United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Human Resources, Committee on Government Reform and Oversight, House of Representatives

For Release on Delivery
Expected at 10:00 a.m.
Tuesday, March 18, 1997

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Management Challenges and Opportunities

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GAO/T-HEHS-97-98

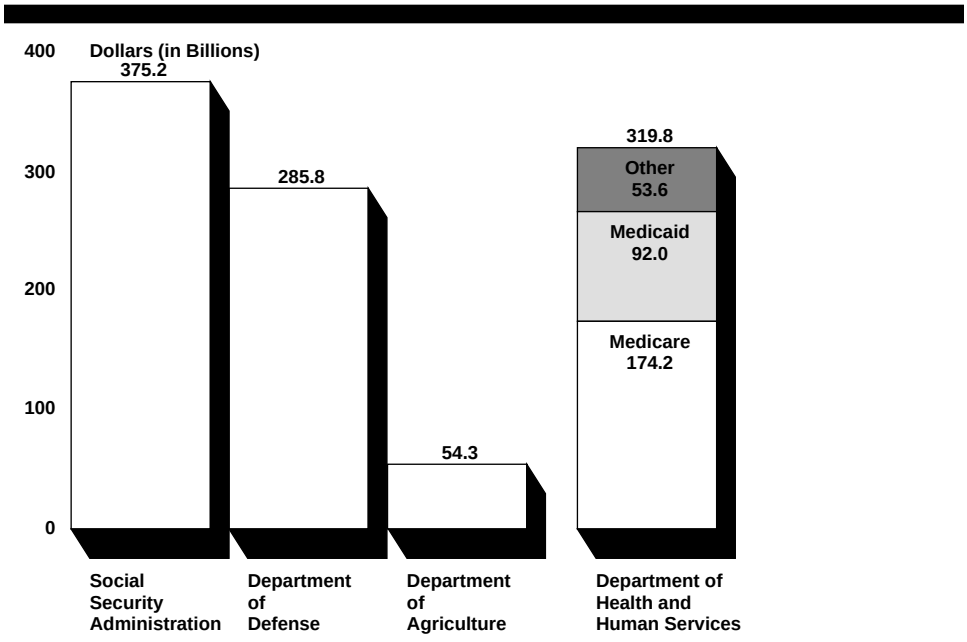
Department of Health and Human Services: Management Challenges and Opportunities

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the challenges facing the Department of Health and Human Services (HHS) in carrying out its mission effectively and cost-efficiently.

A department of the size and complexity of HHS deserves careful oversight. It is one of the largest federal departments: in fiscal year 1996, HHS had budget outlays of $319.8 billion and a workforce of over 57,000. HHS is the largest grant-making agency in the federal government, providing approximately 60,000 grants per year. Its Medicare program is the nation's largest health insurer, annually handling more than 800 million claims; Medicare alone spends far more than most cabinet departments. (See fig. 1.) The Food and Drug Administration's (FDA) activities to regulate the safety of food and cosmetics and the safety and effectiveness of drugs and medical devices affect products representing $.25 out of every $1 in U.S. consumer spending.

Figure 1: Budget Outlays of the Four Largest Federal Agencies, FY 1996



Note: The Department of the Treasury's budget outlay was $364.6 billion; however, $344 billion of that total was interest on the public debt.

Moreover, HHS' many missions affect the health and well-being of every person in the country. HHS provides health insurance for about one in every five Americans, including elderly and disabled people and poor children. Its agencies ensure the safety of food, drugs, and medical devices; help to contain the outbreak of infectious diseases; conduct groundbreaking medical research on curing and preventing disease; provide health care services to populations, such as Native Americans, who might otherwise lack such services; provide income support for needy children and families; and support many services to help elderly people remain independent.

Over the years, GAO, the Inspector General (IG), and others have examined programs and suggested numerous improvements for many HHS programs. Today, however, I would like to highlight three challenges HHS faces in meeting its mission. These challenges focus on core problems that often obstruct HHS' effective functioning. By successfully addressing these underlying problems, HHS will be much better positioned to manage its responsibilities effectively and efficiently and to assure the Congress and the American people that it is fulfilling its vital missions.

In summary, the first challenge HHS faces is its ability to define its mission, objectives, and measures of success and increase its accountability to taxpayers. Because of the size and scope of its mission and the resulting organizational complexity, managing and coordinating HHS' programs so that the public gets the best possible results are especially difficult. The Department has eleven operating divisions responsible for more than 300 diverse programs. HHS has not always succeeded in managing the wide range of activities its agencies carry out or fixing accountability for meeting the goals of its mission. Another complicating factor is that HHS needs to work with the governments of the 50 states and the District of Columbia to implement its programs, in addition to thousands of private-sector grantees. Developing better ways of managing is essential if HHS is to meet its goals.

The 1993 Government Performance and Results Act (GPRA), 1990 Chief Financial Officers Act, and Government Management Reform Act of 1994 now require federal agencies to be more accountable for the results of their efforts and their stewardship of taxpayer dollars. GPRA presents HHS with opportunities to bring discipline to management of all levels of the Department, define the types of information it needs to implement and assess its programs, and identify ways to progress toward accomplishing its goals. GPRA also poses a challenge to HHS, however, because meeting the

law's requirements to prepare strategic plans, design performance measures, and assess and report on program accomplishments will not be an easy task. Similarly, HHS has found it difficult to develop the financial information necessary to permit an audit of its financial statements.

The second challenge confronting HHS—one that it shares with most other federal agencies—is ensuring that it has the information systems it needs to manage and evaluate its programs and to track its progress in meeting performance goals. Managers must have reliable information both to implement their programs in a way that best serves the public and to assure the American people that federal programs are performing responsibly and well. This is especially challenging for the Department because it relies so much on contractors, grantees, and state and local governments as its information partners.

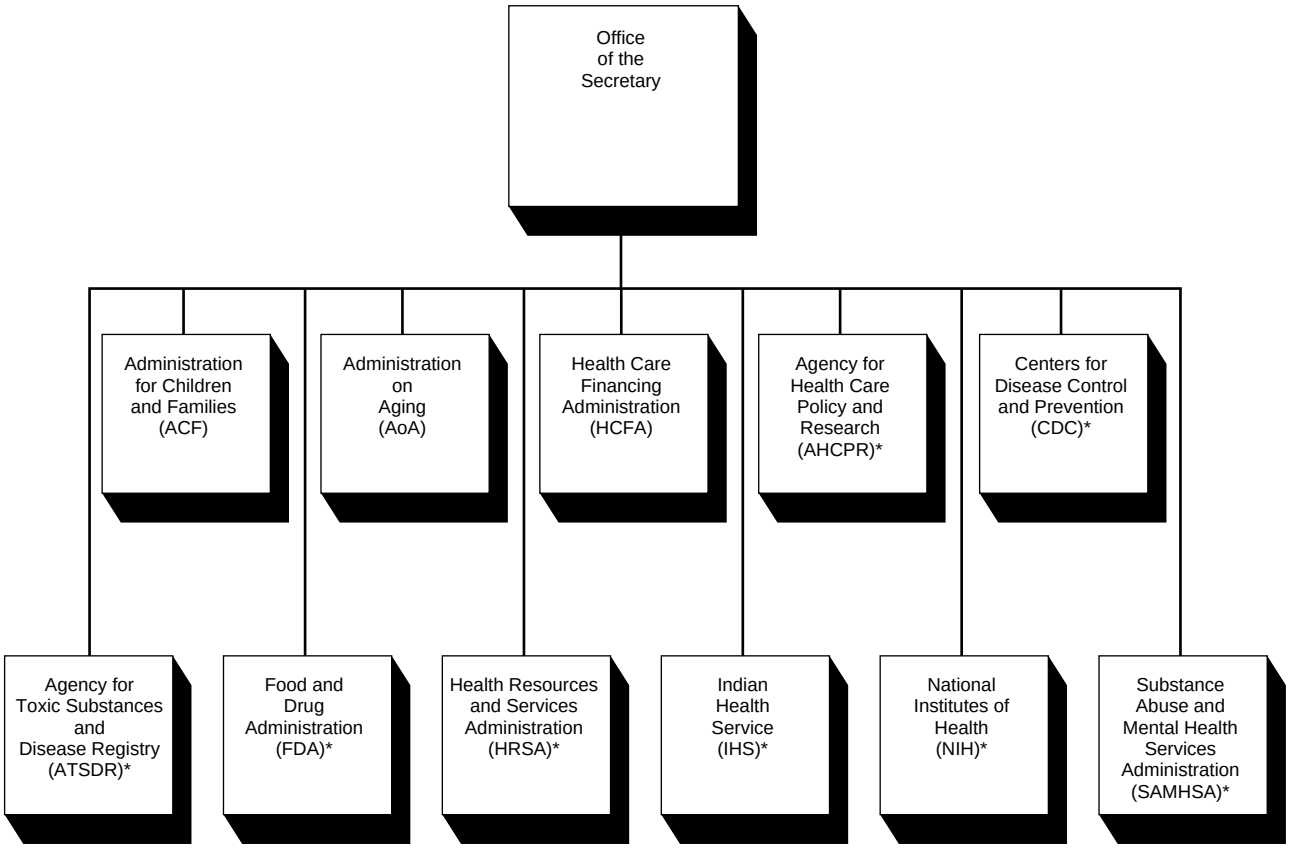
Finally, HHS' responsibilities require it to constantly combat fraud, waste, abuse, and mismanagement. HHS has several programs that are vulnerable to such exploitation. For example, the size and nature of Medicare, which accounts for over half of HHS' total budget, make this program particularly vulnerable. HHS needs to be vigilant now and in the future because its programs will probably continue to be the targets of fraud and abuse and because waste and mismanagement can have such serious effects on taxpayers and program beneficiaries.

Scope of HHS' Responsibilities Makes Coordination and Accountability Difficult

The sheer size and complexity of HHS' responsibilities create unique challenges. HHS comprises several large agencies, each of which manages a number of programs, whose many parts also must be administered. (See fig. 2.) For example, the $10.2 billion National Institutes of Health (NIH) is only one of the agencies in the Public Health Service (PHS), yet NIH includes 17 separate health institutes, the National Library of Medicine, and the National Center for Human Genome Research.[1] The Health Care Financing Administration (HCFA) administers the Medicare and Medicaid programs, as well as several quality-of-care programs such as those authorized by the Clinical Laboratory Improvement Amendments of 1988. The Administration for Children and Families (ACF) is responsible for about 60 programs, including the new federal-state welfare program; child support enforcement; and Head Start, which alone serves about 800,000 children.

[1]Budget outlay for fiscal year 1996.

Figure 2: HHS' Major Operating Divisions



Note: Operating divisions marked with an asterisk are part of PHS.

This array of interrelated activities and responsibilities makes it especially important for HHS managers to work together to address the Department's overarching program goals. HHS must improve coordination and accountability among its own agencies as well as work successfully with other federal agencies with related responsibilities, state and local governments, and private-sector grantees.

Better Internal and External Coordination Could Improve Program Results and More Efficiently Use Federal Funds

Coordination among HHS programs with related responsibilities is essential to efficiently and effectively meet program goals. Moreover, many programs under HHS share goals with or relate closely to programs administered by other federal agencies. In addition to coordinating the activities of its own agencies, HHS must also coordinate its efforts with these other agencies. Furthermore, a number of HHS programs, including Medicaid and the welfare block grants, require both federal and state involvement. Therefore, HHS must work with all the state governments—and at times local jurisdictions—to coordinate implementation of these programs.

One program area that requires HHS to focus on both internal and external coordination is alcohol and other drug abuse treatment and prevention. Several years ago, we reported that abuse of alcohol and other substances was a leading cause of death and accidents among Indian people.[2] Yet HHS agencies responsible for research and services for preventing and treating substance abuse—the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the Substance Abuse and Mental Health Services Administration (SAMHSA)—had no process to link their expertise with that of the Indian Health Service (IHS), the agency charged with improving the health of American Indians and Alaskan Natives. We recommended that IHS and the other HHS agencies work together to develop a plan to address substance abuse-related problems among these people. It wasn't until 1996, however, that HHS had developed and implemented such a plan for interagency collaboration on planning, research, evaluation, and training. Although long overdue, this plan should help HHS strategically allocate limited federal resources to address a major public health problem in IHS service areas.

Programs addressing alcohol and other drug abuse issues involve not only several HHS agencies—including SAMHSA, NIH, ACF, and the Centers for Disease Control and Prevention—but also 15 other federal agencies. These include the Departments of Veterans Affairs, Education, Housing and Urban Development, and Justice.[3] HHS also administers 58 programs that address the problems of at-risk and delinquent youths. An additional 73 programs focused on such youths involve 15 other federal Departments

[2]Indian Health Service: Basic Services Mostly Available; Substance Abuse Problems Need Attention (GAO/HRD-93-48, Apr. 9, 1993).

[3]Drug and Alcohol Abuse: Billions Spent Annually for Treatment and Prevention Activities (GAO/HEHS-97-12, Oct. 8, 1996).

and agencies, including the Departments of Justice, Education, Labor, Agriculture, and Housing and Urban Development.[4]

Accountability for Meeting Program Goals Needs More Emphasis

In addition to complicating coordination efforts, the size and scope of HHS' responsibilities also challenge the Department's ability to maintain accountability for meeting its mission goals. We have reported an example of this difficulty concerning the Rural Health Clinic (RHC) program, which is administered by HCFA.[5] Established two decades ago by federal law, the program allows RHCs to receive higher Medicare and Medicaid reimbursement to support health care professionals, including nurse practitioners and physician assistants, in underserved areas. The program was designed to improve access to health care in areas too sparsely populated to sustain a physician practice. RHC program goals are similar to those of many programs in the Health Resources and Services Administration (HRSA), the HHS agency charged with ensuring that underserved and other vulnerable populations receive quality health care. HCFA has relied on HRSA criteria for identifying geographic areas where providers could qualify for higher Medicaid or Medicare payments under RHC. As the program has grown, however, neither HCFA nor HRSA has been held accountable for ensuring that its resources have been directed at improving access in rural, underserved areas.

In our review of 144 RHCs in four states, some clinics clearly improved access in rural underserved areas; however, many clinics were in more populated areas that already had well-developed health care delivery systems. Nevertheless, once certified, all RHCs are eligible for the higher reimbursements, even after they may no longer be located in rural or underserved areas. These higher reimbursements continue indefinitely because neither HCFA nor HRSA routinely recertifies the geographic area or the provider as eligible for such reimbursements. The RHC program is adrift, in part because neither HCFA nor HRSA has accepted responsibility for routinely measuring or monitoring the RHC program's results.

In administering programs that are the joint responsibility of the state and federal governments or that involve many local grantees, HHS must continually balance program flexibility with oversight and maintaining program controls. A case in point is Head Start, which was designed to

[4]At-Risk and Delinquent Youth: Multiple Federal Programs Raise Efficiency Questions (GAO/HEHS-96-34, Mar. 6, 1996).

[5]Rural Health Clinics: Rising Program Expenditures Not Focused on Improving Care in Isolated Areas (GAO/HEHS-97-24, Nov. 22, 1996).

ensure maximum local autonomy. The accountability structure for overseeing the program is not conducive to strong internal controls. For example, although all Head Start programs are governed by a single set of performance standards, these standards are largely self-enforcing. Grantees report annually on the extent to which they have complied with the performance standards. Although HHS does have a triennial monitoring system, several HHS IG reports have raised questions about accountability in Head Start. For example, a May 1993 report found significant differences between the number of services grantees reported they had provided and the number they had actually documented in their files. The IG also found that grantee files and records were often incomplete, inconsistent, and hard to review.[6]

The Medicaid program provides another example of the balancing act between flexibility and accountability. Federal statutes and regulations give states substantial flexibility in designing and administering their Medicaid programs. HCFA is authorized to provide states with even greater latitude by waiving certain statutory requirements. Such waivers permit states, for example, to provide managed care services or home and community-based service alternatives to long-term care. Although HCFA performs structural reviews of waiver programs during the planning stage, as programs are implemented and continue to operate, problems have developed in some states. Flexibility can be positive for beneficiaries as well as the states; however, HCFA's ongoing monitoring and oversight are important to ensure the appropriate use of federal funds. The need for accountability will be even more pronounced if the need for waivers to enroll beneficiaries in managed care is eliminated, as the President has proposed in his fiscal year 1998 budget.

With welfare reform, though states have more flexibility, HHS' important responsibilities continue. The recent welfare reform law replaces Aid to Families With Dependent Children with block grants to states, a program known as Temporary Assistance for Needy Families (TANF).[7] The law has fundamentally changed HHS and state responsibilities in providing income support to needy families. States may design and implement their own assistance programs within federal guidelines, and HHS has a broad range of responsibilities for ensuring accountability from the states. Some of these duties include setting standards for states to earn performance

[6]Evaluating Head Start Expansion Through Performance Indicators, HHS Office of the Inspector General, OEI-09-91-00762 (May 1993) and Summarization of Concerns With the Financial Management Systems and Control Structures Found at Head Start Grantees, HHS Office of the Inspector General, A-17-93-00001 (Sept. 1993).

[7]The Personal Responsibility and Work Opportunity Reconciliation Act of 1996, P.L. 104-193.

bonuses that reward them for achieving program goals, monitoring work participation rates, and ensuring that states maintain spending for poor families. Although the law has explicitly limited HHS' power to regulate the states' implementation of the law and reduced the federal welfare workforce, HHS must enforce certain aspects of the law.

GPRA and Related Legislation Provide Framework for Improved Program Performance, Cost Savings, and Accountability

The complexity of HHS' responsibilities makes it especially important for the Department to integrate program goals and activities at a departmental planning level. As we have just pointed out, the Department needs to become more accountable for its responsibilities. Concerned that federal agencies such as HHS have not always effectively managed their activities to ensure accountability, the Congress has created a legislative framework to address long-standing management challenges throughout the federal government. The centerpiece of this framework is GPRA. Other elements include the Chief Financial Officers Act and the Government Management Reform Act. These laws respond to the need for appropriate, reliable information for executive branch and congressional decision-making.[8]

HHS is in the process of implementing these laws, which combine to provide a useful framework for developing (1) fully integrated information about HHS' mission and strategic priorities, (2) performance data to evaluate the achievement of those goals, and (3) accurate and audited financial information about the costs of achieving mission goals. The type of strategic planning and performance measurement GPRA requires is familiar to HHS. Some agencies in HHS have experimented—some very successfully—with results-oriented management. HHS, however, has not had experience with the type of far-reaching, coordinated reform required by GPRA.

HHS Faces Opportunities and Challenges in Complying With GPRA Requirements

GPRA provides HHS with a good opportunity to improve program performance. Under GPRA, every major federal agency—and in many cases, bureaus in each agency—must now ask some basic questions: What is our mission? What are our goals and how will we achieve them? How can we measure our performance? How will we use that information to improve? GPRA forces federal agencies to shift their focus from such traditional concerns as staffing and activity levels to a single overriding concern: results.

[8]Managing for Results: Using GPRA to Assist Congressional and Executive Branch Decisionmaking (GAO/T-GGD-97-43, Feb. 12, 1997).

Specifically, GPRA directs agencies to consult with the Congress and obtain the views of other stakeholders and to clearly define their missions. It also requires them to establish long-term strategic goals as well as annual goals linked to the strategic goals. Agencies must then measure their performance according to their goals and report to the President and the Congress on their success. In addition to ongoing performance monitoring, agencies are expected to identify performance gaps in their programs and to use information from these evaluations to improve programs.[9]

Meeting the GPRA requirements will challenge HHS for several reasons. Some of HHS' major programs have never been fully responsible for measuring and improving program performance. For example, the Medicaid program has historically paid claims for medical services and paid limited attention to monitoring program results for the majority of beneficiaries. Other HHS functions, such as those related to research, are not as conducive to results-based management as others are. In addition, because many HHS programs are operated by states, localities, or nongovernmental organizations, HHS agencies will have to develop a way to make their many partners accountable for program results. Moreover, the data necessary for meaningful performance measurement may not be currently available or may not be comparable from state to state. The immense changes spurred by recently enacted welfare reform also add to the complexity of HHS' task. Nonetheless, GPRA could greatly improve HHS performance—a vital goal when resources are limited and public demands are high.

HHS Has Experience With Results-Based Management Reforms

HHS is familiar with the kind of results-oriented management promoted by GPRA. Healthy People 2000, PHS' national public health initiative that seeks to improve the health of all Americans, exemplifies an HHS results-based management effort. In consultation with HHS stakeholders, other government agencies, and the public health community, PHS developed a series of outcome-based public health goals and measures.

The Congress has incorporated Healthy People 2000 objectives into national legislation. Under the Maternal and Child Health Program, for example, HHS is required to report on the states' progress toward meeting the maternal and child health objectives in Healthy People 2000. The broad acceptance by the public health community of certain measures developed

[9]Executive Guide: Effectively Implementing the Government Performance and Results Act (GAO/GGD-96-118, June 1996) and GAO/T-GGD-97-43, Feb. 12, 1997.

for these reports has encouraged states and localities to create comparable databases and to mobilize to meet program goals.

When it passed GPRA, the Congress understood that most agencies would need to make fundamental management changes to implement this law properly and that these changes would not come quickly or easily. To facilitate this process, GPRA included a pilot phase during which federal agencies could gain experience in implementing key parts of the law to provide valuable lessons for the rest of the government.

The Office of Management and Budget (OMB) designated about 70 pilot tests in 26 federal entities for performance planning and reporting. Two pilots were in HHS' jurisdiction: one in ACF's Office of Child Support Enforcement (OCSE) and the other in FDA's Prescription Drug User Fee Program. The pilots helped OCSE and FDA identify and move toward performance goals. OMB based its selection of OCSE in part on OCSE's previous efforts to develop a 5-year strategic plan; its ability to quantify program goals, such as child support collections; and the involvement of state and local governments as key program administrators. In October 1996, we reported that OCSE's GPRA pilot had made progress in redirecting its management of the child support enforcement program toward results.[10] For example, OCSE approved national goals and objectives focused on key program outcomes such as increasing the number of paternities established, support orders obtained, and collections received. At the time of our review, OCSE and the states had begun to develop performance measures as statistical tools for measuring state progress toward meeting program goals.

A second HHS GPRA pilot involves the Prescription Drug User Fee Act of 1992 (PDUFA), which allows FDA to collect user fees from drug companies seeking approval to market drugs. The law dedicates the revenues to expediting FDA's reviews of human drug applications. The act established time-specific performance goals to be met by the end of fiscal year 1997. To satisfy these objectives, FDA consulted with its stakeholders to determine appropriate performance indicators and target levels and developed output-oriented performance goals. In its Fourth Annual Performance Review, for fiscal year 1996, FDA reported that the PDUFA program had exceeded its performance goals, improving the speed and efficiency of the drug review process.

[10]Child Support Enforcement: Reorienting Management Toward Achieving Better Program Results (GAO/HEHS/GGD-97-14, Oct. 25, 1996).

Status of HHS' GPRA Implementation

GPRA requires that federal agencies develop strategic plans for a period of at least 5 years and submit them to the Congress and OMB no later than September 30, 1997. These plans must include the agency's mission statement; identify the agency's long-term strategic goals; and describe how the agency intends to meet these goals through its activities and its human, capital, information, and other resources.

GPRA also requires agencies to submit an annual performance plan to OMB; the first plans are due in the fall of 1997. The annual performance plan should directly link the strategic goals in the agency's strategic plan to managers' and employees' daily activities. This plan should include the annual performance goals for the agency's programs as listed in the budget, a summary of the necessary resources to conduct these activities, the performance measures that will gauge the progress toward those goals, and a discussion of how the performance information will be verified.

Although governmentwide implementation of GPRA has not yet officially begun, HHS is working with OMB to meet its deadlines for submitting its strategic plan and first annual performance plan. HHS officials have acknowledged, however, that the Department, "must confront some fundamental issues that are central to the successful implementation of GPRA in HHS over the next year. At a minimum, there remains an enormous amount of work to be done."[11] HHS officials do expect to meet the September deadlines, however, for both strategic and performance plans, they said. HHS has drafted its strategic plan, but it is not yet ready for public release.

Strategic plans must consider the views of the Congress and other stakeholders. To ensure that these views are considered, GPRA requires agencies to consult with the Congress and solicit stakeholders' views as they develop their plans. The Department plans to begin congressional consultations in April and to send 200 to 300 stakeholders copies of the draft strategic plan in June, HHS officials said. HHS currently plans to release the draft plan to the public on the Internet.

HHS operating divisions are now developing performance plans, which should include performance measures and objectives linked to data systems. To prepare for the development of GPRA's annual performance plans, HHS officials asked each of its operating divisions to provide

[11]Integrating Performance Measurement Into the Budget Process, Subcommittee Report of HHS' Chief Financial Officers Council, GPRA Implementation Committee (Washington, D.C.: Jan. 21, 1997).

performance objectives and measures for at least one program activity. Officials also asked operating divisions to describe their strategies for aggregating program activities for their performance plans for the fiscal year 1999 budget. Last summer, OMB reported that the performance measurement aspects of GPRA pose the greatest challenge to HHS. At the beginning of this calendar year, however, even the agencies most advanced in their GPRA preparations had not yet finished developing performance measures. Nor had many programs taken the next steps to relate the appropriate performance objectives and measures to the resources needed to accomplish program strategies.

Required Financial Statement Audits Are Ongoing at HHS

To provide decisionmakers with reliable, consistent financial data on the operations of federal agencies, the Government Management Reform Act of 1994 requires each department and major independent agency to submit to OMB an audited agencywide financial statement beginning in fiscal year 1996. The magnitude of this task for HHS is extraordinary. HHS expenses exceed $300 billion a year. Over 80 percent of this amount was spent by HCFA, primarily for the Medicare and Medicaid programs. Although the IG tried to audit HCFA's financial statements in prior years, the IG could not express an opinion on the reliability of these statements primarily because of inadequate supporting documentation for reported amounts. HHS and HCFA management are working to resolve these issues so that an audit can be performed.

The current HHS-wide financial statement audit is designed to follow up on previously reported issues and to address whether program expenditures, such as Medicare benefit payments, complied with laws and regulations and were properly reported. In addition, the audits will evaluate the effectiveness of the agency's related internal controls. The IG will report the results of this audit when it is completed.

Reliable and Comprehensive Management Information Systems Crucial to HHS' Success

Nothing is more crucial to effectively managing an enterprise of HHS' size and scope than accurate information about programs and their effects. The desire of the American people for accountable government, expressed in the GPRA's mandate for measurable performance goals, underscores the critical need for accurate information. In recognition of the importance of agencies' properly managing their information systems, the Congress passed the Paperwork Reduction Act of 1995 to guide them in this effort. The law addresses the acquisition and management of information resources by federal agencies. The Clinger-Cohen Act of 1996 elaborates

on requirements that promote the use of information technology to better support agencies' missions and to improve program performance. Among these acts' provisions are requirements that agencies set goals, measure performance, and report on progress in improving the efficiency and effectiveness of information management generally—and, specifically, the acquisition and use of information technology.

Because HHS' responsibilities involve large health insurance programs, extensive grant-making activities, and vital regulatory responsibilities, the Department must use effective information systems. To implement its programs and meet its responsibilities successfully, HHS must have access to data that are both reliable and appropriate to the task. Without such data, HHS cannot inform the Congress or the American people of its progress toward meeting its performance goals. Creating and implementing the sophisticated systems that will give HHS managers the data they need, however, present another major challenge. Because several important HHS programs, including Medicaid and TANF, are joint federal-state efforts, the current lack of comparable data across states increases the difficulty of obtaining timely and reliable data.

HCFA Needs Better Information About Enrollees and Services to Manage Medicaid Program

Medicaid, a joint federal-state program administered by HCFA, provides health coverage for 36 million low-income people, including 17.6 million children. Medicaid also pays for nursing home coverage for low-income elderly and other vulnerable members of society, accounting for almost half of total national spending for nursing home care. The Medicaid program's federal fiscal year 1996 expenditures totaled about $92 billion, with state expenditures totaling about $68 billion.

Despite Medicaid's magnitude, the federal government has only limited data on its results, and the accuracy of these data is questionable. Using information supplied by the states, HCFA creates a statistical report that has data about beneficiaries served, their eligibility categories, types of services they received, and vendor payments. HCFA also generates a regular financial report. The usefulness of both of these reports, however, is compromised by problems with the state data's accuracy and consistency. Some of these problems stem from collecting data from 50 states and the District of Columbia, which do not all use identical definitions for data categories. Another problem is the difficulty of relating the information that is in these two reports. Problems in data quality and in the ability to link data across data sources make it difficult for HCFA and others to analyze and evaluate Medicaid's results. For example, HCFA's Medicaid

managed care program has been plagued by duplicate reporting on the number of enrollees. Having an inaccurate count from the states makes it difficult to assess the effect of managed care on Medicaid expenditures.

Some of Medicaid's long-standing data problems could worsen because of the program's growing reliance on managed care to provide health services to beneficiaries. The proportion of Medicaid beneficiaries enrolled in managed care, as reported by HCFA, quadrupled from about 10 percent in 1991 to about 40 percent in 1996. Because Medicaid pays many managed care organizations a defined fee for providing a range of services, HCFA usually lacks the detailed utilization data available under fee-for-service billing. This, in turn, makes evaluating the program's success even more difficult.

Welfare Reform Presents HHS With Many Information Challenges

The new welfare reform law gives HHS new administrative and oversight responsibilities, the performance of which will rely on state-provided data. One of HHS' major new administrative requirements is for the child support enforcement program. Using state-provided data, HHS is to establish a national directory of newly hired employees and registry of child support orders to strengthen child support enforcement. Another information management challenge for HHS is ensuring that the states provide comparable and reliable data to help it fulfill its oversight responsibilities under the new legislation. HHS will need such information to ensure that states are enforcing the federal 5-year time limit on receiving welfare benefits, meeting minimum work participation rates, and maintaining a certain level of welfare spending. Enforcing this limit, for example, will be difficult because information on the total amount of time someone has received welfare is often unavailable in a state, let alone across states. In addition, HHS will need to collect state data to assess penalties and provide performance bonuses. With the increased flexibility of states in designing their programs, obtaining comparable and reliable data to assess the effect of welfare reform on children and families could be difficult for HHS.

FDA Needs to Improve Its System for Monitoring Medical Device Problems

Another possible problem in managing information systems is a failure to use the information appropriately to advance program goals. We recently reported on such a problem concerning FDA's medical device adverse event reporting system, used to gather information about problems with marketed medical devices.[12] Medical devices range in complexity from

[12]Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems With Approved Devices (GAO/HEHS-97-21, Jan. 29, 1997).

simple tongue depressors to heart pacemakers. The reporting system enables FDA and the medical device industry to work together to take corrective action on device problems and, when appropriate, to alert the public to potentially hazardous devices to prevent injury or death.

FDA has not systematically acted to ensure that the reported problems have received prompt attention and appropriate resolution. As a result, FDA's adverse event reporting system has not always provided the intended early warning about problem medical devices. Because the increased volume of adverse event reports resulting from changes in the law made it difficult for FDA to process and review reports in a timely manner, the agency chose to give priority to death and serious injury reports. As result, FDA delayed processing and reviewing almost 50,000 malfunction reports for nearly 2 years. Malfunction reports are essential in alerting FDA to potentially serious device problems before they result in death or serious injury.

Moreover, although FDA contends that it notifies manufacturers and user facilities about imminent hazards and industrywide safety concerns, it does not routinely document the corrective actions it takes—or those taken by manufacturers—to address reported medical device problems. As a result, it is unclear how manufacturers and FDA have responded to device problems reported by user facilities. Feedback to medical device users could increase knowledge about medical device performance, improve patient safety awareness, and help users make purchase decisions. FDA, however, does not routinely communicate the results of analyses of medical device problems and corrective actions to the medical device user facility community.

Implementation of Medicare Claims Processing System at Risk

Finally, another information management challenge facing HHS involves the Medicare program, which accounts for over half of HHS' annual budget. An important initiative to improve Medicare claims processing activity could create problems if it is not carefully implemented. To better protect Medicare from fraud and abuse, HCFA has begun to acquire a new claims processing system, the Medicare Transaction System (MTS). HCFA expects MTS to replace the nine different processing systems it currently uses by the year 2000. We have previously reported on the benefits and risks associated with this effort.[13] The intent of using a single automated system is to allow HCFA to improve administrative efficiency, better manage contractors, and place greater emphasis on safeguarding program dollars

[13]High-Risk Series: Medicare (GAO/HR-97-10, Feb. 1997) and Medicare: New Claims Processing System Benefits and Acquisition Risks (GAO/HEHS/AIMD-94-79, Jan. 25, 1994).

and improving beneficiary and provider service. In response to some of the risks we identified, HCFA revised its initial approach for developing and installing MTS, reducing the potential for problems stemming from large-scale system failures. We also reported on risks related to difficulties in defining the system's requirements, inadequate investment analysis, and significant schedule problems. HCFA is working on these concerns. We plan to continue evaluating HCFA's efforts on this important initiative.

Another critical task for HCFA involves revising computerized systems to accommodate dates beyond the year 1999. This year 2000 problem stems from the common practice of abbreviating years by their last two digits. Thus, miscalculations in all kinds of activities—such as benefit payments—could occur because the computer system would interpret "00" as 1900 instead of the year 2000. HHS, along with other agencies that maintain time-based systems, must develop strategies to resolve this potential problem in the near future.

Safeguarding Vulnerable Programs Requires Constant Vigilance and Innovation

With HHS' broad range of programs, large number of grantees and contractors, huge volume of vendor payments, and millions of beneficiaries, the Department must always be vigilant in protecting its programs from fraud, abuse, mismanagement, and waste. The sheer dollar size of HHS' programs makes them attractive targets, and the consequences can be severe. HHS needs to improve its processes for identifying and preventing fraud, abuse, mismanagement, and waste and maintain constant vigilance in the future. The Medicare program offers an example of how important such efforts are.

One of the long-standing management challenges HHS faces is safeguarding Medicare, the government's second largest social program. Medicare provides health insurance for 37 million elderly and disabled Americans; federal Medicare expenditures were $174 billion in fiscal year 1996. Medicare's expansive size and mission make it vulnerable to exploitation. That wrongdoers continue to find ways to dodge safeguards illustrates the dynamic nature of fraud and abuse and the need for constant vigilance and increasingly sophisticated ways to protect the program.

Both the Congress and HCFA have made important legislative and administrative changes to address chronic payment safeguard problems. Because of the hundreds of billions of dollars at stake, however, the government must exercise unflagging oversight and effective management for the foreseeable future to protect Medicare from waste, fraud, abuse,

and mismanagement. Two factors heighten the continuing need to control claims fraud and abuse in Medicare. First, although growth in Medicare costs has moderated somewhat in the last 2 years, many believe even this lower growth rate cannot be sustained. Second, the Medicare trust fund that pays for hospital and other institutional services is expected to be depleted within the next 5 years.

Infusion of Resources and Leadership From HCFA Should Help Lessen Vulnerabilities of Medicare Fee-for-Service Program

HCFA administers Medicare largely through a structure of claims processing contractors. Medicare contractors—insurance companies such as Blue Cross and Blue Shield—use federal funds to pay health care providers and beneficiaries and are reimbursed for their administrative expenses. HCFA has largely delegated its effort to guard against inappropriate payments to these contractors, giving them broad discretion in acting to protect Medicare program dollars. As a result, significant variations exist in contractors' implementation of Medicare's payment safeguard policies.

A pattern of unstable funding for antifraud and abuse activities since 1989 has made it more difficult to guard the large Medicare program. For example, although the number of Medicare claims climbed 70 percent—to 822 million—between 1989 and 1996, resources committed to claims review, without adjusting for inflation, grew less than 11 percent during that period. Passage of the Health Insurance Portability and Accountability Act of 1996 adds new funds to fight fraud and abuse starting in 1997, but this additional funding will still leave per claim safeguard funding in 2003 at about one-half the 1989 level, after adjusting for inflation.

The inadequate funding of Medicare's claims scrutiny activities has hurt contractors' efforts to review the medical necessity of services billed to the program. For example, we reported in 1996 that because of the small number of claims selected for review, home health agencies billing for noncovered services were less likely to be caught than was the case 10 years earlier.[14] Besides covering so few claims, paper reviews of home health claims are simply limited in their ability to detect claims for noncovered care. In the case of a large home health organization we investigated, claims passed review scrutiny even for visits never made because company staff allegedly falsified medical records.

[14]Medicare: Home Health Utilization Expands While Program Controls Deteriorate (GAO/HEHS-96-16, Mar. 27, 1996).

As we noted in many reports and testimonies in recent years, HCFA has not aggressively managed the Medicare claims processing function. HCFA has not taken a leadership role, for example, in managing how contractors select the criteria used to identify claims that may not be eligible for payment or in helping contractors with this task. The agency has not systematically aggregated information on contractors' medical policies or their related use of prepayment screens. As a result, HCFA has not adequately assessed the relative performance of contractors or helped share with all contractors the experience of some in using effective claims screening controls. One of our studies revealed, for example, that 10 of 17 contractors reviewed lacked screens for echocardiography, Medicare payments for which exceeded those for any other diagnostic test in fiscal year 1994 and which increased in use nationwide by over 50 percent between 1992 and 1994.[15] We estimated that Medicare could have denied at least $10.5 million in echocardiography payments made in 1993 if just seven contractors that did not screen for these procedures had applied the medical necessity screens used by other contractors.

Legislative and Other Initiatives Improve HCFA's Ability to Fight Fraud and Abuse

The 1996 Health Insurance Portability and Accountability Act will gradually increase the funding for pursuing health care fraud and abuse, including HCFA's audit and related activities. For fiscal year 1997, the act boosts the claims processing contractors' budget for program safeguard activities 10 percent over 1996; by 2003, the level will be 80 percent higher than for 1996.

Operation Restore Trust is an antifraud initiative involving three HHS agencies—the IG, HCFA, and the Administration on Aging—and the Department of Justice and various state and local agencies. This effort currently targets Medicare abuse and misuse in five states that together account for over one-third of all Medicare beneficiaries and focuses on fast-growing services: home health care, nursing homes, and medical equipment and supplies. In its first year, Operation Restore Trust reported recovering $42.3 million in inappropriate payments. It also resulted in many convictions, fines, and exclusions of fraudulent providers. IG officials believe that the major achievement of this initiative will be continued coordination of the participating agencies and greater awareness of the effectiveness of constant vigilance.

[15]Medicare: Millions Can Be Saved by Screening Claims for Overused Services (GAO/HEHS-96-49, Jan. 30, 1996).

The Health Insurance Portability and Accountability Act has built upon Operation Restore Trust by establishing a program run jointly by the Departments of Justice and HHS to coordinate federal, state, and local law enforcement efforts against fraud in Medicare and other health care programs. The program also establishes a national health care fraud data collection program, specifies health care fraud as a separate criminal offense, and increases criminal penalties.

HCFA has taken other actions to improve Medicare's fraud detection activities. These include efforts to adopt fraud and abuse detection software and to reduce Medicare's vulnerability to abusive billing as well as to prevent fraudulent or excluded providers from continuing to bill the program. For example, HCFA will assign new identification numbers—National Provider Identifiers—to every provider and supplier in the Medicare program and require the use of these numbers for billing purposes. The numbers assigned to providers and suppliers are unique and will identify them throughout their Medicare participation.

HCFA Could Reduce Costs of Medicare Managed Care Program

Programs can also be vulnerable to excess payments because the method for setting prices is flawed. An example of this is the process for setting rates for Medicare risk-contract health maintenance organizations (HMO). Our recent studies have revealed shortcomings in Medicare's risk-contract program that affect both taxpayers and beneficiaries. Because of difficulties in establishing capitation rates, Medicare pays some HMOs too much each year, needlessly spending at least hundreds of millions of dollars a year from the program's trust funds. HMOs tend to attract Medicare beneficiaries whose need for care when joining is low. Although the payment formula includes a crude risk adjustor to correct for this tendency, it is not precise enough to account for its full effect.[16] The Physician Payment Review Commission recently estimated that annual excess payments to HMOs nationwide could total $2 billion.

A second problem with Medicare's risk-contract program is that HCFA has neither adequately enforced nor made beneficiaries aware of HMOs' compliance with federal standards. We have reported on the need for HCFA to more actively serve beneficiaries enrolling in HMOs.[17] HCFA conducted

[16]Medicare HMOs: HCFA Could Promptly Reduce Excess Payments by Improving Accuracy of County Payment Rates (GAO/T-HEHS-97-82, Feb. 27, 1997).

[17]Medicare: Increased HMO Oversight Could Improve Quality and Access to Care (GAO/HEHS-95-155, Aug. 3, 1995) and Medicare: HCFA Should Release Data to Aid Consumers, Prompt Better HMO Performance (GAO/HEHS-97-23, Oct. 22, 1996).

only paper reviews of HMOs' quality assurance plans. Moreover, the agency was reluctant to act against HMOs that used abusive sales practices, unduly delayed appeals of decisions to deny coverage, or exhibited patterns of poor-quality care.

HCFA also misses an opportunity to supplement its regulatory efforts by not sufficiently informing Medicare beneficiaries about competing HMOs. For example, HCFA does not provide beneficiaries with any of the comparative consumer guides that the federal government and other employer-based health insurance programs routinely distribute to employees and retirees. Public disclosure of information, such as comparative disenrollment rates, could help beneficiaries choose among competing HMOs and encourage HMOs to better market their plans and serve enrollees.

Most recent legislative proposals to reform Medicare would expand the program's use of prepaid health plans, which illustrates the importance of addressing these issues. Risk-contract HMOs currently enroll about 10 percent of Medicare's beneficiaries, and such enrollment has grown rapidly. In just 2 years—between August 1994 and August 1996—the number of risk HMOs nationwide rose from 141 to 229 and enrollment grew by over 80 percent, from about 2.1 million to 3.8 million beneficiaries. The Congressional Budget Office projects that, under one Medicare reform scenario that would encourage beneficiaries to join HMOs, enrollment in risk HMOs and other prepaid plans could grow to 25 percent of all beneficiaries by 2002. If HCFA does not correct its rate setting and standards enforcement problems, these proposals could actually increase Medicare costs rather than control cost growth as intended.

In conclusion, although our reviews and studies and those of others have found problems with HHS' many programs, we recognize the difficulties that HHS faces in managing a large and diverse array of activities. Considering, however, the extent to which the American people rely on HHS for essential services and support, it is critical for the Department to focus on achieving its many missions as effectively and efficiently as possible. GPRA provides HHS with an excellent opportunity to orient its management toward producing the results its programs are intended to achieve and to engage in regular self-assessment. As you know, we have already committed to working with the Congress as it reviews draft and final HHS strategic and performance plans and other submissions under GPRA. We urge the administration and the Congress to use this opportunity

to provide the kind of continual oversight needed for a department of HHS' size, diversity, vulnerability, and importance.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or members of the Subcommittee might have.

Contributors

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Related GAO Products

Medicare Home Health Care Benefit (GAO/HEHS-97-70R, Feb. 11, 1997).

FDA's Mammography Inspections: While Some Problems Need Attention, Facility Compliance Is Growing (GAO/HEHS-97-25, Jan. 27, 1997).

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