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Fact Sheet for the Subcommittee on  
Technology, Environment and Aviation,  
Committee on Science, Space, and  
Technology, House of Representatives

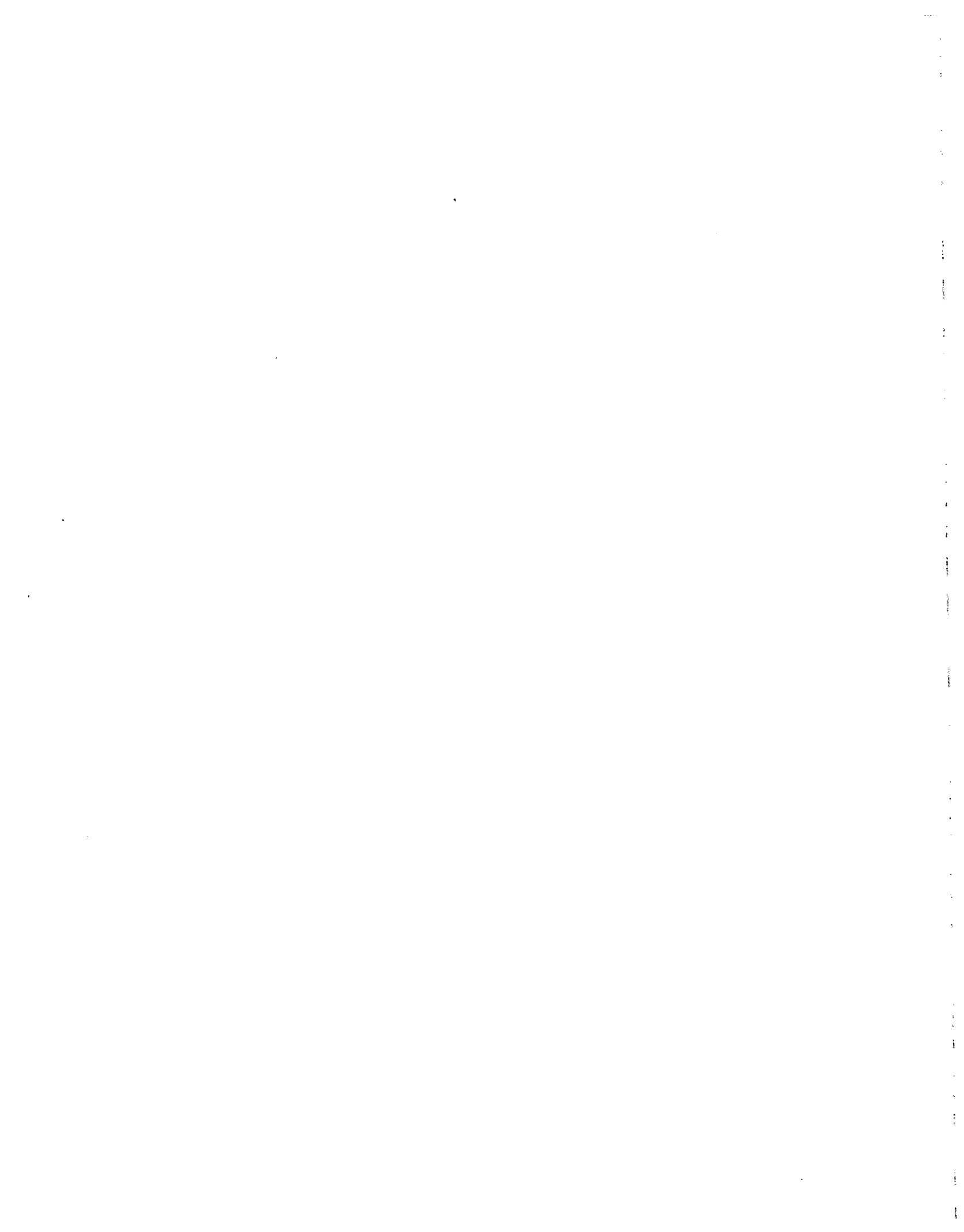
July 1994

# MEDICARE

## Technology Assessment and Medical Coverage Decisions



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United States  
General Accounting Office  
Washington, D.C. 20548

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Health, Education and Human Services Division

B-255636

July 20, 1994

The Honorable Tim Valentine  
Chairman

The Honorable Tom Lewis  
Ranking Minority Member  
Subcommittee on Technology, Environment and Aviation  
Committee on Science, Space, and Technology  
House of Representatives

Literally thousands of medical procedures, devices, and drugs are available for patient care in this country. Each year, public and private health care insurers make coverage decisions for these medical technologies. To make these decisions, insurers increasingly rely on formal technology assessments, which evaluate a technology's safety and effectiveness. Without these assessments, insurers may be more likely to pay for devices and procedures that are not effective and could harm patients.

Insurers and other private-sector organizations, such as the American Medical Association, conduct their own technology assessments. In the public sector, the Health Care Financing Administration (HCFA), which administers the Medicare program, makes a few national coverage decisions annually for medical technologies it believes greatly concern Medicare beneficiaries. For medical technology assessments used to make these national decisions, HCFA has historically relied almost exclusively on the Office of Health Technology Assessment (OHTA), a small organization in the Public Health Service's Agency for Health Care Policy and Research (AHCPR).<sup>1</sup> On the basis primarily of HCFA requests, OHTA formally assesses the safety and effectiveness of between one and nine health care technologies each year and forwards a recommendation on coverage to HCFA.

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<sup>1</sup>The Food and Drug Administration (FDA) also evaluates the safety and effectiveness of new technologies, specifically drugs and devices; however, it does not evaluate new medical procedures.

Most Medicare coverage decisions are, in fact, made by 79 contractors that HCFA hires to process claims.<sup>2</sup> Historically, contractors have played a significant role in making Medicare coverage decisions in order to promote collaboration with the local medical community. The process these contractors use to assess technology and to make coverage decisions is much less structured than the process OHTA uses to conduct formal technology assessments.

This fact sheet responds to your request that we provide general information about AHCPR's technology assessment resources and activities, HCFA's resources and process for making Medicare coverage decisions, and HCFA's process for making hospital payments that account for the use of new technologies.

In summary, AHCPR has few resources for its technology assessment activities. With five professional staff devoted to this activity, it is responsible for responding to HCFA requests for technology assessments on issues of national concern to Medicare. This staffing level has allowed, on average, fewer than 10 technology assessments per year, with about 60 percent of AHCPR's technology assessment activities devoted to HCFA requests. Recent legislation changing AHCPR's priorities for technology assessments may mean fewer assessments for HCFA than in the past.

HCFA makes few national coverage decisions each year and does not devote substantial resources to technology assessments. For example, between October 1992 and February 1994, HCFA published five national coverage decisions, three of which were based on OHTA technology assessments. In the absence of national coverage decisions, HCFA relies on its claims processing contractors to make coverage decisions for their local areas. In making these local coverage decisions, some contractors develop their own criteria and processes. Some use criteria developed by national insurers; others do not use any formal criteria. Some create internal committees to

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<sup>2</sup>Some contractors process claims for the Medicare Part A program, which includes hospital and nursing home services, while others process claims for the Medicare Part B program, which includes physician and hospital outpatient services. When not otherwise indicated, "contractors" refers to both Part A and Part B contractors.

perform technology assessments, although others have a more informal process.

Concerning hospital payments, HCFA has several methods to adjust payment rates to account for changes in technology. First, all hospital payments receive an equal annual adjustment to account for a number of factors, including the overall effect of new technology. Second, HCFA annually revises payment rates for hospital procedures to account for the specific effects of new technologies on individual procedures. Third, HCFA makes separate payments to hospitals for capital-related costs, including those associated with new technology.

We did our work between March 1994 and July 1994 in accordance with generally accepted government auditing standards. We reviewed HCFA's regulations and policies on coverage decisions; discussed them with officials from HCFA, OHTA, and Medicare contractors; and reviewed documentation they provided. We visited two Medicare contractors to examine how they assess new technologies and make coverage decisions. In addition, we reviewed reports on technology assessment activities from several private organizations and studies on Medicare contractor assessment activities from the Office of the Inspector General for the Department of Health and Human Services (HHS). As agreed with your staff, we did not collect information on industry perceptions of these issues because of time constraints and because you already had access to this information through other resources.

We discussed the results of our work with responsible HCFA and OHTA program officials and have incorporated their comments where appropriate.

We are sending copies of this fact sheet to the Secretary of HHS and the Administrator of HCFA; the Director, Office of Management and Budget; and interested congressional committees. Copies will also be made available to others upon request.

B-255636

Please call me at (202) 512-7104 if you or your staff have any questions. Other major contributors to this fact sheet include Edwin P. Stropko, Assistant Director, (202) 512-7108, Joan Mahagan, John Ficociello, Michelle St. Pierre, and Donald Walthall.

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## ABBREVIATIONS

AHCPR	Agency for Health Care Policy and Research
CHAMPUS	Civilian Health and Medical Program of the Uniformed Services
	Services
DOD	Department of Defense
DRG	Diagnostic Related Group
FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
OHTA	Office of Health Technology Assessment
PPS	prospective payment system
PropAC	Prospective Payment Assessment Commission

## SECTION 1

### MEDICARE COVERAGE DECISIONS

**How and when does HCFA decide to cover technologies, and what resources does it devote annually to making national coverage decisions?**

HCFA makes relatively few national coverage decisions each year; it devotes few resources to this activity. Instead, HCFA uses a highly decentralized process whereby 79 Medicare claims processing contractors make individual decisions.

The basic criteria for making both national and local Medicare coverage decisions appears in the legislation that created the Medicare program. The legislation prohibits Medicare payment for services that are not reasonable and necessary for diagnosing or treating a medical condition. Historically, HCFA has interpreted this provision to exclude from Medicare coverage medical services and devices that have not been demonstrated to be safe and effective by acceptable clinical evidence or that have not been generally accepted in the medical community as safe and effective.

#### HCFA Makes Few National Coverage Decisions

HCFA makes relatively few coverage decisions each year applicable to all Medicare beneficiaries. Historically, HCFA has relied on OHTA's assessments as the basis for many of its national coverage decisions. For example, between October 1992 and February 1994, HCFA published five national coverage decisions: three were based on OHTA assessments, one recommending coverage, one recommending denial of coverage, and one recommending withdrawal of existing coverage.

HCFA's Bureau of Policy Development makes national coverage determinations for medical services. The bureau has approximately 20 professional staff who work on coverage determination issues for medical services, but most do not work full time on these tasks. (Other divisions in the bureau work on coverage issues relating to specific medical settings, such as skilled nursing homes.) Provided that a technology is not statutorily barred from coverage, HCFA considers several factors when deciding on the need for a national coverage decision, including the potential expense to the Medicare program, the potential for widespread use in medical practice, the level of disagreement about the technology's safety and effectiveness, and the variation among contractor coverage decisions.

Officials told us that HCFA collects information from many sources when considering national coverage decisions, including physicians, suppliers, and manufacturing groups, as well as its contractors. A major source of input is HCFA's Technology Advisory Committee,



which studies national issues and makes recommendations for national coverage decisions. The 26-member Committee meets for 1-1/2 days every quarter. Half of the Committee members are HCFA physicians and other officials; the remainder are contractor medical directors (7) and officials from the National Institutes of Health, the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), the Blue Cross and Blue Shield Association, FDA, and OHTA. The Committee discusses a number of new technologies each year and distributes meeting minutes to contractors even when no national coverage recommendation is made.

According to HCFA officials, developing and finalizing national coverage decisions can be time consuming. Decisions involving simple issues or expansion of existing coverage can be developed and implemented in 2 to 12 months. When complicated clinical issues are involved, however, the information needed to make coverage decisions can take several years to develop. Further, once HCFA decides to establish a new type of coverage or to withdraw existing coverage, it publishes a proposed rule in the Federal Register, reviews and incorporates public comments, and then publishes a final notice. This can add another 9 to 12 months to the process. It took HCFA 4 to 5 years to decide to cover liver transplants and more than 10 years to withdraw coverage for thermography, a diagnostic technique that measures temperature variation on the body's surface.<sup>1</sup>

Currently, HCFA is seeking to broaden its access to technology assessments beyond OHTA. HCFA would like to better use the medical expertise of its Technology Advisory Committee and is encouraging the Committee to conduct its own uncomplicated technology assessments. In addition, HCFA has \$50,000 for external technology assessments budgeted for fiscal year 1994 but has not yet awarded any contracts for this purpose.

### Contractors Make Most Medicare Coverage Decisions

HCFA relies on its contractors to make most coverage decisions for the Medicare program. In the absence of national coverage decisions, for example, individual Medicare Part B contractors review technologies themselves and make their own local coverage decisions. Each of the 32 Part B contractors is required to have the equivalent of a full-time medical director who is responsible for making these decisions with the contractor's medical staff and consultants. In addition, HCFA requires that representatives from the local provider community review all proposed local medical policies.

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<sup>1</sup>The decision on thermography was delayed several times to review and respond to additional information submitted by interested parties.

In making local coverage decisions, each Part B contractor develops its own criteria and process. Some Part B contractors use criteria developed by the national Blue Cross/Blue Shield Association;<sup>2</sup> others do not use any formal criteria. Part B contractors sometimes create internal committees to conduct technology assessments, although others have a more informal process. The Part B contractor medical directors we spoke with consulted medical literature and local medical specialty societies in making their coverage decisions.

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<sup>2</sup>To be approved for Blue Cross/Blue Shield coverage, technologies must (1) have all necessary regulatory approvals, (2) have scientific evidence that permits conclusions about their effects, (3) improve the net health outcome, (4) be as beneficial as any established alternatives, and (5) be proven effective outside investigational settings.

## SECTION 2

### OHTA TECHNOLOGY ASSESSMENT ACTIVITIES

**For whom does OHTA conduct technology assessments? How are they conducted? How long do they take? What resources are used? What have they recommended? Could outside vendors perform them more efficiently?**

OHTA, with five professional staff, is responsible for responding to HCFA's requests for technology assessments on issues of national concern to Medicare. On average, this staffing level has allowed OHTA to evaluate fewer than 10 technologies per year. About 60 percent of OHTA's work has traditionally been devoted to Medicare requests; however, 1992 legislation changed the way OHTA will prioritize the technologies it assesses.<sup>1</sup> The new procedure may mean that OHTA will do even fewer Medicare requests than it did in the past. OHTA's relatively few resources limit the potential gains that might be expected through contracting with outside vendors.

OHTA assessments present detailed analyses of the risks, clinical effectiveness, and uses of medical technologies. The technologies are reviewed to form the basis for a reimbursement decision by a federally financed health care program such as Medicare or CHAMPUS. Requesting agencies use the assessments and the resulting recommendations in determining coverage policy. OHTA also conducts technology reviews--brief evaluations of health care technologies conducted in place of assessments. Unlike assessments, technology reviews do not contain recommendations for coverage. Since October 1992, assessments also consider the cost-effectiveness of technologies when such information is available and reliable. As shown in table 1, OHTA completed 18 assessments between January 1990 and March 1994, recommending coverage for three-quarters of these technologies.

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<sup>1</sup>The new process, which has yet to be implemented, requires OHTA to solicit public suggestions for potential technology assessments. The suggestions will be ranked in order of importance on the basis of established selection criteria. OHTA will then conduct these assessments in the order of relative importance.

Table 1: Summary of OHTA Coverage Recommendations for Assessments Completed, January 1990 - March 1994

Year	Coverage recommendation		
	Cover	Not cover	Inconclusive
1990	6	2	1
1991	4		
1992	1	1	
1993	1		
1994 (through Mar.)	2		
Subtotal	14	3	1
<b>Total</b>		<b>18</b>	

Note: Three of these assessments were conducted at the request of CHAMPUS, and the remainder were conducted for Medicare.

Once OHTA accepts a request from Medicare or CHAMPUS, it publishes a notice in the Federal Register announcing plans for conducting a technology assessment and soliciting public comments and information about the technology within a 60 to 90 day period. Concurrently with the Federal Register notice, OHTA initiates a comprehensive review of medical and scientific literature to obtain all the information available about the technology. OHTA does not perform or contract for primary research. It collects and synthesizes existing knowledge of health care technologies.

The quality of the medical and scientific evidence is important in formulating assessment conclusions. Although the analysts consider all available evidence, they place the most importance on well-designed studies that are less subject to bias and error. Randomized, controlled trials provide the most reliable medical and scientific evidence. OHTA uses a graded, hierarchical system for examining evidence based on study design. OHTA then uses this evidence to determine if the technology results in improved health outcomes.

OHTA's budget, which is funded by the Medicare Trust Fund,<sup>2</sup> has remained at about \$1 million annually for fiscal years 1992 through

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<sup>2</sup>The Medicare Trust Fund pays for Medicare benefits and administrative expenses. It is financed through a tax on earnings, beneficiary premiums, and general revenues from the federal government.

1994. In addition, OHTA officials told us that the Department of Defense (DOD) annually makes a nominal payment to OHTA for CHAMPUS assessments and reviews.

OHTA's budget supports one part-time and five full-time analysts who work on technology assessments and reviews. According to the Director, OHTA, four are medical doctors, one is a registered nurse and certified registered nurse anesthetist, and one holds a bachelor's degree in chemistry. The Director also told us that several analysts have master's degrees, one holds a doctorate, and all had been previously employed by other health-related government agencies.

Although OHTA does not track resources used for different requesters, the majority of its work has clearly been done for the Medicare program. Since 1983, OHTA has completed 106 technology assessments for Medicare. As shown in table 2, HCFA initiated about 80 percent of the 28 OHTA assessments requested between January 1990 and May 1994. Further, as shown in table 3, for this same period, HCFA requested about 40 percent of the 20 technology reviews; DOD requested about 55 percent of the reviews for the CHAMPUS program.

Table 2: Requests for OHTA Technology Assessments, January 1990 - May 1994

Technologies	Requester
Automatic implantable defibrillator - patient selection criteria	Medicare
Bone mineral density studies (in progress)	Medicare
Cardiac rehabilitation services	Medicare
Carotid endarterectomy	Medicare
Combined kidney-pancreas transplantation (in progress)	Medicare
Computerized signal-averaged EKG (in progress)	Medicare
Electrostimulation of salivary production in Sjogren's disease	Medicare
Expert consensus on the appropriate uses of ultrasound	Medicare
Extracranial-intracranial bypass surgery	Medicare
External insulin infusion pumps	Medicare
Gating and surface coil devices with MRI	Medicare
Hyperthermia with/without chemotherapy for cancer	Medicare

Technologies	Requester
Intermittent positive-pressure breathing	Medicare
Liver transplantation	Medicare
Magnetic resonance angiography	Medicare
PET scanning - release pending FDA review of certain positron emitters	Medicare
Plethysmography (in progress)	Medicare
Protein A columns to treat immune disorders	Medicare
Reassessment of cardiac output measurement by bioimpedance	Medicare
Refractive keratoplasty (in progress)	Medicare
Routine testing requirements for dialysis patients	Medicare
Sleep disorder centers and polysomnography	Medicare
Biofeedback (requested)	CHAMPUS
Intensive EEG video monitoring for epilepsy	CHAMPUS
Isolated pancreas transplantation (in progress)	CHAMPUS
Patient and institutional selection criteria for heart-lung transplantation	CHAMPUS
Peripheral stem cell support of high-dose chemotherapy (in progress)	CHAMPUS
Single and double lung transplantation	CHAMPUS

Note: All 28 assessments are completed unless otherwise noted.

Table 3: Requests for OHTA Technology Reviews, January 1990 - May 1994

Technologies	Requester
Drug delivery devices	Medicare
Implantable electrical stimulator and spinal fusion	Medicare
Laparoscopic cholecystectomy	Medicare
Lymphedema pump	Medicare
Neuromuscular electrical stimulation in patients with a nonintact nervous system	Medicare
Outpatient surgery for cochlear implantation	Medicare
Self-administration of erythropoietin	Medicare
Transluminal angioplasty for hemodialysis fistulae	Medicare
Autologous bone marrow transplantation in chronic myelogenous leukemia	CHAMPUS
Brachytherapy	CHAMPUS
Combined liver-kidney transplants	CHAMPUS
Combined small bowel-liver transplants	CHAMPUS
Home cardiorespiratory monitoring (requested)	CHAMPUS
Hyperfractionated radiation therapy	CHAMPUS
Phototherapy and photochemotherapy for dermatologic diseases	CHAMPUS
Platelet-derived growth factor for treatment of wounds and chronic skin ulcers	CHAMPUS
Proton beam therapy for chordomas	CHAMPUS
Sensory evoked potential testing (requested)	CHAMPUS
Use of serial dilution endpoint titration test and immunotherapy	CHAMPUS
Home uterine monitoring	PHS <sup>a</sup>

Note: All 20 reviews are completed unless otherwise noted.

<sup>a</sup>Public Health Service.

OHTA also does not track the time it takes to conduct assessments. However, we can provide a general estimate by calculating the average number of assessments and reviews OHTA completed during

1990 through 1993. On average, OHTA completed 4.65 technology assessments and 4.2 technology reviews per year during this period. According to the Director, OHTA, the length of time a technology assessment or review takes depends on the complexity of the subject matter as well as the quantity and quality of medical and scientific information available for the assessment.

Because of OHTA's limited resources, it is unlikely that either OHTA or outside vendors could conduct more technology assessments. HCFA may be able to increase its assessment capabilities by more effectively using its contractors' medical directors in evaluating technologies of national concern. HCFA could also make greater use of technology assessments available from private insurers such as Aetna and Blue Cross/Blue Shield.



### SECTION 3

#### DIAGNOSTIC-RELATED GROUP SYSTEM AND NEW TECHNOLOGY

**How does HCFA adjust its diagnostic-related group (DRG) system to account for new or revised technologies? Since implementation in 1983, how many decisions have been made on the coverage/proper payment level for new or revised technologies? How often have new DRGs been created to cover new or revised technologies?**

The prospective payment system (PPS), which is based on DRGs, accounts for new technology in its payment policies. Under PPS, HCFA groups Medicare patients whose inpatient care is similar (in clinical indications and cost) into DRGs and reimburses hospitals at a predetermined rate for each hospital discharge.<sup>1</sup> Medicare Part A contractors make coverage determinations independently of DRG classifications. In the absence of a national coverage decision, they remain responsible for making coverage decisions for individual procedures.

Under PPS, HCFA accounts for new technologies in its Medicare reimbursement rates through the three processes described below.

#### Annual Adjustment to Payment Amount

Each year, the Prospective Payment Assessment Commission (PropAC)<sup>2</sup> recommends to the Congress a general payment adjustment for all DRGs to account for the cost-increasing effect of new technologies. For fiscal year 1995, PropAC considered the effects of selected technologies, such as thrombolytic therapy and implantable cardioverter-defibrillators, on overall Medicare spending and recommended a .3-percent increase to payment rates to account for technological advances. For fiscal year 1994, a 1-percent increase was recommended.

#### Annual Revision of the DRG System

HCFA is required by law to revise the DRG system each year to reflect changes in hospital costs due to several factors, including new technology. For this revision, HCFA considers the effects of new technology on individual DRGs. The following examples

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<sup>1</sup>Each DRG has a relative weight, indicating how expensive it is relative to the other DRGs. To calculate DRG prices, Medicare multiplies the DRG relative weight by a standard (base) payment amount adjusted for several hospital-specific factors.

<sup>2</sup>PropAC was established in 1983 as an independent, nonpartisan commission to advise the Congress on Medicare-related payment issues.

illustrate how HCFA takes new technologies into account for this annual revision.

- HCFA revises DRG weights each year using the most recent charge data. As HCFA incorporates charges for new technologies into its database, DRGs that cost more receive a higher weight and, therefore, receive higher payments. So, if a new technology increases the cost of a DRG compared to other DRGs, it will receive a higher weight and increased payment.
- HCFA adjusts the procedures assigned to DRGs as necessary to ensure that assigned procedures have proper payment levels. For example, HCFA received complaints that reimbursement for cochlear implants, devices for treating severe deafness, was too low. HCFA analyzed hospital cost data and determined that the complaints were valid. In fiscal year 1994, HCFA rearranged the procedures assigned to the particular DRG in order to increase the payment level for cochlear implants and other procedures in the DRG.
- HCFA creates new DRGs when necessary, generally when too much variation occurs in average costs within a DRG. For instance, HCFA created three new DRGs for fiscal year 1991 for patients with HIV because these patients had higher costs than other patients in the same DRGs. PPS began in October 1983 with 470 DRGs; since that time, HCFA has created 24 additional DRGs. HCFA does not typically create DRGs for a single technology but did create a new DRG exclusively for liver transplants and bone marrow transplants when it decided to expand coverage for these procedures. In addition, in fiscal year 1994, HCFA created new DRGs specifically for a new technology used in gall bladder removal surgery or cholecystectomy, a very common procedure for Medicare patients. The two new cholecystectomy DRGs reflect the lower average cost for cholecystectomies when done laparoscopically.<sup>3</sup>

#### PPS for Capital Expenses

In fiscal year 1992, HCFA began reimbursing the inpatient capital-related costs of PPS hospitals on a prospective basis.<sup>4</sup> Under this

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<sup>3</sup>In laparoscopic surgery, surgical instruments and a viewing instrument are inserted into the abdomen through several small incisions. The surgeon views a remote image of the abdominal area on a television monitor while operating. This technique is less invasive than traditional "open" surgery and results in shorter hospital stays.

<sup>4</sup>PPS for capital-related costs is in its transition period, during which capital-related costs are reimbursed partly on the basis of prospective rates and partly on the traditional reasonable cost

system, a predetermined amount per hospital discharge is made for Medicare inpatient capital-related costs. These costs include depreciable assets used for patient care, such as magnetic resonance imaging machines and lithotripters, which break up kidney stones using shock waves. The cost of the actual equipment is reimbursed under this system, while the associated operating costs continue to be reimbursed under the DRG system described above. HCFA plans to determine an annual update for this system based on increases in the cost of capital and appropriate changes in capital requirements resulting from new technology and other factors.

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method. By October 1, 2001, all PPS hospitals will receive payment for capital-related costs under a completely prospective method.

