

January 2003

# Major Management Challenges and Program Risks

## Department of Health and Human Services



G A O

Accountability \* Integrity \* Reliability

## A Glance at the Agency Covered in This Report

The Department of Health and Human Services is responsible for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The department includes the nation's two largest individual health insurers and is the largest grant-making agency in the federal government. Its multiple activities include

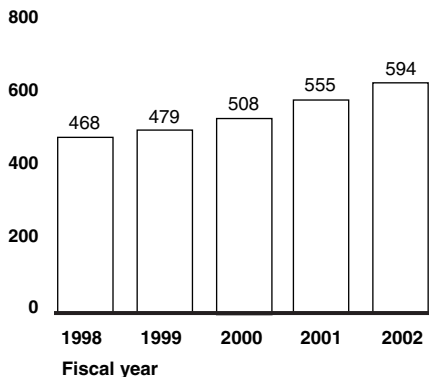
- Medicare (health insurance for elderly and some disabled Americans);
- Medicaid (health insurance for low-income people);
- infectious disease prevention, including immunization services;
- food and drug safety;
- financial assistance and services for low-income families, including Head Start;
- comprehensive health services for Native Americans;
- substance abuse treatment and prevention; and
- medical and social science research.

### The Department of Health and Human Service's Budgetary and Staff Resources

---

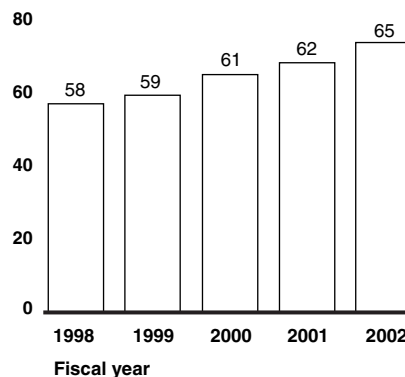
#### Budgetary Resources <sup>a, b</sup>

Dollars in billions



#### Staff Resources <sup>b</sup>

FTEs in thousands



Source: Budget of the United States Government.

<sup>a</sup> Budgetary resources include new budget authority (BA) and unobligated balances of previous BA.

<sup>b</sup> Budget and staff resources are actuals for FY 1998-2001. FY 2002 are estimates from the FY 2003 budget, which are the latest publicly available figures on a consistent basis as of January 2003. Actuals for FY 2002 will be contained in the President's FY 2004 budget to be released in February 2003.

---

## This Series

This report is part of a special GAO series, first issued in 1999 and updated in 2001, entitled the *Performance and Accountability Series: Major Management Challenges and Program Risks*. The 2003 Performance and Accountability Series contains separate reports covering each cabinet department, most major independent agencies, and the U.S. Postal Service. The series also includes a governmentwide perspective on transforming the way the government does business in order to meet 21st century challenges and address long-term fiscal needs. The companion 2003 *High-Risk Series: An Update* identifies areas at high risk due to either their greater vulnerabilities to waste, fraud, abuse, and mismanagement or major challenges associated with their economy, efficiency, or effectiveness. A list of all of the reports in this series is included at the end of this report.



Highlights of [GAO-03-101](#), a report to Congress included as part of GAO's Performance and Accountability Series

## Why GAO Did This Report

In its 2001 performance and accountability report on the Department of Health and Human Services (HHS), GAO identified key management challenges faced by HHS and its constituent agencies associated with the Medicare program, oversight of nursing homes, medical product safety and efficacy, and ensuring the well-being of children and families. The information GAO presents in this report is intended to sustain congressional attention and a departmental focus on continuing to make progress in addressing these challenges—and others that have arisen since 2001. This report is part of a special series of reports on governmentwide and agency-specific issues.

## What Remains to Be Done

HHS's management challenges remain as profound as they are diverse: the effective management of the Medicare and Medicaid programs has significant fiscal implications for the longer term, while strengthening the nation's public health infrastructure is critically important in the shorter term. HHS must further strive to obtain current and reliable data for effective program monitoring, conduct well-targeted oversight activities to safeguard billions of program dollars, and hire and retain a sufficiently skilled workforce.

[www.gao.gov/cgi-bin/getrpt?GAO-03-101](http://www.gao.gov/cgi-bin/getrpt?GAO-03-101).

To view the full report, click on the link above. For more information, contact Leslie G. Aronovitz at (312) 220-7600 or [aronovitzl@gao.gov](mailto:aronovitzl@gao.gov).

## PERFORMANCE AND ACCOUNTABILITY SERIES

### Department of Health and Human Services

## What GAO Found

**Medicare program.** Medicare remains on GAO's 2003 list of high-risk programs due to the program's size and complexity. The Centers for Medicare & Medicaid Services (CMS) continues to have difficulty refining Medicare's payment methods in ways that reward fiscal discipline while ensuring beneficiary access to care. Since 2001, the agency has made progress in estimating improper payments, collecting overpayments and conducting other financial activities, and identifying information system needs, but further improvements are needed in payment safeguard, financial, and information management activities.

**Medicaid program.** GAO has added Medicaid to its 2003 list of high-risk programs, owing to the program's size, growth, diversity, and fiscal management weaknesses. Limited oversight has afforded states and health care providers the opportunity to increase federal funding inappropriately.

**Medicare and Medicaid care oversight.** CMS has taken steps to improve nursing home oversight, but efforts to ensure quality care at nursing homes, home health agencies, kidney dialysis facilities, and other providers continue to be jeopardized by problems in the performance of state inspections, complaint investigations, and enforcement of federal standards.

**Public health emergency preparedness.** Serious problems in coordination among federal, state, and local public health agencies and in hospital and laboratory capacity could limit emergency responses. HHS is also challenged to balance basic public health needs with critical homeland security priorities.

**Medical product safety and efficacy.** While the Food and Drug Administration has stepped up the rigor of its biologics inspections, it faces several challenges in ensuring the availability, safety, and efficacy of marketed products, including vaccines, and struggles to retain its expert staff.

**Economic independence and well-being of children and families.** Oversight by HHS of the states' implementation of social service program reforms has been encumbered by limitations in states' information systems, program effectiveness measurement, and efforts to foster and disseminate research findings.

**Financial management systems, processes, and controls.** HHS has improved its financial management, but its systems and processes do not routinely generate financial information that is timely or reliable. Further, HHS cannot ensure that it can protect the confidentiality of sensitive information from unauthorized access or its systems from service disruption.

---

# Contents

---

Transmittal Letter	1
Major Performance and Accountability Challenges	2
GAO Contacts	70
Related GAO Products	71
Performance and Accountability and High-Risk Series	78

This is a work of the U.S. Government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. It may contain copyrighted graphics, images or other materials. Permission from the copyright holder may be necessary should you wish to reproduce copyrighted materials separately from GAO's product.



**G A O**

Accountability \* Integrity \* Reliability

**Comptroller General  
of the United States**

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

January 2003

The President of the Senate  
The Speaker of the House of Representatives

This report addresses the major management challenges and program risks facing the U.S. Department of Health and Human Services (HHS) as it works to carry out its multiple and highly diverse missions. The report discusses the actions that HHS has taken and that are under way to address the challenges GAO identified in its Performance and Accountability Series 2 years ago, and major events that have occurred that significantly influence the environment in which the department carries out its mission. Also, GAO summarizes the challenges that remain and further actions that GAO believes are needed.

This analysis should help the new Congress and the administration carry out their responsibility and improve government for the benefit of the American people. For additional information about this report, please contact Leslie G. Aronovitz, Director, Health Care, at (312) 220-7600 or at [aronovitzl@gao.gov](mailto:aronovitzl@gao.gov).

David M. Walker  
Comptroller General  
of the United States

---

# Major Performance and Accountability Challenges


---

The Department of Health and Human Services (HHS), with a \$460 billion budget and a workforce of more than 65,000 people, presents one of the more massive and complex management challenges in the federal government. The more than 300 federal health and social programs it oversees tangibly affect the lives and well-being of virtually all Americans and encompass some of the most costly issues facing the nation. Among its many tasks, HHS provides health insurance for millions of individuals, is responsible for ensuring quality standards are met across a number of health care settings, regulates drugs and medical devices, and administers a multipronged effort to help low-income children and families gain economic independence. HHS's fiscal year 2003 budget presentation document is entitled "Ensuring a Safe and Healthy America," and its role in this regard has been particularly significant in light of the events of September 11, 2001, and its aftermath.

With such varied and significant missions, the performance of HHS and its component agencies involves many dimensions. In our 2001 Series, we reported on the following key missions: the administration of Medicare, oversight of nursing homes, safety and efficacy of medical products, and the economic independence and well-being of children and families. These missions are principally addressed by HHS's Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Administration for Children and Families (ACF). These agencies faced challenges in obtaining current and reliable data needed to monitor programs effectively, conducting well-targeted oversight activities needed to safeguard billions of program dollars, and hiring or retaining a sufficiently skilled workforce. For Medicare, which remained on our list of high-risk programs, CMS's leadership and administrative capacity were stretched by its many responsibilities for other programs—such as oversight of Medicaid, the State Children's Health Insurance Program, and survey and certification activities for nursing homes, home health agencies, and clinical laboratories. At the same time, implementing several new Medicare payment methods introduced additional challenges to safeguarding program payments. Our work on nursing home quality found that state surveyors continued to miss or understate the seriousness of care problems that harmed residents; this occurred during a period of transition in which federal and state initiatives for improving facility inspections were beginning to be implemented. Our work on oversight of medical devices and products found shortcomings in the FDA's resource targeting strategy for inspecting device manufacturers and in monitoring adverse events that may occur after products are marketed. Our work on oversight of social service program reforms implemented by the states discussed the

substantial challenges ACF and CMS faced in getting the information needed to hold multiple state and local government agencies accountable for the use of federal funds to ensure the well-being of children and families.

Our 2003 Series considers these same missions while highlighting additional ones, as shown below.



## Performance and Accountability Challenges

---

- Provide current and future generations with a well-designed and well-administered Medicare program
- Safeguard the integrity of the Medicare program
- Enhance the fiscal and management oversight of the Medicaid program
- Improve oversight of care delivered to Medicare and Medicaid beneficiaries
- Strengthen preparedness for public health emergencies, including bioterrorism
- Ensure the safety and efficacy of medical products
- Enhance the programs that target the economic independence and well-being of children and families
- Improve financial management systems, processes, and controls

Our discussions on the administration and safeguarding of Medicare, the safety and efficacy of medical products, and the well-being of children and families include issues of congressional interest in the past 2 years and abiding challenges involving information, financial, and human capital management. New issues raised in this Series include CMS's oversight of the Medicaid program, oversight of care delivered to Medicare and Medicaid beneficiaries, the preparedness of HHS agencies for public health emergencies, and needed improvements in HHS agencies' financial

systems, processes, and controls. In brief, we make the following observations:

- *Design and administration of Medicare.* In 2001, we reported that major gaps in information about patients' health status and use of services make it difficult to set prospective payment rates at the appropriate level. CMS continues to lack adequate information to set rates and refine payment methods in ways that reward fiscal discipline while ensuring beneficiary access to care. The agency similarly lacks the information and flexible approaches needed to price medical services and products in line with market rates. We have made several recommendations to improve payment methods that the agency has not acted on.
- *Medicare payment integrity safeguards.* CMS has made improvements in assessing the level of improper payments, collecting overpayments from providers, and building the foundation for modernizing its information technology. Nevertheless, much work remains to be done, given the magnitude of its challenge to safeguard program payments. This includes more effectively overseeing Medicare's claims administration contractors, managing the agency's information technology initiatives, and strengthening financial management processes across multiple contractors and agency units. In light of these challenges and the program's size and fiscal significance, Medicare remains on our list of high-risk programs.
- *Fiscal and management oversight of Medicaid.* Our growing concern about the difficulties CMS faces in managing a program of enormous size, growth, and diversity has led us to add Medicaid to our 2003 list of high-risk programs. Key problems we have identified in recent years include schemes by some states to inappropriately leverage federal funds, state waiver programs that inappropriately increase the federal government's financial liability, and insufficient federal and state oversight to ensure that payments to health care providers are accurate and appropriate. Consistent with several of our recommendations, CMS and the Congress have taken several significant actions to curb states' inappropriate leveraging of federal funds, but waiver program approvals remain questionable and states' claims scrutiny activities are uneven.
- *Oversight of care delivered to Medicare and Medicaid beneficiaries.* In our 2001 Series, we recapped the problems identified and recommendations we made in earlier work on nursing home surveys



and other oversight activities by CMS and the states. CMS has increased its attention to improving oversight of nursing homes, but it may have done so at the expense of adequate monitoring of home health agencies, kidney dialysis facilities, and other providers serving Medicare and Medicaid beneficiaries. Vulnerable beneficiaries are not assured of adequate protections, owing to problems with the conduct of state surveys, the timeliness of complaint investigations, the strength and use of federal sanctions for noncompliance with Medicare standards, federal monitoring of state survey activities, and the adequacy of numbers of skilled surveyors.

- *Public health emergency preparedness.* Following the events of September 11, 2001, we have added public health emergency preparedness to HHS's key challenges. The department must find ways to coordinate programs that dually address critical homeland security priorities and basic public health needs and ensure that the nation's fragile public health infrastructure is strengthened at the federal, state, and local levels.
- *Oversight of medical product safety and efficacy.* While FDA has stepped up the speed of its drug approvals, its guidance to biologics manufacturers on compliance with good practices has not been sufficiently clear or made readily available. This problem has significance for the manufacture of vaccines, which are currently in short supply. We have recently made recommendations to FDA that aim at producing safe vaccine products while mitigating the effects of supply disruptions. With respect to new drugs, the speed of FDA's review and approval has improved in recent years, largely because the agency has hired more scientists to review applications, using fees collected from the drugs' sponsors. However, FDA faces several challenges in its effort to monitor the availability, safety, and efficacy of marketed products, including the difficulty of retaining its expert staff.
- *Economic independence and well-being of children and families.* HHS continues to face the challenges associated with oversight of the states' implementation of social service program reforms. These include facilitating states' efforts to implement information systems, systematically measuring the extent to which programs are serving their intended beneficiaries, and fostering efforts to conduct research and disseminate findings on program effectiveness.

- *Financial management systems, processes, and controls.* While HHS's financial statements are achieving unqualified, or "clean opinions"—indicating that the statements fairly present their information—its financial systems and processes do not routinely generate information that is timely or reliable and do not ensure that the confidentiality of sensitive information is adequately protected from unauthorized access or service disruption.

In all, HHS's management challenges are as profound as they are diverse. The long-term significance of effectively managing the Medicare and Medicaid programs cannot be overstated, as together they consume an enormous and growing share of the federal budget. Similarly compelling is the shorter-term importance of strengthening the nation's public health infrastructure in light of recent historical events and looming threats to the nation's domestic security.

---

## Provide Current and Future Generations with a Well-designed and Well-administered Medicare Program

Medicare spending growth remains one of the most pressing and complex issues facing the Congress and the nation. The program provides health insurance for people aged 65 and older, some disabled people under age 65, and people with end-stage kidney disease. In fiscal year 2001, Medicare program expenditures were about \$241 billion, accounting for about 1 of every 8 federal dollars spent that year. Based on the Medicare Trustees' 2002 annual report, spending on Medicare is expected to double as a share of the economy by 2035, which could crowd out other spending and other valuable economic activity. The program's projected growth has focused congressional attention on the need to reform Medicare. At the same time, there is considerable public pressure to expand program benefits. Although a broad consensus exists to make program changes, there is much less agreement about what the changes should be and whether they should be comprehensive or incremental. Thus, until some agreement can be reached and reforms implemented—which could take a number of years—it is imperative to concentrate on making the existing program run as efficiently as possible.

An abiding challenge for the HHS agency that administers Medicare—CMS—is to design payment methods that reward fiscal discipline while maintaining access to quality care.<sup>1</sup> CMS sets payment amounts for

---

<sup>1</sup> Until its name was officially changed July 1, 2001, CMS was called the Health Care Financing Administration (HCFA).

---

thousands of services and items, but the agency's responsibility to run the program in a fiscally prudent manner can often leave an array of interested parties—hospitals, physicians, and other providers of health care services—discontented with payment policies. Payment rates that are too low can impair beneficiary access to services and products, while rates that are too high add unnecessary financial burdens to the program. Paying appropriately requires accurate cost data and current information on access to needed services.

---

### Paying Appropriately for Medicare Services Requires Frequent and Carefully Targeted Refinements

Over the past two decades, at the Congress's direction, Medicare has implemented a series of payment reforms designed to promote the efficient delivery of services and control program spending. Some reforms required establishing set fees for individual services; others required paying a fixed amount for a bundle of services. The payment methods introduced during this time were designed to include—in addition to incentives for efficiencies—a means to calibrate payments to ensure beneficiary access and fairness to providers.

A major challenge in administering payment methods—either through fee schedules or bundled payments—involves adjusting the predetermined amounts to better account for differences in patients' needs and providers' local markets to ensure that the program is paying appropriately and adequately. Providers adapting to Medicare's payment methods have often raised concerns about payment adequacy. As Medicare has sought to set more efficient prices, payment adjustments for cost differences of providers and services become more important, and timely and accurate information about beneficiaries' use of services becomes paramount.

CMS has had mixed success in making refinements to payment methods. The agency's difficulties stem, in part, from insufficient data on providers' costs and beneficiaries' use of services. Such information provides the systematic evidence needed to determine whether payments are adequate and care is accessible. Medicare's experience with payments for home health agencies, skilled nursing facilities, and physicians' fees illustrate the importance of current, robust data on which to base or support payment policies, as the following examples illustrate.

- *Payments for skilled nursing facility services.* After the implementation of the prospective payment system as required by the Balanced Budget Act of 1997 (BBA), skilled nursing facilities contended that Medicare's new payments were not adequate and brought intense public pressure to undo BBA payment reforms. Our September 2000 study found that, in the aggregate, payments to facilities were adequate but that there was the potential for facilities serving a disproportionate share of high-cost patients to be disadvantaged.<sup>2</sup> The payment methodology that CMS developed may not adequately target high-cost patients and distribute payments accordingly. However, as CMS lacked the data needed to calibrate payments sufficiently in line with the expected needs of patients served, the Congress twice provided several increases in payments, requiring that some of the increases be temporary until CMS could make adequate refinements to the payment methodology and others expired on October 1, 2002. CMS does not expect to obtain the data needed to propose refinements before 2004.<sup>3</sup>
- *Payments for home health services.* In previous work, we noted that the design of the prospective payment method for home health services contained flaws that would likely generate excessive payments for some home health agencies. In addition, it lacked a means to provide financial relief to other home health agencies that served a disproportionate share of high-cost patients. CMS did not adopt our 2000 recommendation that would minimize excessive payments to some home health agencies and extreme losses for others.<sup>4</sup> In their comments on our report, officials expressed concern that the industry needed time to adapt to the new payment method without further complications. We believe that adequate time has elapsed and that our recommendation is warranted, given the number of home health agencies and beneficiaries affected.

---

<sup>2</sup> U.S. General Accounting Office, *Nursing Homes: Aggregate Medicare Payments Are Adequate Despite Bankruptcies*, [GAO/T-HEHS-00-192](#) (Washington, D.C.: Sept. 5, 2000).

<sup>3</sup> U.S. General Accounting Office, *Skilled Nursing Facilities: Providers Have Responded to Medicare Payment System by Changing Practices*, [GAO-02-841](#) (Washington, D.C.: Aug. 23, 2002).

<sup>4</sup> U.S. General Accounting Office, *Medicare Home Health: Prospective Payment System Will Need Refinement as Data Become Available*, [GAO-HEHS-00-9](#) (Washington, D.C.: Apr. 7, 2000) and U.S. General Accounting Office, *Medicare Home Health Care: Prospective Payment System Could Reverse Recent Declines in Spending*, [GAO-HEHS-00-176](#) (Washington, D.C.: Sept. 8, 2000).

- *Payments for physician services.* Following a 5.4 percent reduction in Medicare's payments to physicians in 2002—a reduction imposed by a statutorily mandated formula—representatives of the physician community voiced concerns about continued participation in the Medicare program. An official of the American Medical Association testified that the 2002 reduction could lead to serious beneficiary access problems, citing examples of physicians and nurse practitioners in various states who said they would no longer be able to accept Medicare patients. In our view, however, whether beneficiaries are experiencing problems getting access to physician care across localities cannot be determined through anecdotes. Rather, CMS needs the capacity to generate adequate, timely and relevant data regarding access to ensure that payment policies that impose fiscal discipline are not compromising access.<sup>5</sup>

---

### CMS Has Difficulty Calibrating Payments for Medical Products in Line with Market Prices

Setting payments appropriately for medical products has also been challenging for CMS, because Medicare's payment approaches lack the flexibility to keep pace with market changes.<sup>6</sup> Medicare's method of paying for medical equipment and supplies is through fee schedules that remain tied to suppliers' historical charges to the program rather than market prices. Similarly, Medicare's method of determining outpatient drug payments is based on list prices, not prices that purchasers actually pay for the drugs. Under these approaches, Medicare often pays higher prices than other payers for medical products.

---

<sup>5</sup> U.S. General Accounting Office, *Medicare Physician Payments: Spending Targets Encourage Fiscal Discipline, Modifications Could Stabilize Fees*, [GAO-02-441T](#) (Washington, D.C.: Feb. 14, 2002).

<sup>6</sup> U.S. General Accounting Office, *Medicare: Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs*, [GAO-02-833T](#) (Washington, D.C.: June 12, 2002).

---

Medicare Often Pays Higher  
Prices for Medical Products  
Than Other Payers

The Congress introduced fee schedules for medical equipment and supplies in 1987. Statewide fees were determined on the basis of average supplier charges from previous years and have been updated for inflation in some years, but not in others. However, mechanisms to adjust fees to reflect marketplace changes have been lacking, and disparities between some fee schedule amounts and market prices have developed over time. For example, until 1998, Medicare paid much more for home oxygen equipment and supplies provided to patients with pulmonary insufficiency than did the Department of Veterans Affairs (VA), even after accounting for differences between Medicare and the VA program. We estimated that Medicare could have saved over \$500 million in fiscal year 1996 if it had paid rates for home oxygen comparable to those paid by VA.<sup>7</sup> The BBA reduced Medicare's home oxygen fees by 25 percent effective in 1998 and by an additional 5 percent in 1999.

Medicare's payments for the limited number of outpatient drugs that it covers have been similarly excessive, although the methodology used to determine payment amounts is somewhat different. Medicare's supplementary medical insurance, called part B, covers roughly 450 outpatient drugs—generally those that cannot be self-administered and are related to physicians' services, such as cancer chemotherapy, or are provided in conjunction with covered durable medical equipment, such as inhalation equipment. The rates paid for most covered outpatient drugs are equal to 95 percent of the national average wholesale price (AWP). However, the term AWP is not defined in law or regulation. Essentially, drug manufacturers determine AWP, and there are no requirements or conventions that AWP reflect the price of any actual sale. Data have repeatedly demonstrated that the price manufacturers give to physicians and suppliers may be significantly lower than the AWP on the manufacturers list. As a result, Medicare's payments often significantly exceed market prices—that is, the transaction prices actually paid by other purchasers.

---

<sup>7</sup>U.S. General Accounting Office, *Medicare: Comparative Information on Medicare and VA Patients, Services, and Payment Rates for Home Oxygen*, [GAO/HEHS-97-151R](#) (Washington, D.C.: June 6, 1997).

Our September 2001 report documented the excess that Medicare paid in 2001 for outpatient drugs compared to the prices widely available to physicians and pharmacy suppliers.<sup>8</sup> For example, the physician-administered drugs we examined (which included drugs used in chemotherapy) had widely available discounts ranging from 13 to 34 percent of AWP. Two physician-administered drugs had discounts of 65 and 86 percent. Pharmacy suppliers also purchased drugs at prices considerably lower than Medicare payments. For example, two inhalation drugs accounting for most of Medicare payments to pharmacy suppliers had widely available discounts averaging 78 percent and 85 percent of AWP. In this report, we made several recommendations to improve drug pricing that CMS has not acted upon.

#### Medicare's Ability to Adjust Payments for Medical Products Is Limited

Despite instances of wide disparities between market prices and Medicare's payment rates for equipment, supplies, and outpatient drugs, CMS is not in a position to take prompt action. To lower unreasonably high payment rates, the agency must follow a lengthy and complicated regulatory process for making payment adjustments. The BBA gave the agency authority to use a streamlined process to adjust payment rates for most medical equipment items, supplies, and outpatient drugs. However, the agency's attempt to use this authority drew intense industry criticism, in part because the agency acted before it responded to public comment on how it would implement the authority. The Congress then prohibited use of either the original or streamlined regulatory process until the agency addressed public comments and issued a final rule. In our 2000 report on this subject, we made several recommendations regarding improved data collection for rate-setting purposes.<sup>9</sup> On December 13, 2002, CMS issued an interim final rule that included provisions related to our recommendations. The rule will become effective on February 11, 2003.

To experiment with other ways of setting Medicare's payments for medical equipment, supplies, and outpatient drugs, the BBA provided authority for the agency to conduct demonstration projects using competitive bidding.

---

<sup>8</sup> U.S. General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, [GAO-01-1118](#) (Washington, D.C.: Sept. 21, 2001).

<sup>9</sup> U.S. General Accounting Office, *Medicare Payments: Use of Revised "Inherent Reasonableness" Process Generally Appropriate*, [GAO/HEHS-00-79](#) (Washington, D.C.: July 5, 2000).

Evidence from two competitive bidding projects suggests that, for most of the items selected, competition might provide a tool that facilitates setting more appropriate payment rates that result in program savings. By competing a small number of products and limiting the geographic area of competition, CMS took steps to manage the process, which included monitoring beneficiary access and product quality. To use competitive bidding outside of a demonstration, however, CMS would require not only new authority but substantial administrative preparations, as competing a larger number of products nationally would entail bidding in multiple markets and monitoring access and quality once prices had been set.

---

### CMS Efforts Limited in Obtaining Data-Driven Feedback to Assess Payment Policies

Analyses of data on providers' transaction costs and beneficiaries' use of Medicare services can provide a window on the effectiveness or shortcomings of a given payment policy. When such information is lacking or when the data collected are not viewed as sufficiently reliable and timely, CMS has a difficult time defending its position to adjust payments downward. These adjustments can mean, in the aggregate, tens of millions of dollars or more annually to affected parties, so external pressures to maintain or raise payments are substantial.

Our work on payments for covered outpatient drugs illustrates the value of accurate information for determining appropriate payments. For example, the Congress has used the leverage of state Medicaid programs and other public purchasers to allow VA to secure verifiable information on actual market transactions by private purchasers—specifically, the prices that drug manufacturers charge their “most-favored” private customers. To enable VA to determine the most-favored customer price, by statute, manufacturers that wish to sell their products to the public agencies involved are required to provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery practices. The manufacturers provide this information and agree to offer VA and other government purchasers drugs at these prices, subject to a VA audit of their records<sup>10</sup> in order to have state Medicaid programs—which, jointly with the federal government, pay for health care for about 44 million low-income Americans each year—cover their drugs. The way Medicare

---

<sup>10</sup> VA negotiates prices for and purchases medical equipment, supplies, and drugs through the Federal Supply Schedule. Federal Supply Schedule prices are available to any federal agency that directly procures pharmaceuticals or medical equipment and supplies.



pays for drugs likely makes it inappropriate for the program to seek the most-favored customer prices as VA does. However, detailed information on market prices that is available to VA would assist Medicare in setting appropriate, efficient payment amounts for covered drugs.

No matter how payments are set, monitoring to ensure that beneficiaries continue to have access to items and services is a critical management activity. CMS's monitoring of access in its small competitive bidding demonstration was required by statute and is not routinely done when the agency makes fee schedule revisions. As with physician payments, the importance of using current and reliable data to make payment policy decisions cannot be overstated because of the impact such decisions have on beneficiaries, providers, and taxpayers alike.

---

## Safeguard the Integrity of the Medicare Program

Medicare was among the first programs that we designated in 1990 to be at high risk of considerable losses to waste, fraud, abuse, and mismanagement because of the program's vast size and complex administrative structure. It remains among the programs that we consider high-risk. In fiscal year 2001, Medicare paid about \$241 billion for a wide variety of inpatient and outpatient health care services for 40 million elderly and disabled Americans. To help administer claims for the traditional program, CMS—the agency within HHS responsible for Medicare—contracts with about 38 health insurance companies. These claims administration contractors process about 900 million claims submitted each year by nearly 1 million hospitals, physicians, and other health care providers. For the 5 million beneficiaries enrolled in Medicare's managed care option—Medicare+Choice—CMS has 155 contracts with managed care plans, which are paid a fixed monthly fee to provide needed Medicare services to enrolled beneficiaries.

CMS has an important responsibility to safeguard fee-for-service and Medicare+Choice payments and ensure that beneficiaries receive needed program services. It must effectively oversee the claims administration contractors that run the day-to-day operations of Medicare's traditional program and the managed care plans that provide services to beneficiaries enrolled in Medicare+Choice.

In recent years, our work has cited various weaknesses in CMS oversight of contractors and managed care plans. The agency has addressed some of them, but considerable oversight and other agency management challenges remain. These include the need to reduce improper payments costing the

government billions of dollars annually; improve communication with Medicare providers; monitor managed care plans to ensure that services are provided as promised and payments made are appropriate; improve financial management processes and controls; modernize the agency's information technology to carry out basic management functions effectively; and make adequate preparations in the event that the Congress grants CMS new contracting authority.

---

### Better Contractor Performance Information Could Help CMS Oversee Efforts to Address Improper Claims Payments

Since 1996, annual audits by HHS's Office of the Inspector General (OIG) have found that Medicare contractors have improperly paid claims worth billions of dollars. These claims successfully passed through Medicare's highly automated claims processing systems because the claims appeared valid on their face; the claims were disputed only after pertinent patient medical records were reviewed or when requested medical record documentation was not provided to the auditors. Such improperly paid claims may not be spotted by contractors, because they appear to be properly billed, and it is neither practical nor efficient for a contractor to request and conduct detailed reviews of medical records for more than a tiny fraction of claims, given the volume Medicare processes.

The magnitude of estimated improper payments (over \$12 billion in fiscal year 2001), coupled with the difficulty in detecting them, underscores the importance of having the agency and its contractors implement effective strategies to address improper payments. The OIG reports on Medicare's aggregate payment errors have spurred CMS to improve its efforts to safeguard Medicare payments by developing more targeted payment accuracy information. To do so, the agency instituted the Comprehensive Error Rate Testing (CERT) program, which is designed to measure the accuracy of payment decisions made by each contractor. The CERT benchmark will allow CMS to hold the contractors accountable for their claims payment performance and help them target remedial actions to address certain problematic billing practices of the providers in their jurisdictions. CMS currently has comparative information on the payment accuracy of the four carriers that pay claims for durable medical equipment. CERT information on all of the claims processing contractors is expected to be available by June 2003.

CERT is expected to provide a much needed measure of contractor performance. The agency's previous oversight of its contractors had several failings, including reliance on unverified contractor-supplied performance information, limited checking of contractors' internal

management controls, and oversight staff developing inconsistent evaluation reviews and conducting uneven follow-up. In recent years, the agency has responded to our work by improving contractor oversight and adopting several of our recommendations. The agency has developed a more consistent and strategic oversight approach that is directed by a management board composed of senior executives. The agency has also assigned additional staff to monitor the contractors. It has created teams responsible for evaluating contractors, to ensure more consistency, and has separated that function from day-to-day responsibilities for managing contractors. In addition, CMS contracted for a more intensive review of selected contractors' management controls and has increased its oversight of financial management activities.

---

**Balance Needed to Reduce  
Provider Burden While  
Guarding Program  
Payments**

While the agency has focused on specific contractor activities that it believes need improvement, other activities, such as communication with providers, may also need attention.<sup>11</sup> Claims administration contractors play a major role in communicating with physicians and other providers who have raised concerns that Medicare's efforts to provide information on billing rules fall short of their needs for clear explanations. Our February 2002 report on Medicare's communication with physicians found that physicians often do not receive complete, accurate, clear, or timely guidance on Medicare billing and payment policies.<sup>12</sup> At the contractors we studied, we found significant shortcomings in the printed materials, Web sites, and telephone help lines that contractors use to provide information and respond to physicians' questions. (See table 1.) CMS agreed that it needed to improve communications with physicians. While it elaborated on initiatives it currently has under way, it has not taken action on our specific recommendations.

---

<sup>11</sup> U.S. General Accounting Office, *Medicare Management: CMS Faces Challenges to Sustain Progress and Address Weaknesses*, [GAO-01-817](#) (Washington, D.C.: July 31, 2001).

<sup>12</sup> U.S. General Accounting Office, *Medicare: Communications With Physicians Can Be Improved*, [GAO-02-249](#) (Washington, D.C.: Feb. 27, 2002).

**Table 1: Problems Identified in Medicare’s Communications With Physicians**

**Contractors’ communications**

Contractor bulletins were unclear and difficult to use	CMS relies heavily on contractors’ bulletins to officially notify physicians of their responsibilities and requirements under Medicare law, regulations, and guidelines. Our review of bulletins issued in March through July 2001 by 10 randomly selected contractors found many were unclear and poorly organized, requiring physicians or their staff to scan each article to determine whether it was relevant. Bulletins sometimes provided information too late for physicians to comply with new rules in a timely manner—overall, 6 of 10 contractors did not communicate at least one billing change before its scheduled implementation date.
Contractor call centers provided incomplete or incorrect answers	We made 61 calls to provider inquiry lines at 5 call centers and asked 3 questions from the “frequently asked questions” on contractors’ Web sites. We reported that only 15 percent of the call center answers were complete and accurate after validating our findings with CMS. Lack of standardization of the technological resources available at the call centers affected staff ability to quickly retrieve appropriate information to help answer the questions.
Contractor Web sites varied in usability and content	Most of the Web sites we reviewed lacked features that would allow physicians to quickly and directly obtain the information they needed—such as search engines. Only 2 of the 10 Web sites that we reviewed complied with all of CMS’s content requirements.

**CMS’s management and oversight**

CMS has set few standards for communications with physicians	CMS has not established substantive requirements regarding the content and readability of bulletins to physicians, the completeness and accuracy of call center responses, or the clarity and timeliness of Web-based communications.
CMS monitoring is not sufficient	The agency has not undertaken comprehensive reviews of the quality and usefulness of carriers’ bulletins or Web sites. In 2001, it began to evaluate provider call centers, but the team we observed focused on performance standards that addressed procedures—such as how long the physician was left on hold—rather than the quality of the answers provided. CMS attributed some of its monitoring shortcomings to lack of resources.

Source: GAO analysis.

Physicians have also raised questions about whether the program’s enforcement of payment rules has imposed too great an administrative burden on those billing Medicare. Our May 2002 report on Medicare claims scrutiny found that the vast majority of physician practices—at least 90 percent in fiscal year 2001—had no claims selected for medical review by their contractor.<sup>13</sup> Medical reviews involve a detailed examination of a sample of claims by clinically trained staff and require that physicians submit medical records to substantiate their claims. For the relatively few practices that had any claims reviewed, the contractors typically requested

<sup>13</sup> U.S. General Accounting Office, *Medicare: Recent CMS Reforms Address Carrier Scrutiny of Physicians’ Claims for Payment*, [GAO-02-693](#) (Washington, D.C.: May 28, 2002).

---

patients' medical records for no more than two claims during the year. In an independent assessment that we sponsored, carriers' reviews were found to be highly accurate in their decisions to deny, reduce, or pay claims in full. The overall level of accuracy was consistent across the three carriers at about 96 percent.

---

**Adequate Monitoring of  
Medicare+Choice Plans  
Needed to Ensure  
Adherence to Program  
Rules**

Medicare+Choice, the program designed to allow beneficiaries to enroll in different types of health plans, is subject to different program integrity challenges from those of the traditional fee-for-service program because the payment methods differ. Managed care organizations (MCO) that offer Medicare+Choice health plans receive a fixed monthly payment for each beneficiary enrolled rather than for each service delivered. CMS must ensure that MCOs provide the services to enrollees that are required by their Medicare contracts and are paid appropriately for the beneficiaries enrolled.

If Medicare's payments are expected to exceed an MCO's costs of providing Medicare-covered services combined with the amount of profit or additional revenue that it would normally earn on non-Medicare contracts, the MCO must use the difference either to provide additional services, reduce beneficiary cost sharing, save in a noninterest-bearing escrow account to maintain benefit or cost-sharing levels in future years, or a combination of these. Beginning in 2003, an MCO may pay all or part of a beneficiary's Medicare part B premium. For each Medicare+Choice health plan that an MCO intends to offer, an MCO must annually submit a benefit package proposal—called the adjusted community rate proposal—for CMS review and approval. The rate proposal identifies the health services an MCO will provide to enrollees, the estimated costs of providing these health services, and the estimated payments the MCO will receive. This information is used to ensure that Medicare-covered services will be provided and that excess payments will be used as intended.

The Balanced Budget Act of 1997 required CMS to annually audit the Medicare rate proposals and supporting financial records of at least one-third of the participating MCOs and required that we monitor these audit activities. In October 2001, we reported that, according to CMS, the rate proposal audits showed that 59 of 80 health plans had misreported key financial data or had accounting records too unreliable to support their estimates, but that CMS did not have a follow-up mechanism in place to resolve the issues identified in the audits.<sup>14</sup> Misreporting these data can affect the benefits provided to enrollees, the amounts enrollees must pay in cost sharing, or the amounts the MCO contributes to an escrow account used to maintain benefit or cost-sharing levels in the future. Even small dollar amounts can have a major impact at the MCO level. For example, by underestimating its expected revenue by only \$0.61 per member per month, one MCO with three health plans failed to spend over \$500,000 that could have been used to provide additional benefits, lower enrollee cost sharing, or help maintain future benefit or cost-sharing levels. We recommended that CMS (1) calculate the net effect of errors identified by plans and the overall impact of rate proposal audit findings and adjustments, (2) develop and implement a mechanism to address audit findings in a timely manner, and (3) communicate to each MCO the corrective actions needed for future rate proposal submissions.

CMS disagreed with our finding that the audit program lacked a formal resolution process, stating that we had not given the agency sufficient credit for efforts to develop an audit follow-up process. CMS also stated, in response to our recommendation for better communication with MCOs, that it had adequately communicated by providing MCOs copies of the audit reports. Subsequently, CMS developed a draft action plan to establish a follow-up mechanism for the rate proposal audits. Informally, we provided the agency feedback on areas that we believed would strengthen its draft plan. We will continue to monitor CMS actions in this area.

---

<sup>14</sup> U.S. General Accounting Office, *Medicare+Choice Audits: Lack of Audit Follow-up Limits Usefulness*, [GAO-02-33](#) (Washington, D.C.: Oct. 9, 2001).

---

---

## Financial Management Has Improved, But Considerable Work Remains

As we have reported previously, the agency's and its contractors' financial management procedures for payment of Medicare claims, recovery of overpayments, and recording of financial transactions had certain weaknesses,<sup>15</sup> but the agency has made progress in reducing them. Since the audit of its fiscal year 1999 financial statements, CMS has received an unqualified or "clean" opinion from its auditors each year and has taken significant steps to implement our recommendations for financial management improvements. CMS has developed a comprehensive financial management plan, improved its reviews of contractors' financial management activities, made financial management procedural guidance available to Medicare contractors through an Internet-accessible database, and improved procedures for handling audit findings. The agency is also assessing the skills and competencies needed to manage Medicare's finances. Despite this progress, CMS needs to take further steps to better analyze contractor financial data to ensure it is accurately reported and to develop financial systems, processes, and controls that routinely generate reliable, useful, and timely information for agency decisionmakers.

---

<sup>15</sup> U.S. General Accounting Office, *Major Management Challenges and Program Risks, Department of Health and Human Services*, [GAO-01-247](#) (Washington, D.C.: January 2001).

CMS's efforts to collect Medicare overpayments illustrate both its successes and its challenges. We reported previously that the agency and its claims administration contractors had not been effective at collecting some of the money owed to Medicare, which generally resulted from overpayments made to providers. At the end of fiscal year 1999, over \$7 billion of debt had accumulated on contractors' books as accounts receivable that were neither collected nor written off. Responding to our recommendation to comply with the terms of the Debt Collection Improvement Act of 1996,<sup>16</sup> Medicare contractors have referred over two-thirds of the \$6 billion in reported delinquent debts eligible for referral to the Department of the Treasury or its designee for collection by the third quarter of fiscal year 2002. Nevertheless, as we reported in February 2002, CMS has difficulty ensuring that contractors consistently make these referrals, as the agency lacks a comprehensive database tracking all its debts, has inaccurate information on the debts its limited database contains, and has not developed a comprehensive debt referral plan.<sup>17</sup> To help ensure that CMS promptly refers all eligible delinquent Medicare debts to Treasury or its designee for collection, we made a number of additional recommendations to CMS. The agency is currently addressing most of these recommendations.

At the heart of its financial management problems, CMS does not have a single integrated financial accounting system that contains information to track its financial activities. Lack of such integrated information impedes efforts to monitor contractors' activities, safeguard payments, and prepare yearly financial statements. CMS has begun to develop a project to integrate its financial management systems, but the complexity of this project has been challenging, involving information from over a billion transactions a year and multiple claims contractor systems and data centers. Recognizing the complexity of this project, CMS has established a separate program management office and has hired a systems integrator contractor with expertise to oversee software development and system integration. A pilot test running the new software parallel to the old is scheduled to begin at two claims administration contractors in April 2004,

---

<sup>16</sup> U.S. General Accounting Office, *Medicare: HCFA Could Do More to Identify and Collect Overpayments*, HEHS/AIMD-00-304 (Washington, D.C.: Sept. 7, 2000).

<sup>17</sup> U.S. General Accounting Office, *Debt Collection Improvement Act of 1996: HHS's Centers for Medicare & Medicaid Services Faces Challenges to Fully Implement Certain Key Provisions*, [GAO-02-307](#) (Washington, D.C.: Feb. 22, 2002).



with full implementation of the integrated system scheduled for September 2007.

We have identified other financial management issues, which are addressed in a separate HHS management challenge discussed in this report—“Improve Financial Systems, Processes, and Controls.”

---

Information Technology and  
Management Challenges  
Undermine Efforts to  
Strengthen Program

Financial management is not the only Medicare function hampered by information technology (IT) shortcomings. CMS officials are in the process of modernizing the technology that supports Medicare’s core missions of claims processing and payment, program oversight, and administration of participating health plans. The agency’s information systems are of central importance in carrying out these missions, but the major systems are aged and often incompatible with one another. Because of their design, these systems do not assemble or maintain data in a user-friendly format and are therefore difficult to query. Quick answers are largely unavailable to such questions as the effects of payment policies on beneficiaries’ access to services, the adequacy of payments to providers, or the status of debt owed the program because of uncollected overpayments. Further, auditors of CMS’s fiscal year 2001 financial statements noted numerous weaknesses in the security of Medicare information systems that could result in unauthorized access to sensitive Medicare data. These weaknesses are not only troublesome from a data integrity standpoint but also because of the potential financial loss that could occur through security breaches.

CMS’s IT planning and management processes—intended to increase the likelihood that systems development and implementation will be cost effective and successful—have certain shortcomings that increase the risk that some of its modernization efforts could fail to achieve agency mission goals. In September 2001, we reported that CMS had developed a blueprint documenting its existing and planned IT environments—also known as its enterprise architecture—but this blueprint was missing essential detail.<sup>18</sup> We also found that the agency’s process for managing its IT investments was missing key review, approval, and evaluation steps to ensure that CMS invests in projects that succeed in supporting Medicare program management needs. On the basis of these findings, we recommended that

---

<sup>18</sup> U.S. General Accounting Office, *Medicare: Information Systems Modernization Needs Stronger Management and Support*, GAO-01-824 (Washington, D.C.: Sept. 20, 2001).

---

CMS fully develop its architecture and strengthen its IT management process.

Agency officials reported that they have begun implementing guidance for an improved IT management process. This process will require additional review of the benefits, risks, and technical appropriateness of all projects, except ongoing operations. Officials also reported conducting additional IT development activities, making further progress on detailing the agency's IT architecture, and assessing human capital needs and skill gaps. To address weaknesses in the security controls of the agency's and its contractors' ongoing system operations, CMS has implemented additional requirements for contractors to document compliance with security requirements, increased its scrutiny of contractor internal management controls related to IT systems security, and begun an agencywide mandatory training effort for CMS staff on IT security procedures. Despite CMS's progress, strong and continued management attention will be needed as the agency strives to maintain current program services while working to build more effective and secure information support.

---

### Medicare Contracting Reform Looms as a Potentially Large Management Challenge

Managing Medicare effectively depends on finding a balance between flexibility and accountability—that is, granting the agency adequate flexibility to act prudently while ensuring that it can be held accountable for its decisions. CMS has lacked some of the ability to act prudently in managing claims administration because, under Medicare's statute and regulations, its contracting authority and practices differ from those embodied in standard federal contracting regulations. There is generally no full and open competition for entities to obtain contracts to process Medicare claims; CMS is limited to choosing among health insurers to process Medicare claims; apart from some recent exceptions, contractors must cover the full range of claims processing and related activities; and the agency is limited in its ability to terminate contracts.

Over the years, the agency repeatedly proposed legislation to obtain new contracting authority and flexibility. In June 2001, we testified that Medicare could benefit from Congress removing CMS's contracting limitations and from use of full and open competition in the selection of claims administration contractors.<sup>19</sup> In June 2002, the U.S. House of Representatives passed a bill that would amend the Medicare statute to require competitive contracting and allow CMS greater flexibility in its contracting arrangements.

Should CMS be granted more flexible contracting authority that relies on competition, effectively managing the transition to a different contracting environment will be a major new challenge for the agency in the coming years. As we reported in our 2001 assessment of high-risk federal programs, federal agencies that manage large procurements of contracted services—such as the departments of Energy and Defense—have had difficulties with contract acquisition and management.<sup>20</sup> These have included problems such as cost and schedule overruns and failure to oversee contractors and hold them accountable. CMS would need to carefully plan and manage its own contracting efforts, while being attentive to best practices in the field, to avoid some of the pitfalls experienced by other agencies.

---

## Enhance the Fiscal and Management Oversight of the Medicaid Program

Medicaid is a program jointly funded by the federal government and the states that pays for both acute health care and long-term care services for over 44 million low-income Americans, about half of whom are children and over one-quarter of whom are aged, blind, or disabled. The program's day-to-day administration is conducted by the states and is overseen at the federal level by CMS in HHS. The challenges inherent in overseeing a program of Medicaid's size, growth, and diversity, combined with the open-ended nature of the program's federal funding, puts the program at high

---

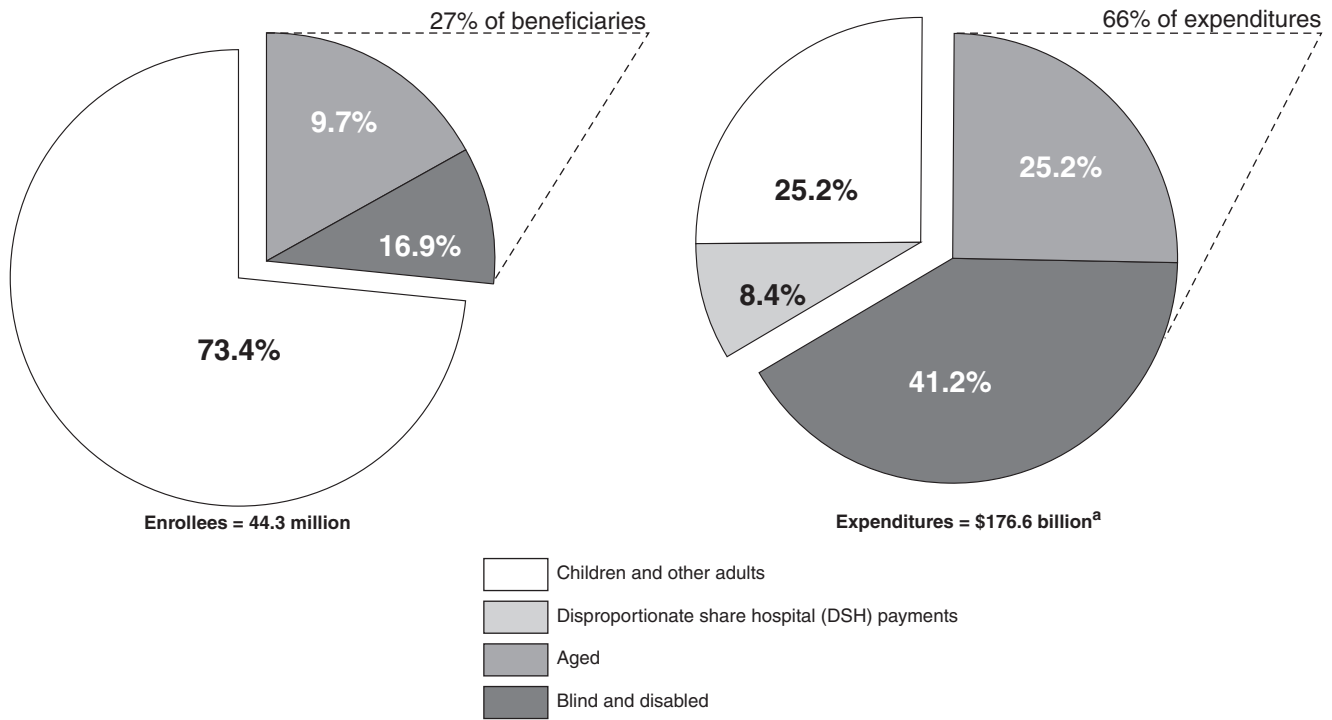
<sup>19</sup> U.S. General Accounting Office, *Medicare Contracting Reform: Opportunities and Challenges in Contracting for Claims Administration Services*, [GAO-01-918T](#) (Washington, D.C.: June 28, 2001). Also see U.S. General Accounting Office, *Medicare: Comments on HHS' Claims Administration Contracting Reform Proposal*, [GAO-01-1046R](#) (Washington, D.C.: Aug. 17, 2001) and U.S. General Accounting Office, *Medicare Contractors: Despite Its Efforts, HCFA Cannot Ensure Their Effectiveness or Integrity*, [GAO/HEHS-99-115](#) (Washington, D.C.: July 14, 1999).

<sup>20</sup> U.S. General Accounting Office, *High-Risk Series: An Update*, [GAO-01-263](#) (Washington, D.C.: January 2001).

risk for waste and exploitation and we have added Medicaid to our 2003 list of high-risk programs. Consider the following program characteristics:

- *Size.* In fiscal year 2001, federal and state Medicaid expenditures totaled \$228 billion. The federal share was about 57 percent, representing 7 percent of all federal outlays. Medicaid is the third largest social program in the federal budget (after Social Security and Medicare) and the second largest budget item for most states (after education), accounting for about 20 percent of states' total expenditures.
- *Growth.* The Congressional Budget Office projects that Medicaid spending will grow each year on average by 8.8 percent, which would more than double total Medicaid spending in 9 to 10 years. Recent Medicaid expenditure growth has been fueled in part by escalating prescription drug and hospital costs, as well as by "creative" state financing schemes that inappropriately increase the federal share of Medicaid expenditures without increasing the states' contribution. Future program spending will also be significantly affected by the growth of the population aged 65 and older, which is expected to more than double by 2040. Individuals who are aged, blind, or disabled already incur significantly higher Medicaid expenditures than those in other eligibility categories. These individuals represent 27 percent of all Medicaid beneficiaries, but they account for 66 percent of expenditures, as shown in figure 1. As the share of the population that is aged grows, so too will associated long-term care expenditures, thus exerting additional financial pressures on future federal and state budgets.

**Figure 1: Medicaid Expenditures Are Disproportionately for Individuals Who Are Aged, Blind, or Disabled**



Source: CMS enrollment and expenditure data, fiscal year 2000, the most recent year for which data are available by type of beneficiary.

<sup>a</sup>Total Medicaid fiscal year 2000 expenditures were \$209.6 billion; expenditures in the figure do not include administrative expenses (\$10.6 billion) and other expenses that could not be attributed to particular beneficiary populations.

- *Diversity.* Within broad federal guidelines, states have considerable flexibility in how they administer their Medicaid programs. Each state determines the amount, duration, and scope of covered services; establishes eligibility guidelines; sets payment rates; and develops its own administrative and delivery system structure. While federal statute requires states to cover certain populations and services under Medicaid, states may choose to expand eligibility or add benefits that the statute defines as optional.<sup>21</sup> About two-thirds of total Medicaid expenditures are attributable to services for optional populations and benefits. The resulting variation across states in populations covered and benefits offered makes Medicaid less like a single program than like 56 separate programs—the 50 states, the District of Columbia, Puerto Rico, and U.S. territories—thus posing significant complexities for federal oversight.
- *Open-ended federal funding.* Under Medicaid, the federal share of each state's expenditures, also called the federal match, is based on a formula that is linked to each state's per capita income and its total program spending. The federal liability for program expenditures is open-ended, as there is no limit on state spending for services that are covered under a CMS-approved state Medicaid plan. In 2001, the federal shares ranged from 50 to 77 percent of a state's total Medicaid expenditures.

Our concerns about the program's risks have been heightened by our work in recent years, which confirms the program's vulnerability to exploitation and mismanagement. Through this work we have identified key problems, including

- schemes by some states to inappropriately leverage federal funds,
- state waiver programs that inappropriately increase the federal government's financial liability, and
- insufficient federal and state oversight to ensure that payments to health care providers are accurate and appropriate.

---

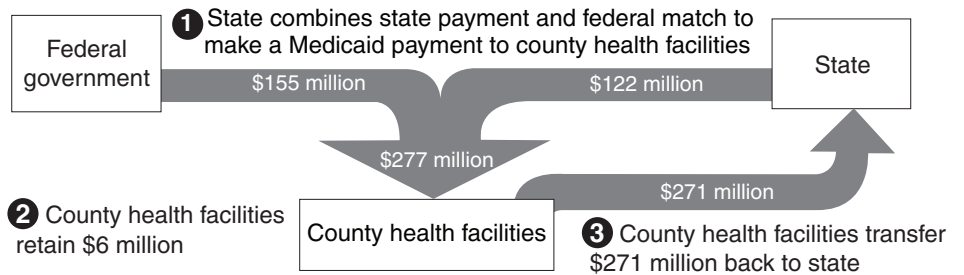
<sup>21</sup> Mandatory services include inpatient and outpatient hospital care; physician services; nursing home care; lab and x-ray services; immunizations, and other early and periodic screening, diagnostic, and treatment services for children; family planning services; health center and rural health clinic services; and nurse midwife and nurse practitioner services. Services that are optional include outpatient prescription drugs, institutional care for persons with mental retardation, personal care, and dental and vision care for adults.

We have also identified consistent weaknesses with federal oversight of the quality of care in nursing homes, which receive billions of dollars annually in Medicaid funds. These issues are addressed in a separate section in this report entitled “Improve Oversight of Care Delivered to Medicare and Medicaid Beneficiaries.”

### State Financing Schemes Often Inappropriately Increase Federal Medicaid Payments

For more than a decade, states have used various financing schemes to inappropriately generate excessive federal Medicaid matching funds while their own share of expenditures has remained unchanged or decreased. Using statutory and regulatory loopholes, some states have created the illusion that they have made large Medicaid payments to certain providers, such as county health facilities, in order to generate federal matching payments. In reality, generally through electronic funds transfers, the states have only momentarily made payments to these providers, as states have required the payments to be returned. In some cases, states have used these federal payments for purposes other than Medicaid. Figure 2 illustrates a financing arrangement under which a state can inappropriately increase federal matching funds with no outlay of state funds.

**Figure 2: One State’s Arrangement to Increase Federal Medicaid Payments Inappropriately**



Source: GAO analysis.

In figure 2, a state makes Medicaid payments totaling \$277 million to certain county health facilities; the total includes \$155 million in federal funds at a matching rate of 56 percent (step 1). On the same day that the county health facilities receive the funds, they transfer all but \$6 million of the payments back to the state, which retains \$271 million—a net gain of \$149 million over the state’s original outlay of \$122 million (steps 2 and 3).

Although the Congress and CMS have repeatedly acted to curtail abusive financing schemes when they have come to light, states have consistently developed new variations to this basic approach. Each variant has the same result: the state's share of program expenditures is shifted to the federal government, while federal Medicaid payments escalate, with no assurances that the excessive federal payments are used for valid Medicaid expenditures for covered beneficiaries. Table 2 describes various abusive Medicaid financing arrangements used by states and the actions taken by the Congress and CMS to curtail them.

**Table 2: Federal Actions to Address Inappropriate State Financing Arrangements**

Financing arrangement	Description	Action taken
Payments to state health facilities	States made excessive Medicaid payments to state-owned health facilities, which subsequently returned these funds to the state treasury.	In 1987, HCFA issued regulations that established payment limits specifically for inpatient and institutional facilities operated by states.
Provider taxes and donations	Revenues from special taxes on hospitals and other providers and from provider "donations" were matched with federal funds and paid to the providers, which returned most of the federal payment to the state.	The Medicaid Voluntary Contribution and Provider-Specific Tax Amendments of 1991 essentially banned provider donations and placed a series of restrictions on provider taxes.
Disproportionate share hospital (DSH) payments	DSH payments compensate hospitals that care for a disproportionate number of low-income patients. Unusually large DSH payments were made to certain hospitals, which returned the bulk of the state and federal payments to the state.	The Omnibus Budget Reconciliation Act of 1993 placed limits on which hospitals could receive DSH payments and capped both the amount of DSH payments states could make and that individual hospitals could receive.
DSH payments to state mental hospitals	A large share of state DSH payments were paid to state-operated psychiatric hospitals, where they were used to pay for services not covered by Medicaid or were returned to the state treasury.	The Balanced Budget Act of 1997 limited the proportion of a state's DSH payments that can be paid to state psychiatric hospitals.
Payments to local government health facilities	In an effort to ensure that Medicaid payments are reasonable, the federal statute and regulations prohibit Medicaid from paying more than what Medicare would pay for comparable services. This upper payment limit (UPL) applies to total payments and not individual services. As a result of the aggregate upper limit, states were able to make large supplemental payments to a few local public health facilities, such as hospitals and nursing homes. The local government health facilities then returned the bulk of the state and federal payments to the state.	The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 required HCFA to issue a final regulation that established a separate payment limit for each of several classes of local government health facilities. In 2002, CMS issued a regulation that further lowered the payment limit for local public hospitals.

Source: GAO analysis.

Financing schemes that some states use to inappropriately generate federal payments can spread quickly to other states. For example, from 1990 to



1992, payments that compensate hospitals that care for a disproportionate number of low-income patients—called DSH payments—spiked from \$1 billion to over \$17 billion. After limits were put on DSH payments, states found that they could exploit the upper payment limit (UPL) on Medicaid payments to conduct other financing schemes. From 1999 to 2000, the number of states using UPL-related schemes grew from 12 to 28, accounting for an estimated \$5.8 billion in excessive federal payments.

The savings estimated to result from curbing states' exploitative practices demonstrate the enormous impact state financing schemes can have on the federal budget. Prompted by our testimony,<sup>22</sup> CMS's 2001 regulation reducing the federal government's financial liability under the UPL provision is estimated to save \$55 billion over 10 years, and the related 2002 CMS regulation is estimated to yield an additional \$9 billion over 5 years.

While the Congress and CMS have often acted promptly to address Medicaid financing schemes once they become apparent, new variations continue to emerge and recommendations to reduce problems remain open. Consequently, we recommended that the Congress consider legislation to prohibit making Medicaid payments to a government-owned facility that exceed the facility's costs. Additionally, CMS has responded, in part, to recommendations made by OIG regarding UPL-related payments, but CMS requirements do not provide for the capture of information to determine whether local government health facilities transfer the federal funds they receive back to the state.

States that have relied on abusive practices to maximize federal funds as a staple for state financing are feeling the budgetary pressure from the loss of these funds. Experience shows that some states are likely to look for other creative means to supplant state financing, making a compelling case for the Congress and CMS to sustain vigilance over federal Medicaid payments.

---

## Waiver Demonstration Programs May Increase Federal Liability for Program Expenditures

HHS oversight responsibilities include ensuring that states' demonstration programs do not put the federal government at risk for spending more on Medicaid than it would without such programs. The Secretary of HHS has broad authority under section 1115 of the Social Security Act to waive certain statutory provisions and allow states to conduct Medicaid research

---

<sup>22</sup> U.S. General Accounting Office, *Medicaid: State Financing Schemes Again Drive Up Federal Payments*, GAO/T-HEHS-00-193 (Washington, D.C.: Sept. 6, 2000).

and demonstration projects that test new ideas for delivering services and covering more people. Specifically, HHS can grant section 1115 waivers to provide federal funds for services and populations not otherwise eligible for federal matching payments. States have commonly used section 1115 waivers to provide health care coverage to Medicaid beneficiaries by enrolling them in managed care plans. An estimated 20 percent of all Medicaid funds are now spent under section 1115 waivers. Historically, HHS and the Office of Management and Budget (OMB) have required that the demonstration projects be budget neutral—that is, the demonstration’s cost to the federal government should be no more than it would have been without the waiver.

Since the mid-1990s, however, adherence to budget neutrality requirements has eroded, as HHS and OMB have permitted states to use questionable methods that in our view do not demonstrate budget neutrality. The section 1115 waivers of two states, approved in 2002, are estimated to cost the federal government at least \$330 million more than if the waivers had not been approved. For one state’s waiver, HHS and OMB continued a practice that we first identified and objected to in 1995, which allows states to disregard substantial new costs that would be incurred under the waiver, thus making it easier to demonstrate budget neutrality. For the other state’s waiver, HHS and OMB allowed the state to include impermissible costs to raise the level of costs estimated without the waiver, thus making it easier to claim that the demonstration was budget neutral and, in turn, inflating the share for which the federal government would be liable. Our concern is that additional states have requested similar waivers that are currently under review. In 2002, we recommended that HHS ensure that only valid methods are used to demonstrate budget neutrality,<sup>23</sup> but the department and OMB continue to allow states to disregard significant amounts of waiver costs when demonstrating budget neutrality.

---

<sup>23</sup> U.S. General Accounting Office, *Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns*, [GAO-02-817](#) (Washington, D.C.: July 12, 2002).

---

---

Shortcomings in Routine  
Oversight and Financial  
Management Practices  
Leave Program Dollars Ill-  
Protected

One of CMS's major challenges is to balance state flexibility with accountability by providing adequate oversight of states' Medicaid financial transactions. Our work shows that CMS falls short in providing the level of oversight required to ensure accountability. In particular, CMS lacks important policies and procedures to guide either its own or states' financial oversight activities, and it has not provided consistent guidance to the states on appropriate payment practices.

Our studies of federal and state agencies' controls over payments have identified systemic weaknesses in both federal and state oversight of Medicaid expenditures.<sup>24</sup> Our February 2002 report on federal oversight of state claims for reimbursement found that CMS's general policies and systems for financial oversight of state Medicaid programs were limited. For example, CMS did not (1) have a sound method for identifying areas at high risk for improper payments, (2) have performance standards for review of state expenditures, or (3) conduct analyses of trend information on the amount and type of Medicaid expenditures deferred or disallowed to monitor performance of this oversight activity. To address these weaknesses, we recommended a range of approaches to strengthen internal controls and target limited resources. In response, CMS has initiated steps to improve financial reviews of Medicaid, which are in the planning and early implementation stages.

In examining states' controls over improper payments to providers, we found that states' efforts to identify billing errors and abusive billing practices have been generally limited and only modestly funded. In our June 2001 review, half the states reported spending no more than one-tenth of 1 percent of program expenditures on activities to safeguard program payments. No state had requested the full amount of federal funds available for antifraud efforts because they would have had to increase their own spending to receive the full federal match.

The potential benefit of improving oversight has been demonstrated by individual state efforts. In our June 2001 study, we reported that, since July 1999, California had identified \$58 million in fraudulent billings by 115 providers and pharmaceutical and durable medical equipment wholesalers

---

<sup>24</sup> U.S. General Accounting Office, *Medicaid Financial Management: Better Oversight of State Claims for Federal Reimbursement Needed*, GAO-02-300 (Washington, D.C.: Feb. 28, 2002), and U.S. General Accounting Office, *Medicaid: State Efforts to Control Improper Payments Vary*, GAO-01-662 (Washington, D.C.: June 7, 2001).

and suppliers; it was investigating an additional 300 entities for suspected fraud that could exceed \$250 million. Kentucky's analysis of claims payment data identified \$137 million in overpayments to providers between January 1995 and June 1998.

Our review of certain Medicaid services provided to children through their schools also demonstrates the importance of heightened scrutiny over Medicaid expenditures.<sup>25</sup> In one state alone, there were \$324 million in disallowed claims involving school-based services for three-and-a-half years ending in fiscal year 2001.<sup>26</sup> Some claims were for services not covered by Medicaid or for services provided to non-Medicaid-eligible children. Our work also showed that, in some states, very little of the federal reimbursement went directly to schools where the services were provided. Some schools ended up with as little as \$7.50 for every \$100 that the state claimed for reimbursement, once states retained a portion of federal reimbursements and private consulting firms were paid contingency fees.

Our review of Medicaid reimbursement in schools further illustrated CMS's weaknesses in providing the states sufficient program guidance and oversight. Schools in some states conduct outreach for the Medicaid program and perform certain diagnostic, screening, and therapy services. States that provide school-based Medicaid services must establish procedures for determining Medicaid's payment rates within broad federal guidelines.<sup>27</sup> Under these procedures, the costs identified for schools' administrative services claims must be directly attributable to supporting the Medicaid program. Our analysis found that some CMS regions failed to (1) provide clear and consistent guidance to schools and state agencies or (2) exercise adequate controls over the approval of claims for school-based services. Our recommendations to CMS on school reimbursement were aimed at improving the agency's oversight and establishing more consistent policies about what constitutes appropriate payment. CMS has taken action to clarify reimbursement policies addressing administrative

---

<sup>25</sup> U.S. General Accounting Office, *Medicaid in Schools: Improper Payments Demand Improvement in HCFA Oversight*, GAO/HEHS/OSI-00-69 (Washington, D.C.: Apr. 5, 2000).

<sup>26</sup> This fiscal year 2001 figure updates the findings in our April 2000 report.

<sup>27</sup> States must abide by the cost allocation principles described in OMB Circular A-87, which requires, among other things, that costs be "necessary and reasonable" and "allocable" to the Medicaid program.

---

activities performed by certain medical personnel in schools. Additionally, CMS is developing more consistent guidance for its regions, states, and schools regarding what is allowable in submitting claims for reimbursement for school-based administrative costs from Medicaid.

---

## Improve Oversight of Care Delivered to Medicare and Medicaid Beneficiaries

CMS and the states share oversight responsibility for thousands of health care providers that deliver care directly to Medicare and Medicaid beneficiaries. (See table 3.) In response to congressional requests, in recent years we have reviewed oversight efforts for three of these types of providers—nursing homes, home health agencies, and kidney dialysis facilities—that provide critical and often life-saving care to nearly 4.5 million vulnerable individuals and that receive over \$70 billion annually in Medicare and Medicaid payments. Providers become eligible for federal reimbursement for services provided by adhering to federal quality standards, including statutory, regulatory, and other requirements designed to help ensure that patients receive appropriate care or treatment and are protected from harm. To ensure that providers remain eligible for federal funding, CMS contracts with state agencies to conduct periodic inspections, called surveys, of the providers' services. CMS, in turn, is charged with overseeing the adequacy of states' activities in monitoring providers' performance.

**Major Performance and Accountability  
Challenges**

**Table 3: Providers Required to Meet Federal Quality Standards, Survey Frequency, and Budgeted Federal Survey Expenditures**

<b>Provider</b>	<b>Number of providers</b>	<b>Survey frequency (as required by statute or CMS)</b>	<b>Budgeted federal survey expenditures, fiscal year 2003</b>
Nursing homes	16,582	Every year (statute)	\$352,100,492
Home health agencies	6,944	Every 3 years (statute)	25,469,304
Intermediate care facilities for the mentally retarded	6,693	Every year (CMS)	38,623,812
Accredited hospitals	4,461	1% per year (CMS)	5,528,523
Kidney dialysis facilities	4,266	Every 3 years (CMS)	8,049,312
Ambulatory surgical centers	3,532	Every 6 years (CMS)	2,482,379
Rural health clinics	3,296	Every 6 years (CMS)	1,285,470
Outpatient physical therapy	2,930	Every 6 years (CMS)	1,430,167
Hospices	2,316	Every 6 years (CMS)	3,977,717
Nonaccredited hospitals	1,551	Every 3 years (CMS)	7,615,329
Portable X-ray suppliers	645	Every 6 years (CMS)	157,029
Comprehensive outpatient rehabilitation facilities	564	Every 6 years (CMS)	293,220
Other direct survey costs <sup>a</sup>			10,359,246
<b>Total</b>			<b>\$457,400,000<sup>b</sup></b>

Source: CMS.

Note: Other providers, including organ procurement organizations, community mental health care centers, and psychiatric residential treatment facilities, require surveys by either CMS or state surveyors, but funding for these surveys is not included in the survey budget. In addition, a small proportion of the roughly 160,000 clinical laboratories are required to be surveyed, but these laboratories pay for the surveys themselves through fees instead of federal appropriations and are therefore not included in budgeted federal survey expenditures.

<sup>a</sup>Other direct survey costs are funds provided to state survey agencies, but CMS is unable to allocate these costs among specific provider types.

<sup>b</sup>Total does not reflect the sum of the provider amounts because of rounding.

In response to our recent findings and recommendations on the need to improve the quality of care provided by nursing homes, home health agencies, and kidney dialysis facilities, CMS has increased its attention to improving oversight of survey activities, especially for nursing homes. While this additional attention to nursing home oversight is warranted, CMS may have shifted its focus and resources to nursing homes at the expense of adequate oversight of home health agencies, kidney dialysis facilities, and other providers serving Medicare and Medicaid beneficiaries. As such, CMS confronts significant management challenges—first, ensuring that its monitoring of compliance with federal quality standards by myriad providers is effective and consistent across its 10 regional offices, and second, ensuring that the 51 state survey agencies take appropriate actions to enforce federal quality standards and protect beneficiaries. Specifically, our work on federal and state oversight of survey activities points to problems with the conduct of state surveys, the timeliness of complaint investigations, the strength and use of federal sanctions for providers' noncompliance with Medicare standards, federal monitoring of state survey activities, and survey staffing.<sup>28</sup>

---

### Quality of Care Is Uncertain Because Some Providers Are Surveyed Infrequently and Deficiencies Are Understated

State survey problems we have noted frustrate efforts to determine quality of care. Some providers are surveyed very infrequently and, while state surveyors identified a disturbing prevalence of quality problems in nursing homes, we have noted repeatedly that the seriousness of deficiencies was understated. During our reviews of the home health agency survey process, we reported similar problems with understated deficiencies. We noted flaws in the following areas for the three providers:

- *Nursing homes.* Because of weaknesses in the survey process, state surveyors often missed or understated serious deficiencies, masking the actual extent to which residents are harmed or placed in danger. The 1.6 million elderly and disabled nursing home residents, often very dependent or incapacitated, may be totally reliant on nursing home staff for medical care as well as assistance with basic activities of daily living,

---

<sup>28</sup>U.S. General Accounting Office, *Nursing Homes: Sustained Efforts Are Essential to Realize Potential of the Quality Initiatives*, GAO/HEHS-00-197 (Washington, D.C.: Sept. 28, 2000); U.S. General Accounting Office, *Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issues*, GAO-02-382 (Washington, D.C.: July 19, 2002); and U.S. General Accounting Office, *Medicare Quality of Care: Oversight of Kidney Dialysis Facilities Needs Improvement*, GAO/HEHS-00-114 (Washington, D.C.: June 23, 2000).

such as dressing, grooming, and eating. Our work since 1998 has demonstrated that state surveyors failed to identify serious nursing home care deficiencies or classified such deficiencies, including weight loss, dehydration, pressure sores, and incontinence, at an inappropriately low severity level. In independent reviews conducted to evaluate the quality of state survey agencies' performance, CMS's surveyors often identified serious deficiencies where state surveyors did not. Factors contributing to the understatement of deficiencies included lack of sufficient rigor in the survey process and nursing homes' ability to predict the timing of their surveys so that, if a home chooses to do so, it may conceal problems. In response to our recommendations, CMS has introduced strengthened survey methods to spot serious deficiencies, but is still developing important additional steps. To reduce survey predictability, CMS has varied the starting times of surveys, but this change has had limited effectiveness.

- *Home health agencies.* Patients receiving home health care are homebound, may have little contact with anyone except home health staff, and are therefore often isolated and vulnerable to poor care. Surveys of home health agencies are required less frequently than those of nursing homes—a minimum of once every 3 years as opposed to annually—and branch offices, constituting about one-quarter of home health locations, generally escape routine scrutiny. Some agencies must be surveyed annually if, for example, they have had prior serious deficiencies, but about half of these agencies did not receive required annual surveys. A home health agency survey is less comprehensive than a nursing home survey in that CMS does not require surveyors to review about half of the conditions for participating in Medicare, including assessing the quality of skilled nursing care. Although state surveyors identified a small proportion of home health agencies with deficiencies that either harmed or could harm patients, we found evidence that such problems also were understated. Moreover, two states accounted for over two-thirds of serious deficiencies reported nationwide, suggesting that states have disparate survey practices that may not consistently capture the actual status of quality. We found deficiencies in some states documented at a lower level of seriousness than similar deficiencies in other states that were documented as harming or potentially harming patients. In July 2002, we recommended several steps CMS could take to improve the home health agency survey process, including strengthening reviews of branch offices. The following month CMS began assigning these offices identification numbers to improve oversight.



- *Kidney dialysis facilities.* Dialysis facilities treat more than 280,000 patients suffering from end-stage renal disease, an irreversible state of kidney impairment that requires either a transplant or regular dialysis. If performed improperly, dialysis can cause serious complications or even death; many dialysis patients are especially vulnerable because they are elderly and have other conditions, such as diabetes. No statutory requirements exist for the frequency of state surveys of dialysis facilities, and the number of facilities surveyed each year declined steadily during the 1990s. For instance, in 1999, only 11 percent of existing facilities received a recertification survey, compared with 52 percent in 1993. The limited frequency of surveys made it impossible for us to determine the exact extent to which dialysis facilities were in compliance with federal quality requirements. However, 15 percent of the most recent surveys conducted at the time of our 2000 review identified deficiencies severe enough, if uncorrected, to warrant terminating participation in Medicare. In fiscal year 2001, CMS received additional funding that resulted in its increasing the number of facilities surveyed annually to one-third and indicated that, again, 15 percent of the facilities surveyed had at least one deficiency severe enough to lead to termination, if uncorrected.

---

### Many States' Complaint Intake and Investigation Processes Are Ineffective

Complaint investigations are an important opportunity for state survey agencies to intervene promptly when care problems are reported. This is especially true given the varying frequency with which surveys are conducted for different types of providers. The ability to lodge complaints against providers—whether by patients, family members, or caregivers themselves—and to have them resolved promptly is an essential aspect of protecting patient health and safety. Our reviews of nursing home and home health agency oversight revealed continuing weaknesses with complaint investigation practices in many states, including problems with the filing of complaints and the timeliness of state investigations.

In reviewing the nursing home and home health agency complaint investigation processes for several states, we identified numerous shortcomings, including complaint hotlines that were not easily accessible, not publicized, limited to in-state callers, or that had no voice mail capability; states that required or encouraged written complaints over telephone calls; investigations of apparently serious complaints that were delayed because they were assigned a low investigation priority; and information systems that were inadequate for properly monitoring the status of complaint investigations. CMS currently has a complaint

improvement project under way that is designed to strengthen and improve the nursing home complaint process. CMS expects to determine how the findings from this project can be applied to other providers as well and to issue guidance for states' complaint investigation processes.

---

### CMS's Use of Sanctions Does Not Ensure Provider Compliance

Although sanctions can be an important enforcement tool, CMS does not use the full array of sanctions available. CMS uses a broad array of sanctions to penalize nursing homes that repeatedly harm residents or fail to correct deficiencies within certain time frames. Sanction options for nursing homes include, among others, assessing monetary penalties and denying Medicare payments for new admissions, in addition to termination from the program. In contrast, CMS limits its sanctions for home health agencies and kidney dialysis facilities to termination from the program, despite statutory authority and direction to do more. Termination—or, in reality, the threat of termination—is an all-or-nothing option that is limited in effectiveness. Under this sanction, a provider can avoid termination by taking short-term corrective action to show compliance when a surveyor revisits the facility, thus stopping the termination process. Deficient facilities often temporarily return to, but do not necessarily remain in, compliance.

We believe that using termination as the sole sanction option does not prevent a cycle of recurring noncompliance. In many states, we found home health agencies that had corrected their deficiencies, but were found to have serious problems shortly afterward. Some of these home health agencies had serious deficiencies cited in the same quality-of-care category on three of four surveys, yet were still participating in Medicare. Although the length of time between surveys of dialysis facilities makes it difficult to determine how quickly and how often they slip out of compliance, the results of our review suggested a similar pattern. For instance, almost 40 percent of dialysis facilities with deficiencies on their most recent survey also had a deficiency with at least one of the same requirements on their last survey. More than half of them had two or more such repeat deficiencies.

Since 1987, CMS has had statutory authority to use an array of sanctions other than termination for home health agencies comparable to those used for nursing homes. However, CMS has not implemented this authority, as it was required to do by 1989, nor followed our 1997 recommendation to implement additional sanctions for home health agencies that are repeatedly out of compliance with Medicare participation requirements.

Thus, we suggested in 2002 that the Congress consider giving CMS a new deadline for implementing additional sanctions for home health agencies. Although CMS also has broad authority to implement most sanctions for dialysis facilities, it does not have the authority to assess civil monetary penalties, except under one specific condition. In 2000, we suggested that the Congress consider authorizing CMS to assess similar monetary penalties on dialysis facilities as are imposed on nursing homes that have severe or repeated deficiencies. For its part, CMS is in the process of developing a rule and procedures to strengthen sanction procedures for one quality standard associated with dialysis care.

---

### CMS Oversight of State Survey Agencies Is Inadequate to Identify Systemic Problems

CMS and its 10 regional offices are responsible for ensuring that state survey agencies effectively identify and resolve problems with provider quality of care. Our work has consistently identified weaknesses in CMS's monitoring efforts. Although CMS had data available to assist in monitoring state performance of nursing home surveys, it instead relied heavily on states' self-evaluation—essentially allowing states to write their own report cards on the adequacy of surveyors' inspections or complaint investigations. CMS has responded to our recommendations to strengthen its state nursing home oversight by initiating annual assessments of each state's compliance with specific performance requirements and by making greater use of survey data. Additional management attention would further strengthen these efforts and ensure greater consistency across CMS's regional offices. CMS's oversight of home health agencies has been less stringent, with limited use of the numerous tools it has available for monitoring states' nursing home surveys.

To improve its monitoring of state nursing home survey activities, in 2001, CMS began producing and using reports from its numerous databases and established an annual state performance review process. As part of the annual performance review, it identified seven specific performance standards that states are required to meet, for example, survey timing, deficiency documentation, and complaint investigation criteria, and assessed each state's compliance with each standard. Our ongoing work is examining the results of this review, and we will comment on it in a future report.

Another important component of CMS's oversight activities is monitoring its new January 2000 requirement that states refer to CMS for immediate sanction those nursing homes that were found on successive surveys to have harmed one or more residents. This policy was implemented at our

recommendation to eliminate the practice of continually allowing such homes a grace period to correct deficiencies and thus escape sanctions indefinitely. Our ongoing work also will address the extent to which CMS has monitored states' compliance with this new policy.

CMS's oversight of states' home health agency surveys is particularly important because a new prospective payment system introduced in October 2000 not only encouraged home health agencies to provide care more efficiently but also created a situation in which reducing services increases net revenues. Yet, CMS does not routinely review whether states are complying with key statutory, regulatory, or other requirements, such as annually surveying home health agencies with serious deficiencies and ensuring that sample sizes of medical records and patient visits meet minimum federal standards. Moreover, CMS does not assess the adequacy of state agency surveys of home health agencies by conducting its own on-site comparative survey at a sample of agencies shortly after the state's survey. CMS is statutorily required to perform such surveys for nursing homes and is currently planning to more than double the number of these surveys. We recently suggested to the Congress that it require CMS to perform similar surveys of home health agencies. Although CMS is poised to conduct annual reviews of state compliance with federal home health survey requirements, the limited areas it selected for its first such review in 2002 did not focus on critical issues requiring more immediate attention, such as ensuring that home health agencies with serious deficiencies are surveyed annually and that states assign complaints to appropriate categories so that investigations are timely. In response to our recommendations, CMS has proposed taking some limited steps to improve oversight of home health agency surveys.

---

### Staffing Issues Create Human Capital Challenges to Meeting Survey Quality Requirements

CMS and state survey agencies face an increasingly difficult challenge to ensure that experienced survey staff—generally registered nurses—are available to assess quality of care across the multitude of providers serving Medicare and Medicaid beneficiaries. Some states indicated that the numbers of their survey staff were inadequate to meet expanding survey requirements, including complaint investigations, and therefore planned to hire additional surveyors. However, we were informed that it could take as long as 3 years for newly hired surveyor staff to gain sufficient knowledge and experience to perform their jobs well and independently. We found that, for home health agencies, a substantial number of surveyors assigned during 2000 in some states we reviewed had neither taken the basic training

course that CMS offers nor acquired substantial on-the-job experience by conducting home health agency surveys.

State officials cited surveyor turnover as a reason they must often rely on relatively inexperienced surveyors to conduct surveys. In addition, CMS has expressed concern that the economic downturn in the past 2 years may have affected state budgets, to the extent that states are unable to ensure that sufficient numbers of skilled staff are available to survey providers as required. We have ongoing work that addresses, among other things, states' ability to maintain a well-trained and experienced surveyor workforce in order to meet their obligations to the federal government to assess the quality of care provided to public beneficiaries.

---

## Strengthen Preparedness for Public Health Emergencies, Including Bioterrorism

Enhancing preparedness for public health emergencies has become an important national and local priority since the attacks of September 11, 2001, and the subsequent anthrax incidents. Federal, state, and local governments and the private sector share responsibility for improving emergency preparedness. While responding to a public health emergency, such as a natural disaster or a bioterrorist attack, is initially a local responsibility, the federal government helps support these efforts. The private sector also plays an important role in preparedness because many clinical laboratories and hospitals are privately owned and the blood industry is privately managed.

HHS, among other federal agencies, provides funding and assistance to state and local jurisdictions to improve their emergency preparedness and response capabilities. This includes funding and assistance to conduct laboratory testing to identify biological agents and ensure adequate treatment space in hospitals for a sudden increase in patients. The department also supports research related to emergency response and preparedness. These preparedness efforts are administered through several different agencies within HHS—the Centers for Disease Control and Prevention (CDC), which is responsible for health surveillance and coordination of response to infectious diseases, the Health Resources and Services Administration (HRSA), which provides health resources to local areas, FDA, which is responsible for the safety and efficacy of drugs and biologics such as blood, and the National Institutes of Health (NIH), which supports medical research.

Ensuring that every community, and each of the approximately 2,850 local public health agencies across the nation, meets a basic standard of

preparedness is a significant challenge. It requires sustained funding and attention, as well as substantial cooperation and coordination among multiple federal, state, local, and private sector agencies. Our reports have found significant weaknesses in key elements of the public health infrastructure that are critical to emergency response at the state and local levels. In addition, we have noted a lack of coordination among programs with responsibility for public health emergency preparedness at the local, state, and federal levels. With the recent influx of additional federal funds, responsiveness at the state and local level is changing. Although the creation of a Department of Homeland Security has the potential to streamline overall funding and oversight responsibilities for preparedness and response for certain types of emergencies, some key preparedness functions that are basic to HHS's public health and research mission remain with HHS. Therefore, HHS continues to have coordination challenges.

---

## Public Health Infrastructure Needs Strengthening

The nation's public health infrastructure, as well as related aspects of the private sector health care system, needs to be strengthened in the following areas:

- *Laboratory capacity.* Many states' public health laboratory systems were overwhelmed by the volume of testing during the initial outbreaks of West Nile virus in the northeast in the fall of 1999 and during the fall 2001 anthrax attacks.<sup>29</sup> The 1999 West Nile virus outbreak, which was relatively small, taxed the federal, state, and local laboratory resources to the point that officials told us that CDC would not have been able to respond to another outbreak had one occurred at the same time. In the West Nile outbreak of 2002, many laboratories ceased some testing because of the large volume. During the anthrax attacks in 2001, over 70,000 samples were tested in laboratories across the country. Even states in which no anthrax was found conducted emergency testing; officials in these states told us that their state laboratories were overwhelmed and that they could not have sustained the testing effort for long without their other work suffering. CDC was forced to keep its anthrax-testing laboratory operating 24 hours a day, 7 days a week, and open another laboratory to meet the demand for testing.

---

<sup>29</sup> U.S. General Accounting Office, *West Nile Virus Outbreak: Lessons for Public Health Preparedness*, GAO/HEHS-00-180 (Washington, D.C.: Sept. 11, 2000).

- *Infectious disease surveillance.* States collect data to monitor the incidence of infectious diseases, which are then reported to CDC. Some states still rely on traditional, paper-based surveillance systems that suffer from underreporting and significant time delays between diagnosis and reporting. Reliance on such outdated systems could cause delays in the recognition of a public health emergency and adversely affect its management.
- *Hospital surge capacity.* Federal, state, and local officials are concerned that the nation's hospitals and associated treatment facilities do not have enough capacity to treat a large, sudden influx of patients as might be seen in an emergency. Capacity can be limited by insufficient space in facilities such as emergency departments and intensive care units, insufficient numbers of personnel, and a lack of equipment such as ventilators. Some local officials report that they often do not have enough capacity to treat patients on a typical Friday night, much less in a large-scale emergency.
- *Blood supply.* The high volume of blood collected immediately after the September 11, 2001, attacks put a strain on the collection system and resulted in a surplus of blood.<sup>30</sup> The survivors needed little of the blood: an amount equal to one-third of the additional units of blood expired and was discarded. Although the blood supply is generally adequate, lessons learned from blood collection and usage after the September 11 attacks have prompted HHS and the blood industry to examine ways to improve how blood suppliers respond to public health emergencies.<sup>31</sup> Maintaining an adequate supply year-round is key to preparing for emergencies where blood is needed immediately. The demand for blood is increasing at the same time that new screening for additional contaminants and donor eligibility policies in response to emerging concerns about blood-borne disease transmission may reduce the pool of potential donors. Therefore, more comprehensive, long-term monitoring of the safety and adequacy of the blood supply by HHS may be needed.

---

<sup>30</sup> U.S. General Accounting Office, *Public Health: Maintaining an Adequate Blood Supply Is Key to Emergency Preparedness*, [GAO-02-1095T](#) (Washington, D.C.: Sept. 10, 2002).

<sup>31</sup> U.S. General Accounting Office, *Public Health: Blood Supply Generally Adequate Despite New Donor Restrictions*, [GAO-02-754](#) (Washington, D.C.: July 22, 2002).

- *Communications.* Serious communication problems exist between and among federal, state, and local government agencies. For example, during the West Nile virus outbreak, the CDC and New York State Department of Health databases were not linked to those in New York City, requiring laboratory results to be manually entered. Physicians, local health departments, and laboratory officials indicated that it was sometimes difficult to determine the status of patients' samples and laboratory results.
- *Human capital.* Increasing staffing of public health departments and laboratories is a top priority for enhancing preparedness in many areas. Officials told us that they did not have enough trained epidemiologists, laboratory technicians, and other professionals to respond to the anthrax incidents while meeting normal, day-to-day responsibilities such as preventing the transmission of sexually transmitted diseases.
- *Research and development.* The experiences with anthrax and the possibility of future bioterrorist attacks drew attention to a number of public health needs. These include new antibiotics and antivirals to treat infectious diseases, a next generation of vaccines to prevent infections, and tests to determine earlier in the infection cycle whether individuals have been infected.<sup>32</sup>

HHS has a number of programs designed to enhance these key elements of the public health infrastructure and increase preparedness. At the federal level, HHS has invested in expanding capacity at CDC, and NIH has launched an expanded program to develop new ways to detect, treat, and prevent diseases caused by biological agents likely to be used by terrorists. HHS also manages three efforts to provide assistance to state and local governments—CDC's Bioterrorism Preparedness and Response Program, HRSA's Bioterrorism Hospital Preparedness Program, and the Metropolitan Medical Response System in the Office of Emergency Response. These programs provide funds to state health departments and hospitals to improve the public health infrastructure at the state and local level for activities such as making capital improvements and purchasing equipment so hospitals can be better prepared for a public health emergency. These three programs alone provided a total of \$1.1 billion to state and local

---

<sup>32</sup> U.S. General Accounting Office, *Homeland Security: New Department Could Improve Coordination but May Complicate Priority Setting*, [GAO-02-893T](#) (Washington, D.C.: June 28, 2002).



governments in fiscal year 2002. An additional \$1.2 billion has been requested for this purpose for fiscal year 2003. State and local officials stressed that it is important that funding for these efforts be sustained over the long term in order to make meaningful improvements. The President's budget for fiscal year 2003 requests a total of \$4.3 billion for HHS's efforts to address bioterrorism.

---

Coordination of Public  
Health Emergency  
Preparedness Efforts  
Remains a Significant  
Challenge

Federal, state, and local government officials, as well as significant partners in the private sector, must work together to ensure that communities and the nation as a whole are prepared for a public health emergency. Our reports over the last 2 years have repeatedly found that coordination among the federal departments and agencies that have a role in preparing for emergencies, including terrorist attacks, is fragmented.<sup>33</sup> In October 2001, the Office of the Assistant Secretary for Public Health Emergency Preparedness (originally named the Office of Public Health Preparedness) was created in HHS to serve as the focal point within the department for activities relating to public health emergencies. Specifically, its mission is to direct HHS's efforts to prepare for, protect against, respond to, and recover from all acts of bioterrorism and other public health emergencies that affect the civilian population. However, coordination across departments remains a challenge; for example, vaccine research and development programs conducted by NIH require careful coordination with efforts under way at the Department of Defense to avoid duplication of the capabilities that currently exist in the federal laboratories.<sup>34</sup>

The new Department of Homeland Security has the potential to repair this fragmentation in certain areas and to reduce some of the overlap and duplication in federal programs.<sup>35</sup> However, some programs that have aspects that deal with preparedness will remain at HHS and will need to be carefully coordinated with activities of the new department. Just as with the West Nile virus outbreak in New York City—which initially was feared

---

<sup>33</sup> U.S. General Accounting Office, *Bioterrorism: Federal Research and Preparedness Activities*, [GAO-01-915](#) (Washington, D.C.: Sept. 28, 2001).

<sup>34</sup> U.S. General Accounting Office, *Homeland Security: New Department Could Improve Biomedical R&D Coordination but May Disrupt Dual-Purpose Efforts*, [GAO-02-924T](#) (Washington, D.C.: July 9, 2002).

<sup>35</sup> U.S. General Accounting Office, *Homeland Security: New Department Could Improve Coordination but May Complicate Priority Setting*, [GAO-02-893T](#) (Washington, D.C.: June 28, 2002).

to be the result of bioterrorism—when an unusual case of disease occurs, public health officials must investigate to determine whether it is naturally occurring or intentionally caused. Although the origin of the disease may not be clear at the outset, the same public health resources are needed to investigate, regardless of the source.

---

## Ensure the Safety and Efficacy of Medical Products

FDA regulates medical products with annual sales of roughly \$1 trillion that touch the lives of virtually every American. One of the agency's missions is to ensure that human and animal drugs, medical devices, and vaccines, among other products, are safe and effective. In overseeing the safety of these products, FDA requires manufacturers of drugs and devices to obtain approval before marketing their products. Once products are marketed, FDA continues to monitor product safety by collecting and analyzing hundreds of thousands of reports of adverse events related to medical product use each year. To carry out this broad mandate, FDA has about 9,000 employees. These include approximately 2,100 scientists who evaluate new product applications and about 1,100 inspectors, who ensure that the country's almost 95,000 FDA-regulated businesses comply with minimum safety and quality standards.

Over the past 2 years, our work has focused on drug review and approval issues. The speed of FDA's review and approval of new drugs has improved in recent years, largely because the Prescription Drug User Fee Act of 1992 allowed FDA to collect fees from the sponsors of new drug and biologic applications for the purpose of hiring more medical officers and other scientists to review the applications. Further, FDA has increased the rigor of its biologics industry inspections. However, FDA faces several challenges in its effort to monitor the availability, safety, and efficacy of marketed products. These include ensuring that the supply of childhood vaccines is adequate, that new drugs are adequately tested on the individuals who will use them, and that the drug approval process works efficiently without jeopardizing safety.

---

## FDA Faces Difficulties in Regulating Production of Childhood Vaccines

Immunizations are widely considered one of the leading public health achievements of the 20th century. Mandatory immunization programs have eradicated polio and smallpox in the United States and have reduced the number of deaths from several childhood diseases, such as measles, to near zero. A consistent supply of many different vaccines is needed to support this effort. However, recent childhood vaccine shortages have prompted

federal authorities to recommend deferring some immunizations and have caused states to reduce immunization requirements.

FDA's role in licensing and regulating the manufacture of all vaccines sold in the United States involves monitoring the clinical trials conducted to demonstrate that a vaccine is safe and effective and conducting periodic inspections of vaccine production facilities. FDA recently announced that it is examining its regulatory standards governing the manufacturing process to determine if reform is needed. In considering such reforms, the agency seeks to balance the need for requirements that will ensure product safety against the need to prevent unnecessary disruptions of vaccine supply.

Part of the problem is that relatively few vaccine manufacturers produce routine childhood vaccines.<sup>36</sup> Five of the eight recommended childhood vaccines have only one manufacturer each. Because long lead times are needed to produce vaccines and alter production volumes, even short-term disruptions in manufacturers' production have created significant shortages of several childhood vaccines during the last 2 years. In our recent report on vaccine shortages, we recommended that FDA take the following measures to help mitigate the effects of future disruptions on vaccine supply:

- *Provide guidance on compliance with good manufacturing practices.* In 1997, FDA began tightening its biologics industry inspections, including those of vaccine manufacturers. In a phased approach, FDA grew more rigorous in assessing manufacturers' compliance with requirements, which included, among other things, quality assurance, recordkeeping, personnel qualifications, equipment cleaning, and laboratory controls. At the same time, manufacturers reported problems with how well FDA communicated the changes in approach and expectations for compliance. In October 1999, FDA issued a compliance program guidance manual for its own staff, which could have provided manufacturers a better understanding of the scope of the inspections. However, the manual was available only on request; 3 years after its issuance, it is still not available on line, nor is it included in FDA's annual comprehensive list of guidance documents published in the *Federal Register*.

---

<sup>36</sup> U.S. General Accounting Office, *Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges*, [GAO-02-987](#) (Washington, D.C.: Sept. 13, 2002).

- *Reconsider including certain vaccines as eligible for expedited review.* A substantial number of vaccines are in the development pipeline, but the clinical trials that need to be conducted prior to obtaining a license to sell vaccine products in the United States can take years, even when the products are licensed for use in other countries. FDA's expedited review process cannot be used for most vaccines under development because the agency's policy to use this process generally applies only to the approval of new products that address an unmet medical need or represent a significant improvement in the safety and efficacy of treatment. Childhood vaccines under development usually involve an existing vaccine or a combination of existing vaccines. In our view, the recent shortages indicate a substantial unmet medical need.

---

## FDA Could Strengthen Its Drug Oversight For Specific Populations

FDA approves drugs for sale in the United States based on its determination that they are safe and their clinical benefits outweigh potential health risks. To make this decision, FDA reviews supporting data collected from several thousand patients during a drug's development. Once a drug is approved for marketing and used by potentially hundreds of thousands of patients, however, the type, rate, and severity of adverse events caused by the drug can be much different from those detected during the drug's development. In some cases, FDA or drug manufacturers have acted to remove drugs from the market that have been shown to have unacceptable health risks once they were in widespread use. Because the reaction of children and women to drugs can differ from the adult male population, it is critical that children and women continue to be included in clinical drug trials and that FDA monitor the trials for safety, efficacy, and compliance with documentation requirements.

## Labeling Drugs for Children

As directed by the Federal Food, Drug, and Cosmetic Act, FDA gives considerable attention to manufacturers' labeling of drugs, as label approval is FDA's chief means for ensuring that a drug's risks and benefits are adequately communicated to health care professionals and the public. The role of labeling is particularly important in treating children with drugs that have been approved for adults. Only about 25 percent of drugs in use today have been studied and labeled for pediatric patients.

The Congress recognized the importance of learning more about how drugs work in children by including in the FDA Modernization Act of 1997 a financial incentive for pharmaceutical manufacturers and drug sponsors to conduct pediatric studies and submit the results to FDA. The so-called “pediatric exclusivity provision” offered manufacturers an additional 6 months to be a drug’s exclusive marketer in exchange for having the drug tested for use in children. In May 2001, we reported that pediatric drug studies had increased substantially since the 1997 legislation’s enactment, but many manufacturers had not made the labeling changes detailing the appropriate dosages, risks, and benefits for children.<sup>37</sup> Such label changes provide more specific guidance regarding the effective dose for children, additional warnings about adverse events in children, and information on related medications. Of the 60 drugs that had been granted marketing exclusivity extensions, as of August 2002, only 35 of these drugs had their labels changed to incorporate findings from the research conducted to obtain the extensions.

The Congress addressed this problem when it reauthorized the pediatric exclusivity provision in the Best Pharmaceuticals for Children Act, which was signed into law in January 2002. The act created a process whereby FDA can determine that a drug is misbranded and essentially remove it from the market, if the drug manufacturer fails to make the agency’s requested labeling changes. Under the act, FDA has the authority to ensure that drug manufacturers relabel the 25 remaining drugs that were granted marketing extensions and any such drugs in the future. However, the agency is still trying to reach agreement with drug manufacturers on label changes for several of the drugs granted marketing extensions more than a year ago.

## Monitoring the Inclusion of Women in Clinical Trials

Potential sex differences in the safety and efficacy of new drugs underscore the importance of including women and men in all stages of drug development and analyzing the data for these differences. For example, in January 2001, we reported that 3 of the 10 prescription drugs withdrawn from the U.S. market in recent years induced potentially fatal cardiac arrhythmias in women more often than in men.<sup>38</sup>

---

<sup>37</sup> U.S. General Accounting Office, *Pediatric Drug Research: Substantial Increase in Studies of Drugs for Children, But Some Challenges Remain*, [GAO-01-705T](#) (Washington, D.C.: May 8, 2001).

<sup>38</sup> U.S. General Accounting Office, *Drug Safety: Most Drugs Withdrawn in Recent Years Had Greater Health Risks for Women*, [GAO-01-286R](#) (Washington, D.C.: Jan. 19, 2001).

In a July 2001 report, we found that FDA did not know how many women were included in clinical trials for new drugs, despite regulations in 1998 and 2000 requiring that safety and efficacy data be separately presented for men and women in applications for approving new drugs. In conducting our own analysis, we found that women were sufficiently represented in new drug testing, but the agency itself lacks a management system to record and track such information or monitor compliance with regulations for conducting clinical drug trials.<sup>39</sup> Such monitoring is needed to ensure that drug developers are in compliance with regulations for presenting outcome data by sex and tabulating the number of women included in clinical trials.

When clinical trials included women, neither drug developers nor FDA took full advantage of the data available to learn more about the tested drug's effects on women and to explore potential sex differences in dosing. FDA internal documents compiled on each new drug application are not required to include analyses of sex differences. Our study noted that, although about one-third of new drug applications specified that the concentrations of the drug in the bloodstream were greater in people who weighed less, such as women, FDA reviewers did not comment on the lack of dose adjustments based on sex. The potential for higher drug concentration or exposure can lead to an increased risk of adverse events for women. While FDA has taken some promising initial steps to address these deficiencies, it is important that the agency finalizes the pilot programs it has under way and give sustained attention to these management issues.

---

<sup>39</sup>U.S. General Accounting Office, *Women's Health: Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement*, [GAO-01-754](#) (Washington, D.C.: July 6, 2001).

---

---

## FDA Efforts to Reduce Drug Approval Safety Risks and Retain Expert Staff Pose New Challenges

With added resources provided through the Prescription Drug User Fee Act of 1992 and its extensions, the speed of FDA's review and approval of new drugs and biologics has increased, but the rate at which drugs have been withdrawn from the market for safety-related issues has increased as well. Our September 2002 study found that the share of drugs approved from 1997 to 2000 that have since been withdrawn has risen to 5.34 percent, up from 1.56 percent of the drugs approved from 1993 to 1996.<sup>40</sup> While differences in time periods may account in part for this change, the rise in the number of newly approved drugs entering the U.S. market increases the probability of individuals experiencing adverse drug events and puts additional pressure on FDA to ensure the safety of these products.

To address this issue, the agency plans to establish a more rigorous safety monitoring system of newly approved drugs and increase the resources devoted to tracking adverse effects from drugs already on the market. It plans to use about \$71 million over 5 years in funds permitted by the User Fee Act reauthorization for this purpose. The success of FDA's approach will likely depend on the establishment of best practices or other guidance for pharmaceutical and biotechnology industries to conduct risk assessment, risk management, and surveillance activities and the agency's ability to react promptly to the information companies are providing on risks and adverse effects.

FDA's success will also depend on how well it faces the challenge of recruiting and retaining its expert workforce, who are key to ensuring the timely review of drugs and biologics. Our September 2002 study found that, in recent years, with the exception of chemists, FDA's attrition rates for employees in its drug review process are higher than the comparable attrition rates for the same disciplines at CDC, NIH, and similar disciplines governmentwide. Specifically, FDA's studies of staff turnover found that toxicologists, pharmacologists, pharmacokineticists, and statisticians were leaving FDA to work in private industry and academia for higher salaries. The loss of staff is aggravated by the time the agency needs to hire and train replacement reviewers. FDA maintains that hiring a replacement can take up to 6 months and training a reviewer to be fully functional, from 12 to 24 months. The agency's currently employed reviewers have been forgoing training and professional development to meet statutory drug

---

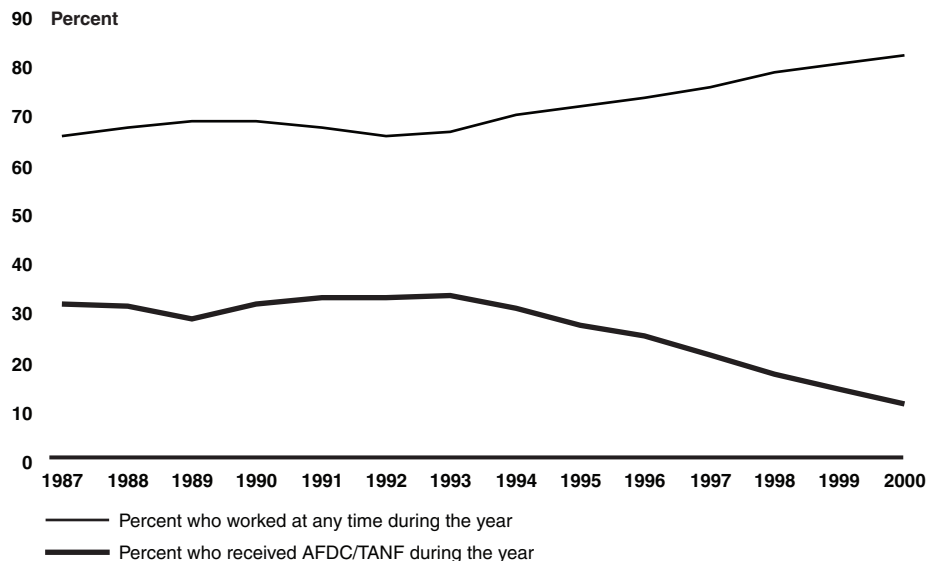
<sup>40</sup> U.S. General Accounting Office, *Food and Drug Administration: Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities*, [GAO-02-958](#) (Washington, D.C.: Sept. 17, 2002).

review time frames. FDA has implemented a number of initiatives to reduce reviewer attrition, including the payment of retention bonuses to expert staff. Such initiatives are intended to help FDA maintain the science base it needs to review increasingly complex applications for new drugs.

## Enhance the Programs That Target the Economic Independence and Well-being of Children and Families

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 significantly changed federal welfare policy by ending the federal entitlement to cash assistance and creating a new program, designed to serve as a transition to help welfare recipients enter and remain in the workforce. Under the new federal welfare program, which provides states with a block grant called Temporary Assistance for Needy Families (TANF), states were afforded wide flexibility to design programs to help needy families find, obtain, and retain jobs. In the years following the enactment of welfare reform, welfare caseloads declined dramatically and the proportion of single mothers in the workforce greatly increased, helped in part by a period of strong economic growth (see fig. 3).

Figure 3: Single Mothers' Work and Welfare Status, 1987-2000



Source: U.S. Census Current Population Survey data.



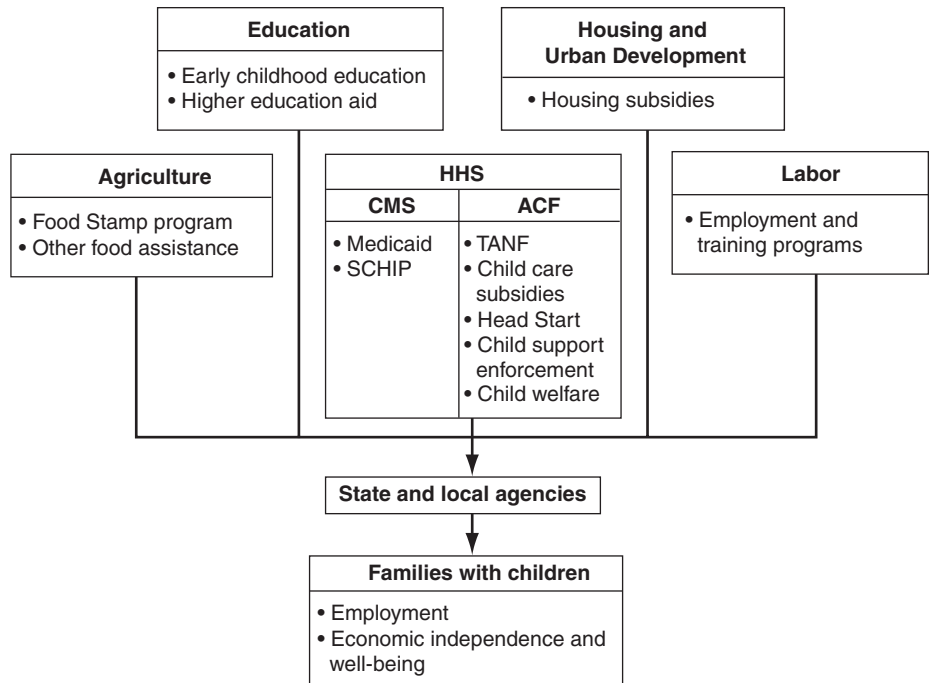
The transformation of the federal welfare program affected more than just welfare caseloads; it fundamentally altered the social safety net by refocusing federal social service programs on their role as work supports. The 1996 welfare legislation ended automatic eligibility previously available for cash assistance recipients for Medicaid, a jointly funded federal and state program that provides health insurance for eligible low-income individuals. Instead, the legislation created a separate Medicaid eligibility category not tied to recipients' eligibility for TANF. To ease their entrance into the workforce, certain families losing Medicaid as a result of employment or increased income may be eligible for up to 1 year of transitional Medicaid assistance. In April 2002, we testified on the role this benefit can play in supporting transitions from welfare to work.<sup>41</sup> In 1997, a new health insurance program—the State Children's Health Insurance Program (SCHIP)—was established to provide coverage to children living in low-income families whose incomes exceed the eligibility requirements for Medicaid.

Many other programs that HHS oversees have also undergone substantial changes at the federal, state, and local levels in recent years to help them better support working families. The 1996 law that created TANF also provided authority and funding for the Child Care and Development Fund, designed to promote maximum flexibility for states to subsidize low-income working families. The law also mandated changes to child support enforcement and child welfare. In addition to these programs administered by HHS, other federal agencies oversee a variety of programs that complement the new TANF focus on moving people into employment and enhancing family independence and well-being, as shown in figure 4.

---

<sup>41</sup> See U.S. General Accounting Office, *Medicaid: Transitional Coverage Can Help Families Move from Welfare to Work*, [GAO-02-679T](#) (Washington, D.C.: Apr. 23, 2002). The transitional Medicaid provision, which was due to expire in September 2002, has been temporarily extended to allow eligible individuals to receive this benefit through March 31, 2003.

**Figure 4: Many Programs in Separate Departments Can Enhance Family Independence and Well-Being**



Source: GAO analysis.

Although caseloads were declining during the early years of welfare reform, more recently, as the economy has weakened and recent federal and state budget constraints have increased, caseload declines have slowed. Some states have seen increased demand for a range of social service programs. These changes have renewed management challenges for HHS and its agencies—principally the Administration for Children and Families (ACF) and CMS—to develop information and information systems to help states administer these programs and ensure program accountability and effectiveness. HHS’s role is complicated by the need to balance accountability and effectiveness while allowing states the flexibility to tailor these programs to their individual circumstances.

---

---

## Improvements in Information Systems Needed to Strengthen Programs

The major changes in the social safety net since 1996 have led to demands for different types of information from state and local agencies' information systems. Agencies' information systems are no longer used simply to determine eligibility for aid, but are also needed to facilitate and track aid recipients' progress toward employment and to assess program performance. To this end, information is needed on recipients' use of a wide array of safety net services, including TANF, childcare, and other work supports.

Despite their importance, our work on states' information systems shows that state and local systems typically do not meet the changing needs of the new welfare environment. In addition, opportunities for more effective use of state information systems to identify erroneous payments to individuals and reduce program costs are not being fully realized. HHS has a role to play in the following areas:

- *Facilitating states' efforts to improve information systems.* Because of the importance of adequate automated systems to the success of welfare reform and HHS' role as the key federal agency overseeing reform, we recommended in April 2000 that HHS establish an interagency group with other federal agencies, including the Department of Agriculture, which oversees food stamps, to facilitate states' efforts to improve their automated information systems.<sup>42</sup> Officials from ACF, CMS, and the Department of Agriculture have since met regularly to improve the burdensome approval process for federal funding of systems' development and operations, one area we identified as hindering states' efforts. However, the group's progress over the last 2 years has been stymied by a lack of agreement among the agencies about what changes should be made to the approval process.

---

<sup>42</sup> U.S. General Accounting Office, *Welfare Reform: Improving State Automated Systems Requires Coordinated Federal Effort*, GAO/HEHS-00-48 (Washington, D.C.: Apr. 27, 2000).

- *Sharing information to reduce program costs.* In 1997, staff at ACF initiated the Public Assistance Reporting Information System (PARIS), an information-sharing project that can help states reduce program costs by identifying individuals who may be erroneously receiving benefits from more than one state simultaneously. However, only a third of the states participate in the project, and efforts by federal agencies to increase participation in PARIS have been minimal. ACF devotes very few resources to PARIS; and CMS, the federal agency that stands to reap the greatest savings from the project by identifying duplicate Medicaid payments made by states, has made no effort to encourage state Medicaid agencies to participate. In our 2001 report, we recommended that the Secretary of HHS direct the Administrators of ACF and CMS to formally support PARIS and provide guidance to participating states.<sup>43</sup> Although HHS agreed with the recommendation's intent, it has not taken any substantive action, arguing that the states were better able to determine procedures for engaging this system.

---

## Efforts Needed to Ensure State Accountability

Many of HHS' programs for low-income families and children are funded through grants and administered by states, localities, and other entities. This allows administrators the flexibility to tailor their programs to meet state and local needs, but poses challenges to federal efforts to maintain fiscal accountability and appropriate programmatic performance.

---

<sup>43</sup> See U.S. General Accounting Office, *Public Assistance: PARIS Project Can Help States Reduce Improper Benefit Payments*, [GAO-01-935](#) (Washington, D.C.: Sept. 6, 2001).

HHS could do more to ensure fiscal accountability among the many players involved in the new welfare environment. For example, while a system to develop annual state audit reports—designed to meet federal audit needs while minimizing the burden on states—is in place, we found that HHS does not use the reports systematically to assess accountability among the nongovernmental contractors that state and local TANF offices use to provide TANF services. In our June 2002 report, we recommended that HHS make better use of these audit reports to determine contractor problems and take actions that could help prevent and correct such problems.<sup>44</sup> Fiscal accountability for states' TANF programs would also be increased if HHS worked with the states to develop more informative and transparent reporting on unspent TANF balances. Improved reporting on these balances could enhance congressional oversight of how federal funds are being used to meet the goals of the program. We also recommended in an earlier report that HHS take steps to gather data that would allow it to monitor changes in the federal-state fiscal balance, given the dramatic changes from the welfare entitlement program to the TANF block grant and states' increased flexibility in spending decisions.<sup>45</sup> HHS agreed that such data would be essential during TANF reauthorization but expressed reservations about its ability to collect this information and has not acted to implement this recommendation.

---

<sup>44</sup> U.S. General Accounting Office, *Welfare Reform: Federal Oversight of State and Local Contracting Can Be Strengthened*, [GAO-02-661](#) (Washington, D.C.: June 11, 2002).

<sup>45</sup> U.S. General Accounting Office, *Welfare Reform: Challenges Maintaining a Federal-State Fiscal Partnership*, [GAO-01-828](#) (Washington, D.C.: Aug. 10, 2001).

HHS could also improve accountability by having performance measures and data in place to adequately assess its progress in meeting program goals. For example, in our March 2002 review of Head Start and Even Start programs, we found that one of these programs' goals is to increase literacy in families of children enrolled, but the programs did not measure their progress in this area. We recommended that HHS coordinate with the Department of Education to develop performance outcome measures for adult education and literacy programs similar to those developed for children's programs.<sup>46</sup> To date, no action has been taken to coordinate the agencies' efforts. In other work, we found that data integral to efforts to improve federal programs are not always collected. Our June 2002 review of the Adoption and Safe Families Act showed that important information to assess the act's impact on children in foster care is still unavailable, despite federal and state efforts to improve it<sup>47</sup> As a result, we recommended that HHS review the feasibility of collecting data on states' use of provisions that aim to place children in permanent situations as quickly as possible. We noted that more information could help HHS better target its limited resources to key areas where the states may need assistance in achieving the act's goals. ACF concurred and reported establishing a team to review data issues.

In some instances, HHS has used performance data to better inform resource allocation decisions. In our 2002 review of how ACF used performance information to guide resource allocation decisions, we found several examples of ways in which the agency strengthened the link between program performance and budgeting.<sup>48</sup> For example, regional staffs were able to allocate training and technical assistance funds and organize staff resources based on program performance and needs. To improve the link between performance and budgeting, ACF told us that it collaborated with grantees to focus its resources on areas where grantee and federal performance goals coincided.

---

<sup>46</sup> U.S. General Accounting Office, *Head Start and Even Start: Greater Collaboration Needed on Measures of Adult Education and Literacy*, [GAO-02-348](#), (Washington, D.C.: Mar. 29, 2002).

<sup>47</sup> U.S. General Accounting Office, *Foster Care: Recent Legislation Helps States Focus on Finding Permanent Homes for Children, but Long-Standing Barriers Remain*, [GAO-02-585](#) (Washington, D.C.: June 28, 2002).

<sup>48</sup> U.S. General Accounting Office, *Managing for Results: ACF's Effort to Strengthen the Link Between Resources and Results*, [GAO-03-09](#) (Washington, D.C.: December 2002).

---

---

## Efforts Needed to Ensure Program Effectiveness

HHS faces considerable challenges ensuring that its programs reach eligible children with services that improve their well being, in part because responsibility for enrollment and service delivery policies and practices largely reside at the state level. HHS must rely on states and localities to develop effective outreach and enrollment methods, as well as ensure that services are available for program participants. However, HHS can work with states to better identify program shortcomings and correct them.

One shortcoming of HHS's health insurance programs is that they do not always reach individuals who may need them. Although Medicaid and SCHIP provide insurance coverage to millions of low-income individuals, many eligible children are not enrolled and remain uninsured. Our September 2001 review of state Medicaid and SCHIP enrollment policies showed that differences in enrollment practices within states affect the ability of children to obtain and keep health insurance coverage.<sup>49</sup> Differing application requirements and processing times can lead to delayed coverage—and in some cases, to no coverage—if families do not return to complete additional application requirements. Well-coordinated programs, however, can minimize the effect of such differences and facilitate enrollment and continuity of care for children.

---

<sup>49</sup> U.S. General Accounting Office, *Medicaid and SCHIP: States' Enrollment and Payment Policies Can Affect Children's Access to Care*, [GAO-01-883](#) (Washington, D.C.: Sept. 10, 2001).

Once enrolled, beneficiaries in some states may face difficulty getting health care because service availability is largely dependent on providers' willingness to participate in the programs. Since physicians decide whether to participate in Medicaid and SCHIP partly on the basis of the payment rates, lower Medicaid payments relative to other payers continue to be a source of concern. Additionally, the extent to which states set specific requirements for—and routinely monitor—access to care for Medicaid and SCHIP beneficiaries often differs according to their service delivery approach, such as managed care or fee-for-service.<sup>50</sup> Moreover, federal and state governments often have limited knowledge about the extent to which enrolled individuals are getting care from Medicaid or SCHIP. For example, under Medicaid, states must provide children and adolescents under age 21 with comprehensive, periodic assessments of health, developmental and nutritional status, as well as treatment for conditions identified—called Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services. Despite their importance, our July 2001 review of EPSDT found that states had unreliable and incomplete data on the extent to which children in Medicaid are receiving these services, particularly for children enrolled in managed care.<sup>51</sup>

Federal efforts to ensure that children are receiving EPSDT services have focused largely on changing the format and specificity of state reports so that states can collect more reliable data on the extent to which children are screened. While a positive step, this did not adequately address the difficulty states face in obtaining service information. Therefore, we recommended that CMS work with states to develop criteria and a timetable for assessing and improving the reporting and provision of EPSDT services. Further, although some states may have taken effective actions to improve the delivery of EPSDT services, CMS has not taken steps to identify them. Therefore, we also recommended that CMS develop mechanisms for identifying and highlighting state EPSDT service delivery practices that could be used as models for other states.

---

<sup>50</sup>See U.S. General Accounting Office, *Medicaid and SCHIP: States Use Varying Approaches to Monitor Children's Access to Care*, [GAO-03-222](#) (Washington, D.C.: Jan. 14, 2003), available February 2003.

<sup>51</sup> U.S. General Accounting Office, *Medicaid: Stronger Efforts Needed to Ensure Children's Access to Health Screening Services*, [GAO-01-749](#) (Washington, D.C.: July 13, 2001).



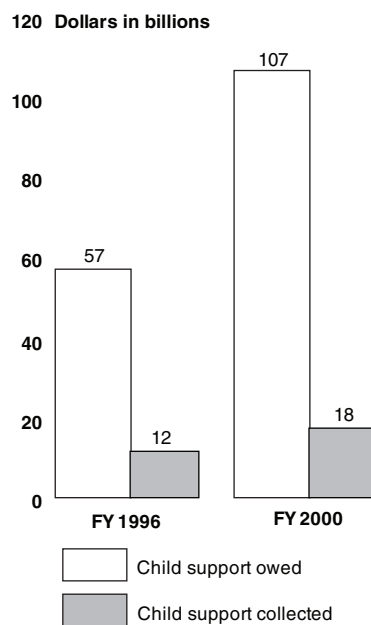
In addition to improving its health insurance programs, HHS could also take steps to improve the effectiveness of the child support program, which provides income for many children who do not live with both parents. Although total collections from parents who owe support money have increased in recent years, collections remain low relative to the amount owed, as shown in figure 5. Our work shows that collecting social security numbers from all drivers' license applicants, as required under federal law, and providing the information to the responsible child support agencies can result in increased collection from parents who owe child support. This is especially true for some particularly difficult-to-collect payments—those that are overdue and that are from noncustodial parents who are self-employed or who work informally for cash. Yet, at the time of our February 2002 review, six states did not enforce this requirement.<sup>52</sup> We recommended that the Office of Child Support Enforcement in ACF more effectively track, and take formal steps to bring about, compliance with this requirement. In response, HHS has since begun a review of its processes to track agency compliance and guidance on this issue. We also found that, despite the demonstrated effectiveness of wage withholding as an enforcement tool, the withholding form and related guidance developed by the Office of Child Support Enforcement make it difficult for employers to determine whether it is proper to begin withholding wages. This can result in instances in which employees' wages are inappropriately withheld. We recommended that the form and related guidance be improved;<sup>53</sup> since then, the office has begun drafting revisions to the form and agency guidance.

---

<sup>52</sup> U.S. General Accounting Office, *Child Support Enforcement: Most States Collect Drivers' SSNs and Use Them to Enforce Child Support*, [GAO-02-239](#) (Washington, D.C.: Feb. 15, 2002).

<sup>53</sup> U.S. General Accounting Office, *Child Support Enforcement: Clear Guidance Would Help Ensure Proper Access to Information and Use of Wage Withholding by Private Firms*, [GAO-02-349](#) (Washington, D.C.: Mar. 26, 2002).

Figure 5: Child Support Owed and Collected in Fiscal Years 1996 and 2000



Source: HHS Office of Child Support Enforcement.

In addition to other steps to improve effectiveness of programs, HHS could also better identify where research on its programs' effects is lacking, conduct or support the needed research, and coordinate and disseminate its research findings. In some of our recent work we have identified specific information gaps and recommended that HHS devote resources to increasing the information available on the effects of the following.

- *State child care quality improvement initiatives on children's development.* Although little evidence exists on the effectiveness of states' child care quality improvement initiatives, some literature suggests that there is a link between child care quality attributes and children's developmental progress. We recommended that HHS include this analysis in its planned multiyear evaluation of the net impact and benefits of state child care policies.<sup>54</sup> In response, HHS expressed

<sup>54</sup> U.S. General Accounting Office, *Child Care: States Have Undertaken a Variety of Quality Improvement Initiatives, but More Evaluations of Effectiveness Are Needed*, [GAO-02-897](#) (Washington, D.C.: Sept. 6, 2002).

optimism that this type of analysis would be included in the multistate evaluation.

- *Coordinated service delivery on outcomes of TANF clients.* In looking at coordination between Workforce Investment Act and TANF services, we found that little is known about the effect of such coordination efforts on recipient outcomes. We recommended that HHS, either alone or jointly with the Department of Labor, promote research in this area, while HHS contended that designing such research may not be feasible.<sup>55</sup>
- *Federal programs that provide counseling and mental health services for children who have experienced traumatic events.* The effectiveness of federal programs that could help children who have experienced trauma remains largely unknown. For example, in examining the long-standing federal Crisis Counseling Assistance and Training Program administered by the Federal Emergency Management Agency (FEMA) in collaboration with HHS's Substance Abuse and Mental Health Services Administration (SAMHSA), we found that the agencies had not conducted an evaluation of the program's effectiveness. Therefore, we recommended that the Director of FEMA work with the Administrator of SAMHSA to evaluate the effectiveness of the program, including its assistance to children who need mental health services as the result of a disaster. While both agencies agreed that program evaluation is important, FEMA did not indicate whether it intends to coordinate with SAMHSA to conduct such an evaluation.

---

## Improve Financial Systems, Processes, and Controls

HHS sustained the important achievement of an unqualified, or “clean,” opinion on its fiscal year 2001 financial statements, making this the third consecutive year it received such an opinion. An unqualified, or “clean,” opinion indicates to financial statement users that the information included in the statements is fairly presented as of the date of the financial statements—the last day of the fiscal year. While this is an important milestone, a clean audit opinion does not provide assurances about the effectiveness and efficiency of financial systems used to prepare the statements or the quality of internal control. The ultimate goal for effective

---

<sup>55</sup> U.S. General Accounting Office, *Workforce Investment Act: States and Localities Increasingly Coordinate Services for TANF Clients, but Better Information Needed on Effective Approaches*, [GAO-02-696](#) (Washington, D.C.: July 3, 2002).

agency financial management is achieving accountability, which is having major systems and controls in place to provide accurate, timely, and useful financial information to manage the department and its component agencies on a day-to-day basis.

HHS continues to have two weaknesses in its control over financial management that auditors have identified as significant—deemed material weaknesses—and that impair its ability to establish sound financial accountability.<sup>56</sup> First, the department and its component agencies have ineffective financial systems and processes that hamper preparation of timely and reliable financial statements. Because HHS and its agencies lack integrated financial systems capable of automating all internal and external financial reporting needs, their current systems are not in compliance with requirements in the Federal Financial Management Improvement Act of 1996 (FFMIA).<sup>57</sup> In addition to these system issues, HHS and its agencies have weaknesses in oversight and the conduct of key financial processes. Auditors have identified problems with analysis and reporting of Medicare financial data by HHS's contractors and of NIH's and ACF's grant accounting.

HHS's second material weakness is having ineffective controls over Medicare information systems, particularly relating to system security. CMS relies on information systems operations at both its central office and Medicare contractors to administer the Medicare program. Weaknesses in security controls for these systems increase the risk that sensitive program and financial data processed is not being adequately protected from unauthorized access or service disruption. Controls over these operations are essential to ensure the integrity, confidentiality, and reliability of critical data while reducing the risk of errors, fraud, or other illegal acts.

---

<sup>56</sup> A material weakness is a condition in which the design or operation of one or more of the internal control components does not reduce, to a relatively low level, the risk that errors or irregularities in amounts that would be material to the financial statements may occur and not be detected promptly by employees in the normal course of performing their duties.

<sup>57</sup> FFMIA of 1996, Public Law 104-208, requires that the 24 major departments and agencies named in the Chief Financial Officers Act implement and maintain financial management systems that substantially comply with (1) federal financial management systems requirements, (2) applicable federal accounting standards, and (3) the *United States Government Standard General Ledger* at the transaction level. Except for the federal financial management systems requirements, HHS is in compliance with the act's provisions.

---

For more information on financial management in relation to Medicare, see the section entitled “Safeguard the Integrity of the Medicare Program.”

---

### Improvements in Financial Systems And Processes Are Needed to Help Ensure Financial Accountability

Preparing financial statements that provide accurate and timely information is a key aspect of accountability. In preparing its financial statements for fiscal year 2001, the lack of integrated financial systems made it difficult for HHS and its agencies to prepare reliable, timely financial statements. HHS had to rely on extensive, time-consuming manual spreadsheets and adjustments at year-end in order to report accurate financial information. These year-end efforts helped HHS prepare statements that were materially and fairly presented. Nevertheless, such efforts are expensive; prone to errors, mistakes, and inaccuracies; and cannot be sustained.

Auditors reported problems in financial systems at some of the HHS agencies that are responsible for their own financial management systems and accounting functions—CMS, NIH, CDC, and FDA—as well as some that are not, such as ACF. Agencies that are not responsible for their own financial management systems rely on the Program Support Center’s Division of Financial Operations (DFO) for financial systems and accounting.<sup>58</sup>

Examples of systems weaknesses reported by auditors follow:

- CMS did not have an integrated accounting system to capture expenditures at the Medicare contractor level and thus was not in compliance with federal system requirements under FFMIA. CMS’s systems did not have capabilities necessary to properly process and record data on accounts receivable activity. As a result, CMS paid for extensive consultant time to establish reliable balances for its financial statement.
- System inadequacies at NIH resulted in the agency developing financial data necessary for the financial statements through a substantial year-end process. This included creating and posting new balances to the correct standard general ledger accounts. Through this process, NIH generated about 19,000 nonstandard accounting entries with an absolute

---

<sup>58</sup> DFO provides financial management services for ACF, HRSA, SAMSHA, the Indian Health Service and the Administration on Aging.

value of about \$348 billion. Posting nonstandard entries of this size and magnitude is a concern because of the increased risk that they could bypass normal accounting controls.

- ACF and CDC both used manually intensive processes and numerous adjusted journal entries to prepare accurate financial statements. The process used by these agencies often resulted in the untimely reporting of financial information supporting management decision-making.

Auditors also reported that HHS's ability to ensure financial accountability was hampered by weaknesses in key financial processes, including financial analysis and reporting and grant accounting. At present, HHS and some of its agencies do not routinely perform analysis and reconciliation of financial data to ensure that program dollars are properly accounted for. Financial analysis and reconciliation is key to ensuring accurate, timely financial information because it helps to detect unusual variances and fluctuations in data and pinpoint problems and inconsistencies in reporting. Auditors reported the following problems in financial analysis and reporting at HHS:

- CMS did not use adequate analysis procedures in overseeing Medicare contractors and the financial data that they manage. Specifically, CMS analysis did not detect errors in the amount of debt owed to the Medicare program as reported by contractors. Also, while some analysis procedures were implemented by CMS to help detect unusual variances and fluctuations, the benefit of this analysis was lost because CMS did not consistently follow up to determine the cause of inconsistencies in financial data.
- At NIH and ACF, insufficient analysis was done to determine if transactions were processed and recorded properly. Both agencies had to make significant adjustments to accounts several months after their financial statements were provided to auditors because they had not analyzed account balances in time, including those for program expenditures and accounts payable. NIH and ACF also failed to conduct timely periodic reconciliations that would have detected errors in amounts reported for accurate grant accounting. For example, auditors reported that NIH's reconciliation process failed to detect and resolve a \$193 million difference between the amounts recorded in its supporting accounting ledger and main accounting ledger for a liability account.

- Auditors reported many differences between the grant data that NIH and ACF records showed as reported to the HHS component responsible for centralized grant accounting services—the Program Support Center (PSC)—and the data in PSC’s Payment Management System. In one case, ACF failed to properly review expenditures reported in the Payment Management System before they were released for other use. Once reviewed, the agency decreased the amount that the grantee was authorized to receive by \$58 million, and as a result, by the time the mistake had been rectified, the grantee exceeded its authorized expenditures by \$29 million.

It is especially important for HHS and its agencies to replace existing financial systems and eliminate their manual efforts, given OMB’s new financial reporting requirements. OMB now requires agencies to prepare interim financial statements and has accelerated their year-end financial statement deadlines. For fiscal year 2002, the deadlines have been accelerated by about 1 month—to February 1—and OMB plans to significantly accelerate the deadlines for fiscal year 2004 when financial statements will have to be submitted by November 15, 2004. Failure to meet these deadlines could undermine HHS’s financial management achievements, including the clean audit opinion on its financial statements. HHS will need to provide continued management attention and funding to maintain current financial systems and processes while working to develop major systems and controls that provide accurate, timely, and useful information to manage the department and its agencies on a day-to-day basis.

---

### Improved Controls over Medicare Information Systems Needed To Protect Data Security Integrity

Controls over the information systems that process Medicare program and financial data are essential to ensure data integrity and reduce the risks of illegal access. Auditors noted weaknesses in almost every aspect of the controls established for Medicare information systems. Most of the problems cited related to controls that could allow unauthorized system access, including the ability to make software changes, but others could also prevent service continuity in case of disaster. Poor control over system access compromises CMS’s ability to ensure security over sensitive programmatic and financial data. Although most of the problems cited by auditors were at Medicare contractors, some were also identified in the systems maintained by CMS’s central office, as the following examples illustrate.

- Access to sensitive data. Medicare contractors' staff had access to sensitive data, including patient information, although it was not required for their job duties. Their access could result in unauthorized changes to Medicare information.
- Access to Medicare facilities. At several Medicare contractors and CMS's central office, auditors noted that data centers did not have sufficient procedures for continuously monitoring staff activities within the centers. The data centers also lacked procedures to prevent access to sensitive areas by staff whose job duties did not require such access.

Auditors found no evidence of an actual compromise of security as a result of the lax controls. Nevertheless, the integrity of Medicare program and financial data remains at risk until CMS corrects these control weaknesses.

---

### HHS Efforts Under Way to Correct Weaknesses in Financial Systems, Processes, and Controls

HHS and its agencies have started to implement corrective actions to address weaknesses in financial systems, processes, and controls. For example, the department implemented an internet-based Automated Financial System (AFS) to reduce the manually intensive spreadsheets that had been used in the past to consolidate component financial statements. Recognizing that AFS does not fully address the financial system weaknesses that affect its ability to quickly generate accurate and timely financial information, HHS has developed plans to replace various existing and antiquated financial systems with a Unified Financial Management System (UFMS). This unified system will consist of two major subcomponents. One subcomponent—the Healthcare Integrated General Ledger System (HIGLAS)—will be for CMS and the Medicare contractors that CMS has begun developing and anticipates implementing by 2007. The other subcomponent will be for all other HHS component agencies.

HHS and its agencies are implementing other corrective actions to address weaknesses in financial processes and Medicare information systems controls, as the following examples illustrate.



- Financial processes. NIH developed plans to implement numerous additional analyses and reconciliations to ensure that financial statement balances are accurate. CMS made significant improvements in its financial processes including (1) updating policies for contractors on financial matters such as debt collection and cost reporting and (2) publishing an accounting procedures manual to help ensure that its staff process financial transactions properly.<sup>59</sup>
- Medicare information systems controls. CMS has undertaken several actions to improve security controls. CMS revised the information security requirements for contractors based on a synthesis of requirements as promulgated by several federal agencies including OMB and GAO.<sup>60</sup> CMS began requiring contractors to document their compliance with the new security requirements and has also committed to providing funding to establish controls where gaps are identified in contractors' compliance with security requirements—to the extent that funds are available.

These and other actions that HHS and its agencies have taken to improve financial management are positive steps towards resolving their major management challenges in this area. Sustaining financial management achievements while implementing the major system enhancements needed to improve financial accountability will require long-term management commitment and follow-through.

---

<sup>59</sup> U.S. General Accounting Office, *Medicare Financial Management: Significant Progress Made to Enhance Financial Accountability*, [GAO-03-151R](#) (Washington, D.C.: Oct. 31, 2002).

<sup>60</sup> The core requirements are based on a syntheses of controls as included in OMB Circular A-130, PDD 63, *General Accounting Office Federal Information System Controls Audit Manual*, Internal Revenue Service Publication 1075, the Health Insurance Portability and Accountability Act of 1996, and new CMS requirements for systems architecture and security handbook.

---

# GAO Contacts

---

---

---

<b>Subject(s) covered in this report</b>	<b>Contact Person</b>
Medicare Program Design and Administration	Laura A. Dummit, Director Health Care—Medicare Payment Issues (202) 512-7119 <a href="mailto:dummitl@gao.gov">dummitl@gao.gov</a>
Medicare Program Integrity Safeguards	Leslie G. Aronovitz, Director Health Care—Program Administration and Integrity Issues (312) 220-7600 <a href="mailto:aronovitzl@gao.gov">aronovitzl@gao.gov</a>
Medicaid Fiscal and Management Oversight/Medicare and Medicaid Care Oversight	Kathryn G. Allen, Director Health Care—Medicaid and Private Health Insurance Issues (202) 512-7118 <a href="mailto:allenk@gao.gov">allenk@gao.gov</a>
Public Health Emergency Preparedness/Medical Product Safety and Efficacy	Janet Heinrich, Director Health Care—Public Health Issues (202) 512-7119 <a href="mailto:heinrichj@gao.gov">heinrichj@gao.gov</a>
Economic Independence and Well-Being of Children and Families	Cynthia M. Fagnoni, Managing Director Education, Workforce, and Income Security Issues (202) 512-7215 <a href="mailto:fagnonic@gao.gov">fagnonic@gao.gov</a>
Financial Management Systems, Processes, and Controls	Linda M. Calbom, Director Financial Management and Assurance (202) 512-9508 <a href="mailto:calboml@gao.gov">calboml@gao.gov</a>

---

---

# Related GAO Products

---

---

## Medicare Program Design and Administration

*Skilled Nursing Facilities: Providers Have Responded to Medicare Payment System by Changing Practices.* [GAO-02-841](#). Washington, D.C.: August 23, 2002.

*Medicare: Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs.* [GAO-02-833T](#). Washington, D.C.: June 12, 2002.

*Medicare Physician Payments: Spending Targets Encourage Fiscal Discipline, Modifications Could Stabilize Fees.* [GAO-02-441T](#). Washington, D.C.: February 14, 2002.

*Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost.* [GAO-01-1118](#). Washington, D.C.: September 21, 2001.

*Medicare: Higher Expected Spending and Call for New Benefit Underscore Need for Meaningful Reform.* [GAO-01-539T](#). Washington, D.C.: March 22, 2001.

*Nursing Homes: Aggregate Medicare Payments Are Adequate Despite Bankruptcies.* [GAO/T-HEHS-00-192](#). Washington, D.C.: September 5, 2000.

---

## Medicare Program Integrity Safeguards

*Medicare Financial Management: Significant Progress Made to Enhance Financial Accountability.* [GAO-03-151R](#). Washington, D.C.: October 31, 2002.

*Medicare+Choice: Selected Program Requirements and Other Entities' Standards for HMOs.* [GAO-03-180](#). Washington, D.C.: October 31, 2002.

*Medicare: Recent CMS Reforms Address Carrier Scrutiny of Physicians' Claims for Payment.* [GAO-02-693](#). Washington, D.C.: May 28, 2002.

*Medicare: Using Education and Claims Scrutiny to Minimize Physician Billing Errors.* [GAO-02-778T](#). Washington, D.C.: May 28, 2002.

*Medicare: Communications With Physicians Can Be Improved.* [GAO-02-249](#). Washington, D.C.: February 27, 2002.

---

*Debt Collection Improvement Act of 1996: HHS's Centers for Medicare & Medicaid Services Faces Challenges to Fully Implement Certain Key Provisions.* [GAO-02-307](#). Washington, D.C.: February 22, 2002.

*Medicare+Choice Audits: Lack of Audit Follow-up Limits Usefulness.* [GAO-02-33](#). Washington, D.C.: October 9, 2001.

*Medicare: Information Systems Modernization Needs Stronger Management and Support.* [GAO-01-824](#). Washington, D.C.: September 20, 2001.

*Medicare: Comments on HHS' Claims Administration Contracting Reform Proposal.* [GAO-01-1046R](#). Washington, D.C.: August 17, 2001.

*Medicare Management: CMS Faces Challenges to Sustain Progress and Address Weaknesses.* [GAO-01-817](#). Washington, D.C.: July 31, 2001.

*Medicare: Successful Reform Requires Meeting Key Management Challenges.* [GAO-01-1006T](#). Washington, D.C.: July 25, 2001.

*Medicare Contracting Reform: Opportunities and Challenges in Contracting for Claims Administration Services.* [GAO-01-918T](#). Washington, D.C.: June 28, 2001.

*Medicare Management: Current and Future Challenges.* [GAO-01-878T](#). Washington, D.C.: June 19, 2001.

*Medicare Reform: Modernization Requires Comprehensive Program View.* [GAO-01-862T](#). Washington, D.C.: June 14, 2001.

*Regulatory Issues for Medicare Providers.* [GAO-01-802R](#). Washington, D.C.: June 11, 2001.

*Medicare: Opportunities and Challenges in Contracting for Program Safeguards.* [GAO-01-616](#). Washington, D.C.: May 18, 2001.

*Medicare Fraud and Abuse: DOJ Has Improved Oversight of False Claims Act Guidance.* [GAO-01-506](#). Washington, D.C.: March 30, 2001.

*Major Management Challenges and Program Risks: Department of Health and Human Services.* [GAO-01-247](#). Washington, D.C.: January 2001.

---

*High-Risk Series: An Update.* [GAO-01-263](#). Washington, D.C.: January 2001.

*Medicare: HCFA Could Do More to Identify and Collect Overpayments.* HEHS/AIMD-00-304. Washington, D.C.: September 7, 2000.

---

Medicaid Fiscal and  
Management Oversight

*Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns.* [GAO-02-817](#). Washington, D.C.: July 12, 2002.

*Medicaid: HCFA Reversed Its Position and Approved Additional State Financing Schemes.* [GAO-02-147](#). Washington, D.C.: October 30, 2001.

*Medicaid: State Financing Schemes Again Drive Up Federal Payments.* [GAO/T-HEHS-00-193](#). Washington, D.C.: September 6, 2000.

*Medicare and Medicaid: Implementing State Demonstrations for Dual Eligibles Has Proven Challenging.* [GAO/HEHS-00-94](#). Washington, D.C.: August 18, 2000.

*Medicaid in Schools: Poor Oversight and Improper Payments Compromise Potential Benefit.* [GAO/T-HEHS/OSI-00-87](#). Washington, D.C.: April 5, 2000.

*Medicaid in Schools: Improper Payments Demand Improvements in HCFA Oversight.* [GAO/HEHS/OSI-00-69](#). Washington, D.C.: April 5, 2000.

---

Medicare and Medicaid Care  
Oversight

*Skilled Nursing Facilities: Providers Have Responded to Medicare Payment System by Changing Practices.* [GAO-02-841](#). Washington, D.C.: August 23, 2002.

*Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issues.* [GAO-02-382](#). Washington, D.C.: July 19, 2002.

*Nursing Homes: Quality of Care More Related to Staffing than Spending.* [GAO-02-431R](#). Washington, D.C.: June 13, 2002.

*Nursing Homes: More Can Be Done to Protect Residents from Abuse.* [GAO-02-312](#). Washington, D.C.: March 1, 2002.

---

*Nursing Homes: Federal Efforts to Monitor Resident Assessment Data Should Complement State Activities.* [GAO-02-279](#). Washington, D.C.: February 15, 2002.

*Nursing Homes: Sustained Efforts Are Essential to Realize Potential of the Quality Initiatives.* [GAO-HEHS-00-197](#). Washington, D.C.: September 28, 2000.

*Medicare Quality of Care: Oversight of Kidney Dialysis Facilities Needs Improvement.* [GAO-HEHS-00-114](#). Washington, D.C.: June 23, 2000.

---

Public Health Emergency Preparedness

*Homeland Security: CDC's Oversight of the Select Agent Program.* [GAO-03-315R](#). Washington, D.C.: November 22, 2002.

*Public Health: Maintaining an Adequate Blood Supply Is Key to Emergency Preparedness.* [GAO-02-1095T](#). Washington, D.C.: September 10, 2002.

*Public Health: Blood Supply Generally Adequate Despite New Donor Restrictions.* [GAO-02-754](#). Washington, D.C.: July 22, 2002.

*Homeland Security: New Department Could Improve Coordination but Transferring Control of Certain Public Health Programs Raises Concerns.* [GAO-02-954T](#). Washington, D.C.: July 16, 2002.

*Homeland Security: New Department Could Improve Biomedical R&D Coordination but May Disrupt Dual-Purpose Efforts.* [GAO-02-924T](#). Washington, D.C.: July 9, 2002.

*Homeland Security: New Department Could Improve Coordination but May Complicate Priority Setting.* [GAO-02-893T](#). Washington, D.C.: June 28, 2002.

*Homeland Security: New Department Could Improve Coordination but May Complicate Public Health Priority Setting.* [GAO-02-883T](#). Washington, D.C.: June 25, 2002.

*Bioterrorism: The Centers for Disease Control and Prevention's Role in Public Health Protection.* [GAO-02-235T](#). Washington, D.C.: November 15, 2001.

---

*Bioterrorism: Review of Public Health Preparedness Programs.* [GAO-02-149T](#). Washington, D.C.: October 10, 2001.

*Bioterrorism: Public Health and Medical Preparedness.* [GAO-02-141T](#). Washington, D.C.: October 9, 2001.

*Bioterrorism: Coordination and Preparedness.* [GAO-02-129T](#). Washington, D.C.: October 5, 2001.

*Bioterrorism: Federal Research and Preparedness Activities.* [GAO-01-915](#). Washington, D.C.: September 28, 2001.

*West Nile Virus Outbreak: Lessons for Public Health Preparedness.* [GAO/HEHS-00-180](#). Washington, D.C.: September 11, 2000.

---

## Medical Product Safety and Efficacy

*Food and Drug Administration: Effect of User Fees on Drug Approval Times, Withdrawals, and Other Agency Activities.* [GAO-02-958](#). Washington, D.C.: September 17, 2002.

*Childhood Vaccines: Ensuring an Adequate Supply Poses Continuing Challenges.* [GAO-02-987](#). Washington, D.C.: September 13, 2002.

*Women's Health: Women Sufficiently Represented in New Drug Testing, but FDA Oversight Needs Improvement.* [GAO-01-754](#). Washington, D.C.: July 6, 2001.

*Pediatric Drug Research: Substantial Increase in Studies of Drugs for Children, But Some Challenges Remain.* [GAO-01-705T](#). Washington, D.C.: May 8, 2001.

*Drug Safety: Most Drugs Withdrawn in Recent Years Had Greater Health Risks for Women.* [GAO-01-286R](#). Washington, D.C.: January 19, 2001.

---

## Economic Independence and Well-being of Children and Families

*Medicaid and SCHIP: States Use Varying Approaches to Monitor Children's Access to Care.* [GAO-03-222](#). Washington, D.C.: January 14, 2003, available February 2003.

*Mental Health Services: Effectiveness of Insurance Coverage and Federal Programs for Children Who Have Experienced Trauma Largely Unknown.* [GAO-02-813](#). Washington, D.C.: August 22, 2002.

*Human Services: Federal Approval and Funding Processes for States' Information Systems.* [GAO-02-347T](#). Washington, D.C.: July 9, 2002.

*Welfare Reform: Federal Oversight of State and Local Contracting Can Be Strengthened.* [GAO-02-661](#). Washington, D.C.: June 11, 2002.

*Welfare Reform: Interim Report on Potential Ways to Strengthen Federal Oversight of State and Local Contracting.* [GAO-02-245](#). Washington, D.C.: April 23, 2002.

*Medicaid: Transitional Coverage Can Help Families Move from Welfare to Work.* [GAO-02-679T](#). Washington, D.C.: April 23, 2002.

*Welfare Reform: States Provide TANF-Funded Services to Many Low-Income Families Who Do Not Receive Cash Assistance.* [GAO-02-564](#). Washington, D.C.: April 5, 2002.

*Head Start and Even Start: Greater Collaboration Needed on Measures of Adult Education and Literacy.* [GAO-02-348](#). Washington, D.C.: March 29, 2002.

*Child Support Enforcement: Clear Guidance Would Help Ensure Proper Access to Information and Use of Wage Withholding by Private Firms.* [GAO-02-349](#). Washington, D.C.: March 26, 2002.

*Welfare Reform: States Are Using TANF Flexibility to Adapt Work Requirements and Time Limits to Meet State and Local Needs.* [GAO-02-501T](#). Washington, D.C.: March 7, 2002.

*Child Support Enforcement: Most States Collect Drivers' SSN and Use Them to Enforce Child Support.* [GAO-02-239](#). Washington, D.C.: February 15, 2002.

*Human Services Integration: Results of a GAO Cosponsored Conference on Modernizing Information Systems.* [GAO-02-121](#). Washington, D.C.: January 31, 2002.

*Welfare Reform: More Coordinated Federal Effort Could Help States and Localities Move TANF Recipients with Impairments Toward Employment.* [GAO-02-37](#). Washington, D.C.: October 31, 2001.



---

*Medicaid and SCHIP: States' Enrollment and Payment Policies Can Affect Children's Access to Care.* [GAO-01-883](#). Washington, D.C.: September 10, 2001.

*Public Assistance: PARIS Project Can Help States Reduce Improper Benefit Payments* [GAO-01-935](#). Washington, D.C.: September 6, 2001.

*Welfare Reform: Challenges in Maintaining a Federal-State Fiscal Partnership.* [GAO-01-828](#). Washington, D.C.: August 10, 2001.

*Medicaid: Stronger Efforts Needed to Ensure Children's Access to Health Screening Services.* [GAO-01-749](#). Washington, D.C.: July 13, 2001.

*Health and Human Services: Status of Achieving Key Outcomes and Addressing Major Management Challenges.* [GAO-01-748](#). Washington, D.C.: June 15, 2001.

*Welfare Reform: Moving Hard-to-Employ Recipients into the Workforce.* [GAO-01-368](#). Washington, D.C.: March 15, 2001.

*Welfare Reform: Progress in Meeting Work-Focused TANF Goals.* [GAO-01-522T](#). Washington, D.C.: March 15, 2001.

*Welfare Reform: Data Available to Assess TANF's Progress.* [GAO-01-298](#). Washington, D.C.: February 28, 2001.

---

**Financial Management  
Systems, Processes, and  
Controls**

*Medicare Financial Management: Significant Progress Made to Enhance Financial Accountability.* [GAO-03-151R](#). Washington, D.C.: October 31, 2002.

*Medicaid Financial Management: Better Oversight of State Claims for Federal Reimbursement Needed.* [GAO-02-300](#). Washington, D.C.: February 28, 2002.

---

# Performance and Accountability and High-Risk Series

---

*Major Management Challenges and Program Risks: A Governmentwide Perspective.* [GAO-03-95](#).

*Major Management Challenges and Program Risks: Department of Agriculture.* [GAO-03-96](#).

*Major Management Challenges and Program Risks: Department of Commerce.* [GAO-03-97](#).

*Major Management Challenges and Program Risks: Department of Defense.* [GAO-03-98](#).

*Major Management Challenges and Program Risks: Department of Education.* [GAO-03-99](#).

*Major Management Challenges and Program Risks: Department of Energy.* [GAO-03-100](#).

*Major Management Challenges and Program Risks: Department of Health and Human Services.* [GAO-03-101](#).

*Major Management Challenges and Program Risks: Department of Homeland Security.* [GAO-03-102](#).

*Major Management Challenges and Program Risks: Department of Housing and Urban Development.* [GAO-03-103](#).

*Major Management Challenges and Program Risks: Department of the Interior.* [GAO-03-104](#).

*Major Management Challenges and Program Risks: Department of Justice.* [GAO-03-105](#).

*Major Management Challenges and Program Risks: Department of Labor.* [GAO-03-106](#).

*Major Management Challenges and Program Risks: Department of State.* [GAO-03-107](#).

*Major Management Challenges and Program Risks: Department of Transportation.* [GAO-03-108](#).

*Major Management Challenges and Program Risks: Department of the Treasury.* [GAO-03-109](#).

*Major Management Challenges and Program Risks: Department of Veterans Affairs.* [GAO-03-110](#).

*Major Management Challenges and Program Risks: U.S. Agency for International Development.* [GAO-03-111](#).

*Major Management Challenges and Program Risks: Environmental Protection Agency.* [GAO-03-112](#).

*Major Management Challenges and Program Risks: Federal Emergency Management Agency.* [GAO-03-113](#).

*Major Management Challenges and Program Risks: National Aeronautics and Space Administration.* [GAO-03-114](#).

*Major Management Challenges and Program Risks: Office of Personnel Management.* [GAO-03-115](#).

*Major Management Challenges and Program Risks: Small Business Administration.* [GAO-03-116](#).

*Major Management Challenges and Program Risks: Social Security Administration.* [GAO-03-117](#).

*Major Management Challenges and Program Risks: U.S. Postal Service.* [GAO-03-118](#).

*High-Risk Series: An Update.* [GAO-03-119](#).

*High-Risk Series: Strategic Human Capital Management.* [GAO-03-120](#).

*High-Risk Series: Protecting Information Systems Supporting the Federal Government and the Nation's Critical Infrastructures.* [GAO-03-121](#).

*High-Risk Series: Federal Real Property.* [GAO-03-122](#).

---

## GAO's Mission

The General Accounting Office, the investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

---

## Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through the Internet. GAO's Web site ([www.gao.gov](http://www.gao.gov)) contains abstracts and full-text files of current reports and testimony and an expanding archive of older products. The Web site features a search engine to help you locate documents using key words and phrases. You can print these documents in their entirety, including charts and other graphics.

Each day, GAO issues a list of newly released reports, testimony, and correspondence. GAO posts this list, known as "Today's Reports," on its Web site daily. The list contains links to the full-text document files. To have GAO e-mail this list to you every afternoon, go to [www.gao.gov](http://www.gao.gov) and select "Subscribe to GAO Mailing Lists" under "Order GAO Products" heading.

---

## Order by Mail or Phone

The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. General Accounting Office  
441 G Street NW, Room LM  
Washington, D.C. 20548

To order by Phone:   Voice: (202) 512-6000  
                              TDD: (202) 512-2537  
                              Fax: (202) 512-6061

---

## To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: [www.gao.gov/fraudnet/fraudnet.htm](http://www.gao.gov/fraudnet/fraudnet.htm)

E-mail: [fraudnet@gao.gov](mailto:fraudnet@gao.gov)

Automated answering system: (800) 424-5454 or (202) 512-7470

---

## Public Affairs

Jeff Nelligan, Managing Director, [NelliganJ@gao.gov](mailto:NelliganJ@gao.gov) (202) 512-4800  
U.S. General Accounting Office, 441 G Street NW, Room 7149  
Washington, D.C. 20548

---

**United States  
General Accounting Office  
Washington, D.C. 20548-0001**

**Official Business  
Penalty for Private Use \$300**

**Address Service Requested**

---

**Presorted Standard  
Postage & Fees Paid  
GAO  
Permit No. GI00**

