. The CMS does not presently plan to engage in rulemaking on this subject. As GAO notes, we currently publish the rationale for each National Coverage Determination on our Web site. This practice yields a “case law” type approach to helping stakeholders understand how CMS applies “reasonable and necessary” in specific clinical instances. We are examining other options that may help stakeholders understand this topic, and our process, but have no plans to issue any other specific document or guidance at this time.

Appendix VII: GAO Contact and Staff Acknowledgments

GAO Contact

Sheila K. Avruch, (202) 512-7277

Acknowledgments

The following staff members made important contributions to this work: Barrett Bader, Sandra Gove, Karen Kemper, Joy Kraybill, and Craig Winslow.

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