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Health, Education, and
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June 30, 2000

The Honorable Fred Thompson, Chairman
The Honorable Joseph I. Lieberman, Ranking Member
Committee on Governmental Affairs
United States Senate

Subject: Observations on the Department of Health and Human Services' Fiscal Year 1999 Performance Report and Fiscal Year 2001 Performance Plan

As you requested, we have reviewed the 24 Chief Financial Officers Act (CFO) agencies' fiscal year 1999 performance reports and fiscal year 2001 performance plans required by the Government Performance and Results Act of 1993 (GPRA). In essence, under GPRA, annual performance plans incorporate performance goals and measures covering a given fiscal year and provide the direct linkage between an agency's longer term goals and day-to-day activities. Annual performance reports are to subsequently report on the degree to which those performance goals were met.

This letter contains two enclosures responding to your request concerning key program outcomes and major management challenges at the Department of Health and Human Services (HHS). Enclosure I provides our observations on HHS' fiscal year 1999 performance and fiscal year 2001 planned performance for the key outcomes that you identified as important mission areas for the agency. These key outcomes are (1) less fraud, waste, and error in Medicare and Medicaid; (2) beneficiaries receive high-quality nursing home service; (3) poor and disadvantaged families and individuals become self-sufficient; (4) improved prevention of diseases and disabilities; (5) reduced use of illegal drugs[1]; and (6) the public has prompt access to safe and effective medical drugs and devices. Enclosure II lists the major management challenges facing the agency that we and HHS' Inspector General (IG) identified, how its fiscal year 1999 performance report discussed the progress the agency made in resolving these challenges, and the applicable goals and measures in the fiscal year 2001 performance plan.

[1]HHS' mission does not involve supply-side activities that can reduce the availability of illegal drugs. Thus, we limited our review of HHS' performance in this area to the reduced use of illegal drugs.

Results in Brief

HHS generally met its fiscal year 1999 goals that were directly related to the outcome of less waste, fraud, and error in Medicare and Medicaid. However, the performance information for its major goal—to reduce the fee-for-service error rate—may not be precise enough to serve as a fully adequate measure of progress. Although HHS has gone further than most other Departments, it has recognized that having specific error rates for contractors, providers, and beneficiary services could better target program integrity efforts and has set goals to develop improved measures. HHS focused more attention on reducing waste, fraud, and error in Medicare by adding new goals for fiscal year 2000 and fiscal year 2001. However, a number of these goals are simply to establish a process to address these problems. Further, in some cases, targets to measure progress have not been developed. Much less attention has been paid to waste, fraud, and error in Medicaid. There is only one goal exclusively addressing Medicaid program integrity for fiscal year 2001—to assist states in conducting payment accuracy studies.

HHS has made progress in working toward ensuring that a vulnerable segment of the U.S. population—nursing home residents—receive high-quality care in a safe environment. For example, the Health Care Financing Administration (HCFA) reported that it had exceeded its 1999 target for reducing the prevalence of restraints in long-term care facilities, and it set a more aggressive restraint reduction target for fiscal year 2000. In addition, HCFA added two new performance goals—one in fiscal year 2000 and one in fiscal year 2001—in the nursing home quality area. Nevertheless, HCFA's 2001 performance plan does not fully address the agency's overall performance in implementing the broad range of ongoing nursing home initiatives, including preventing dehydration and malnutrition and combating resident abuse. Further, it will be difficult for the Congress and other interested parties to track agency progress in key performance areas, including decreasing the prevalence of pressure ulcers in long-term care facilities, because the agency has not yet developed performance measures or established baseline data.

The extent to which HHS accomplished its fiscal year 1999 goals for the outcome of helping poor and disadvantaged families and individuals become self-sufficient cannot be determined because data generally are not available for the performance measures associated with these goals. HHS' performance report acknowledges that time lags in obtaining these data from the states make it difficult to provide a comprehensive summary of agency performance. However, even though these time lags will likely present a problem every year in assessing agency performance in achieving the outcome of self-sufficiency, HHS' performance report does not indicate how the agency plans to address this problem. Some new and revised performance measures for HHS' fiscal year 2000 and fiscal year 2001 plans should provide a more precise and comprehensive indication of agency performance. The 2001 performance plan also reflects agency progress in addressing key weaknesses that we previously identified in HHS' 2000 plan, such as certain performance measures that lacked targets. However, the 2001 plan does not address the problem that we previously

cited of not adequately identifying actions to compensate for unavailable or poor quality data in the area of child support enforcement.

HHS' progress toward achieving its many performance goals for the outcome of improved prevention of diseases and disabilities cannot be determined because the Department provided performance data for fiscal year 1999 for only about one-third of its targeted performance measures. HHS met its targets for the vast majority of measures for which it did report performance and usually indicated when the missing performance data would be available, typically a date during calendar year 2000. The Centers for Disease Control and Prevention (CDC) is the lead HHS agency for this outcome, and for many of its goals, it has set progressively higher performance targets to meet in fiscal years 2000 and 2001. CDC, the Health Resources and Services Administration (HRSA), HCFA, and Indian Health Service (IHS) have also added new prevention goals to their already extensive number of fiscal year 1999 goals—many related to chronic diseases. HHS' agencies with prevention goals demonstrate a keen awareness of the ways they can work together with their state and local government and other partners to enhance their programs to improve prevention of disease and disability. Achieving this outcome depends heavily on reliable health surveillance systems at all levels of government, as well as on other types of data; the HHS agencies need to continue their work to expand and improve their data collection efforts.

HHS and its Substance Abuse and Mental Health Services Administration (SAMHSA) made progress in fiscal year 1999 toward achieving the outcome of reduced use of illegal drugs. Many of the performance goals and measures directly related to this outcome focused on the development and implementation of prevention and treatment interventions in selected study sites, and SAMHSA met or exceeded its fiscal year 1999 targets for these goals. The agency's fiscal year 1999 performance plan established an important performance measure that should provide state-level data on the effectiveness of substance abuse treatment services; in their fiscal year 2000 substance abuse prevention and treatment block grant applications, states will voluntarily report outcome data on the percentage of substance abuse treatment clients who had reduced substance use and criminal involvement, had a permanent place to live, and were employed. Although SAMHSA made some progress in developing a core set of outcome measures for states to report, it will continue to be a challenge for the agency to obtain complete, consistent, and reliable outcome data. Some states do not currently collect these data, and others may not have the capacity to collect and report it. Further, while it appears that states will be responsible for validating the data they collect, SAMHSA's fiscal year 2001 performance plan does not discuss whether and how the agency plans to verify the quality of the data states report.

HHS' progress toward achieving the outcome of the public's having prompt access to safe and effective medical drugs and devices cannot be determined because performance data for many of the Food and Drug Administration's (FDA) fiscal year 1999 performance goals are missing and some of its targets are not measurable. Final data on certain medical device approval submissions may not be available for up to a year after the end of the goal year, and the absence of performance data for several

Human Drug program goals was not explained. FDA believes it will either meet or exceed most targets, but the agency indicated that final data will not be available until early 2001. FDA met several targets, including ones for inspecting mammography facilities and drug and medical device manufacturing establishments. The agency, however, did not always provide confidence that the performance information is credible. For example, FDA frequently did not discuss its procedures to verify and validate the major data systems used to compile performance data or the systems' strengths and weaknesses. FDA's performance goals for fiscal year 2001 link well with its strategic goals; they include collaborative initiatives with the scientific community to identify best practices for the manufacture of quality drug products and improvements in premarket review processes for drugs that affect children. However, FDA's fiscal year 2001 performance plan does not discuss the strategies and resources that will be used to achieve the goals. Nor does it discuss several key weaknesses that we identified in earlier assessments related to data limitations in the medical device adverse event reporting system and foreign drug import surveillance system, as well as the absence of a goal to improve the inspection of foreign drug manufacturers.

In responding to its three broad management challenges, HHS has made progress, and its fiscal year 2001 performance plan has performance goals that relate to all of the challenges. HHS and its agencies are making progress in meeting the challenge of coordinating their work both internally and externally and ensuring accountability for program results. HHS agencies are working with their program partners, especially state and local governments, to define measures to assess program results. The agencies' fiscal year 2001 performance plans indicate that agencies with complementary goals are coordinating their efforts to improve outcomes, such as those related to public health. Having reliable data and data systems to manage programs and assess results continues to be a challenge for HHS and its agencies.

HHS was unable to report results for many of its fiscal year 1999 performance goals in its performance report, although it expects much of the required data to be available later in 2000. Some data will not be available until 2001. The Department indicated it is working on issues of data consistency and the use of appropriate measures to assess results. Many HHS agencies continue to grapple with problems of data reliability and timeliness. For example, because of the time lag in receiving data from states and localities, the Administration for Children and Families (ACF) could not report on its progress in meeting goals for the Temporary Assistance for Needy Families (TANF) or child support programs. A significant HHS success in fiscal year 1999 was that all HHS information systems functioned properly while transitioning to the year 2000. Maintaining program integrity, particularly with regard to Medicare, is HHS' third management challenge. HHS achieved a clean opinion on its fiscal year 1999 financial statements, but serious financial management weaknesses remain. Although HCFA reported progress in its stewardship of the Medicare program and has committed more resources to this effort, it is not clear how much progress it has made in reducing improper payments. HCFA's fiscal year 2001 performance plan indicates that the financial and management integrity of Medicare remains one of its highest priorities. The agency has just begun, however, to address program integrity in the Medicaid program.

Objectives, Scope, and Methodology

Our objectives concerning selected key outcomes for HHS were to (1) identify and assess the quality of the performance goals and measures directly related to a key outcome, (2) assess HHS' actual performance in fiscal year 1999 for each outcome, and (3) assess its planned performance for fiscal year 2001 for each outcome. Our objectives concerning major management challenges were to (1) assess how well HHS' fiscal year 1999 performance report discussed the progress it had made in resolving the major management challenges that we and the Department's IG had previously identified, and (2) identify whether HHS' fiscal year 2001 performance plan had goals and measures applicable to the major management challenges.

As agreed, in order to meet the Committee's tight reporting time frames, our observations were generally based on the requirements of GPRA, guidance to agencies from the Office of Management and Budget for developing performance plans and reports (OMB Circular A-11, part 2), previous reports and evaluations by us and others, our knowledge of HHS' operations and programs, and our observations on HHS' other GPRA-related efforts. We did not independently verify the information contained in the performance report or plan. We conducted our review from April through May 2000 in accordance with generally accepted government auditing standards.

Agency Comments and Our Evaluation

On June 21, 2000, we obtained written comments from the Inspector General, Department of Health and Human Services, on our analysis of HHS' fiscal year 1999 performance report and fiscal year 2001 performance plan. The Department agreed with our overall observations on its fiscal year 1999 performance report and fiscal year 2001 performance plan and believes that we consistently identified implementation challenges facing HHS and appropriately characterized its progress in meeting them. HHS further stated that our review was comprehensive and noted that it plans to use our observations as a checklist to ensure long-term responsiveness to concerns about its performance and improve the clarity and presentation of GPRA-related data.

HHS said that it did not report results for many of its fiscal year 1999 performance goals, as we noted, because it experienced significant delays in receiving data from states, grantees, and others for the entire fiscal year. Moreover, HHS believes it is not appropriate to rely excessively on data for one fiscal year to assess program performance and emphasized that performance observations should be based on multiple year data. To illustrate, HHS stated that the performance report includes trend data that show progress in achieving several of the goals related to each of the key outcomes for which fiscal year 1999 data were not available. Although HHS expressed concern about lags in reporting data for some programs, the Department

stated it will not impose early reporting requirements on states and other entities that are costly and burdensome if trend data can satisfy program assessment. HHS, however, stated that it plans to examine what time frames are appropriate and necessary to support the intent of GPRA.

We agree that prior fiscal year data can be helpful in defining baselines and showing trends in program performance. Where appropriate, we have revised this letter to credit the Department for providing earlier trend data. We also understand the significant challenges HHS faces in collecting and reporting performance data. However, the Department's position concerning the use of one fiscal year's data to assess performance is inconsistent with other comments it had about this letter. For example, HHS was able to collect and report complete fiscal year data on the progress made toward achieving goals related to reducing fraud, waste, and error in Medicare and Medicaid; ensuring that beneficiaries receive high-quality nursing home service; and reducing the use of illegal drugs. Because GPRA reporting is intended to provide the Congress and public with results-oriented data on a fiscal year basis, HHS should continue to work collaboratively with states and other reporting entities to develop strategies to meet GPRA's annual reporting requirements.

Finally, in its comments, HHS indicated that it intends in future performance plans to (1) place a greater emphasis on outcome goals and measures, (2) continue to refine data reporting systems and procedures used to verify and validate performance data, (3) develop strategies to increase the reporting of performance data, and (4) provide descriptions of completed program evaluations that support key program goals. We believe these types of actions will greatly assist HHS in producing annual performance reports and plans that fully comply with GPRA requirements. They will also enable the Department, the Congress, and the public to use the reports and plans to help ensure that HHS accomplishes its mission and that programs achieve their intended results.

Each of the Department's operating divisions also provided comments that relate to our observations.

- In its overall comments, HCFA noted our acknowledgement of the significant efforts it has made to develop and meet meaningful, outcome-oriented performance goals. Among other goals, these include its success in meeting the challenge of having its internal and Medicare contractor information systems year 2000 compliant and achieving an unqualified opinion on its financial statements. In the key outcome area of reducing fraud, waste, and error in Medicare and Medicaid, HCFA highlighted the difference in the fee-for-service payment error rate for fiscal years 1996 and 1999 as a measure of its progress as well as the new goals it has developed related to program integrity and management. In its specific comments, HCFA expressed concern with our remarks that the HHS IG's error rate may not be precise enough to fully measure progress. However, as the HHS IG reports, for fiscal year 1999, the estimated range of improper payments at the 95 percent confidence interval is $9.1 billion to $17.9 billion. With such a wide confidence interval, the IG's yearly estimates cannot easily be used to track the effectiveness of particular activities year to year. HCFA is working to develop

subnational error rates—contractor, provider, and benefit specific—that could better allow it to monitor the overall effectiveness of its program integrity activities, including many of the initiatives in the Comprehensive Plan for Program Integrity. HCFA also clarified why several goals had been dropped or changed and more detail added on initiatives—such as the corrective action plan for financial management—to better explain its efforts to reduce fraud and error in Medicare and Medicaid. In the key outcome area of ensuring that beneficiaries receive high-quality nursing home services, HCFA highlighted its progress in significantly reducing the prevalence of physical restraints in nursing homes and noted that it had added a new goal related to the state survey and certification process. In addition, HCFA discussed recent strategies and approaches for developing and implementing quality indicators and performance measures and reporting on its ongoing nursing home initiatives.

- ACF generally agreed with our observations of its performance report and plans and said that fiscal year 1999 data were not available for a significant number of performance measures but cited several measures for which the fiscal year 1999 performance report included earlier years' data and maintained that these data indicated progress in achieving objectives. For example, ACF cited fiscal years 1997 and 1998 data on the number of 90-day job retentions for refugees, which indicate that fiscal year 1998 performance exceeded ACF's target for fiscal year 1999. While we agree that data for prior years can be useful in performance assessment, we do not believe that 1 or 2 years of data represent a trend or provide a sufficient basis for assessing the extent to which the agency met its fiscal year 1999 performance goals. ACF also provided comments on other observations we made. For example, it described its plans to identify ongoing and future evaluations in its fiscal year 2002 performance plan and fiscal year 2000 performance report and discussed its strategies for meeting certain performance goals, such as reducing its target for dollars leveraged from the Administration on Developmental Disabilities' (ADD) federal partners. ACF also provided information on its strategies to address data availability and reliability challenges. For example, ACF stated in its comments that the agency will soon award a contract to study the effectiveness of the Head Start program using a control group design. It also provided information on the new child support data reporting system it is implementing in response to recent legislation as well as agency activities under way to audit the reliability of state-reported data for new child support reporting requirements.

- CDC, HRSA, and the National Institutes of Health (NIH) provided comments regarding the key outcome of improved prevention of diseases and disabilities. In its comments, CDC provided its rationale for choosing performance measures in its diabetes program, explained planned changes to clarify its discussion of occupational safety and health training goals and measures, and highlighted challenges it faces in obtaining high-quality and timely performance data from multiple systems. HRSA discussed its use of various types of prevention goals in its performance plan and indicated that it has worked to increase the use of outcome measures and demonstrate the link between processes and output measures and the desired outcomes. HRSA and NIH each stated that we

improperly characterized certain prevention measures as output goals and measures—in their view, they should be characterized as "intermediate outcome goals." We agree that some of these goals could be characterized as intermediate outcome goals and have recognized this in the letter. Finally, IHS clarified and provided detailed information about the revision of its performance measure for its prevention goal that addresses childhood obesity.

- SAMHSA substantially agreed with our observations regarding its performance report and plan and remarked that this letter accurately identified areas that represent particular challenges for SAMHSA and other operating divisions. SAMHSA recommended that we revise the key outcome of "reduced availability and use of illegal drugs" to "reduced use of illegal drugs" because neither SAMHSA's nor HHS' mission includes supply-side activities that can reduce the availability of illegal drugs. We agree with SAMHSA's position and have modfied this letter accordingly. SAMHSA agreed that its greatest challenge in GPRA implementation is obtaining outcome data from states and noted our acknowledgement that SAMHSA has made consistent progress in collaborating with states to develop appropriate measures as well as data collection and reporting systems. In response to our observation that the fiscal year 2001 performance plan did not discuss its plans to verify the quality of data states report, SAMHSA noted that it will include pertinent information in the fiscal year 2002 plan.

- FDA also agreed with our observations about its fiscal year 1999 performance report. Commenting on our observation of incomplete or delayed data on premarket application review performance goals, FDA acknowledged that its performance report did not have complete and final fiscal year 1999 data for these goals. FDA's position is that performance data for these goals are complete but are reported with a 1-year lag because some applications may be received late in the fiscal year and may have up to a 12-month time frame for action. This, according to FDA, is the same reporting system used for applications covered by the Prescription Drug User Fee Act of 1992 and will result in the agency not having complete and final data for premarket application review goals for the fiscal year covered by the GPRA performance report. While we recognize that FDA may not have complete and final data on reviews for all premarket drug applications received during a reporting period, the performance report would have been more informative if FDA had included estimated data on reviews of drug applications similar to the way the Medical Device program reported estimated data for goals related to device premarket application reviews. In addition, FDA acknowledged that trend data prior to fiscal year 1999 on the timeliness of FDA reviews of drug applications would have been helpful in reviewing FDA performance results. FDA indicated that it intends in future performance reports and plans to (1) provide a more comprehensive description of the major data systems used to track performance data and procedures used to verify and validate data in the fiscal year 2002 performance plan, (2) place greater emphasis on describing linkages between strategies and performance goals, (3) improve performance reporting by updating or providing final information for fiscal year 1999 in the fiscal year 2000 performance report, and (4) improve the

linkage between accomplishments for a single year's goals and FDA's strategic goals. These actions could significantly enhance the quality and usefulness of FDA's plans and reports.

HHS and its component agencies also made technical comments, which we incorporated where appropriate.

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As arranged with your office, unless you announce its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, we will send copies to the Honorable Donna E. Shalala, Secretary of Health and Human Services; appropriate congressional committees; and other interested parties. Copies will also be available through our web site, "www.gao.gov." If you or your staff have any questions, please call me at (312) 220-7600. Key contributors to this letter were Helene Toiv, Darryl Joyce, Sheila Avruch, Kay Daly, Sandra Gove, John Hansen, Donald Keller, James Kernen, Linda Lambert, Andrew Sherrill, Cynthia Teddleton, Victoria Smith, and Karen Whiten.

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Enclosures—2

OBSERVATIONS ON THE HEALTH AND HUMAN SERVICES ADMINISTRATION'S FISCAL YEAR 1999 ACTUAL PERFORMANCE AND FISCAL YEAR 2001 PLANNED PERFORMANCE RELATED TO KEY OUTCOMES

This enclosure contains our observations on HHS' FY 1999 actual performance and FY 2001 planned performance related to the following selected key outcomes: (1) less waste, fraud, and error in Medicare and Medicaid; (2) beneficiaries receive high-quality nursing home services; (3) poor and disadvantaged families and individuals become self-sufficient; (4) improved prevention of diseases and disabilities; (5) reduced use of illegal drugs; and (6) the public has prompt access to safe and effective medical drugs and devices.

Key Agency Outcome: Less Waste, Fraud, and Error in Medicare and Medicaid

Table I-1 shows HCFA's four performance goals and measures that relate to HHS' key agency outcome of having less waste, fraud, and error in Medicare and Medicaid and whether or not these goals were met in FY 1999, as reported in HHS' FY 1999 performance report.

Table I-1: Goals and Measures to Have Less Waste, Fraud, and Error in Medicare and Medicaid and Their FY 1999 Status, as Reported by HHS

Goal/measure	FY 1999 status
Reduce to 9% the percentage of improper payments made under the Medicare fee-for-service program.	Target met (8%)
Achieve more than half of program integrity savings by reducing mistaken or inaccurate payments on a prepayment basis (target: 52%).	Target met
Reduce to 35% the percentage of Medicare home health services for which improper payment was made in California, Illinois, New York, and Texas.	Target met (19%)
Timely processing of clean Medicare+Choice enrollments equal to the effective date on the transaction (target: 98%).	Data not available; expected spring 2000

GAO Observations on HHS' FY 1999 Goals and Measures to Have Less Waste, Fraud, and Error in Medicare and Medicaid and HHS' Performance Report on This Key Outcome

HCFA met almost all of its FY 1999 performance measure targets to reduce waste, fraud, and error in Medicare and generally provided a clear and credible discussion of its actions taken to meet its goals. For FY 1999, HCFA did not set goals to reduce waste, fraud, and error in Medicaid, and thus did not measure its progress.

HCFA has set the outcome of reducing improper payments as a major priority for Medicare and has increased its set of goals in this area. HCFA's central measure of progress has been the rate of improper payments in fee-for-service Medicare—8% in FY

1999. While this represents an improvement over FY 1997, the difference between FY 1997 and FY 1998—which continued to FY 1999—was almost entirely attributed to better documentation provided to auditors, rather than substantive reduction in improper payments. As HHS' IG report indicates, for FY 1999 the estimated range of improper payments at the 95%-confidence interval is $9.1 billion to $17.9 billion. Even though the error rate is estimated to be about $1 billion more in FY 1999 than in FY 1998, this difference could be due to sampling error and is not statistically significant. As a result, it is not clear from meeting this measure that HCFA has made significant progress in reducing improper payments. HCFA is planning to continue to measure improper payments with the help of the IG through FY 2001 following this methodology. Although HCFA has gone further than most other agencies, the IG methodology may not be precise enough to serve as an adequate measure of progress.

Although not grouped with the other Medicare program integrity measures, "timely processing of clean Medicare+Choice enrollments equal to the effective date of the transaction," is relevant for reducing error. It has a target that 98% of "clean" enrollment transactions—generally, those received on the first Tuesday or Wednesday of the month—will be processed with an effective date equal to that requested on the transaction. However, it is not clear that the measure will indicate timely processing of Medicare+Choice claims because only "clean" enrollment transactions will be subject to measurement. Further, data are not currently available to measure these transactions—HCFA does not explain why. It merely expresses an expectation that efforts in this area will lead to the desired result. In its comments, HCFA explained that this goal is designed to measure how well HCFA's systems operate, and measuring "clean" claims will best allow it to do so. HCFA stated that performance data will be reported in its next performance report.

HCFA's FY 1999 performance report notes that it has made a number of improvements that have assisted in the overall development of a representative approach to performance measurement. Some of the improvements were self-initiated, and others were made in response to guidance provided by the Office of Management and Budget and the HHS Office of the Secretary. However, with respect to FY 1999 performance goals, HCFA does not list or summarize any program evaluations that were completed or scheduled to have been completed by either HCFA or other agencies, including HHS' IG. Therefore, it is difficult to determine whether or how HCFA used program evaluations in assessing its FY 1999 performance.

Unmet FY 1999 Performance Goals and Measures for This Key Outcome

HHS had no unmet FY 1999 performance goals and measures for this outcome.

HHS' FY 2000 Performance Goals and Measures to Have Less Waste, Fraud, and Error in Medicare and Medicaid

Goals and Measures Added

- Reduce the payment error rate for inpatient hospital claims (target: baseline—to be developed—minus 12.5%).
- Increase the ratio of recoveries identified through the audit process to audit dollars spent (target: a $13-to-$1 savings ratio).
- Increase Medicare secondary payer liability and no-fault dollar recoveries (target: 5%).
- Review additional claims to improve the efficiency of the medical review (target: 10%).

Goal Dropped

- Achieve more than half of program integrity savings by reducing mistaken or inaccurate payments on a prepayment basis.

Measure Changed

- Reduce the percentage of Medicare home health services for which improper payment was made in California, Illinois, New York, and Texas (target: 10%).

GAO Observations on the FY 2000 Performance Plan for This Key Outcome

HCFA changed some of its performance goals and measures each year, making progress in this area more difficult to track over time. For example, HCFA has changed two of its FY 1999 goals. Although these goals were met, they were subsumed into new goals, and one of the new goals was further subsumed into a new goal for FY 2001.

HCFA generally provided reasons for variations from its FY 1999 goals and measures. For example, HCFA noted in its revised FY 1999 plan that the Balanced Budget Act of 1997 enabled it to take specific corrective actions to reduce the percentage of improper Medicare home health claims from the FY 1999 target of 35%; consequently, it updated its target for FY 2000. HCFA also noted that this goal could be dropped for FY 2001 so that performance plans could focus on other equally compelling vulnerable benefit areas, depending on the fraud and abuse environment and trends in future years. This goal was specific to claims in only four states.

In its revised FY 1999 performance plan, HCFA explained why one of its FY 1999 goals—"achieve more than half of program integrity savings by reducing mistaken or inaccurate payments on a prepayment basis"—was replaced. According to HCFA, recent data indicated that it was already achieving 52% (more than half) of program integrity savings in this manner. However, since the agency was undertaking a variety of post-payment

activities that would lower the prepay ratio while increasing total recoveries, it replaced the FY 1999 goal with three new FY 2000 goals. In HCFA's opinion, the three new goals reflected its renewed efforts and direction in the area of program integrity.

HHS' FY 2001 Performance Goals and Measures to Have Less Waste, Fraud, and Error in Medicare and Medicaid

Goals and Measures Added

- Increase Medicare Secondary Payer dollar recoveries and/or decrease recovery time via the Medicare Credit Balance Report (HCFA-838) (measure not yet developed).
- Assist states in conducting Medicaid payment accuracy studies for the purpose of measuring and ultimately reducing Medicaid payment error rates (measure not yet developed).
- Develop and implement methods for measuring Medicare program integrity outcomes: (1) implement the provider compliance rate to produce a compliance rate through prepay medical review, (2) implement the refined CFO audit methodology to produce a subnational error rate, (3) develop a fraud rate among providers in a contractor's service area (target: implement processes).
- Improve the effectiveness of Medicare and Medicaid program integrity activity through successful implementation of the Comprehensive Plan for Program Integrity's 10 initiatives (target: 100%) and measure effectiveness of each of the 10 initiatives based on achieving a significant portion of the performance measures established for each initiative (target: meet 90% of the measures for each initiative).[2]
- Improve HCFA oversight of Medicare fee-for-service contractors (measure not yet developed).

[2]The Comprehensive Plan for Program Integrity's 10 initiatives are (1) improve the quality of medical review and benefit integrity outcomes by developing and fully implementing Medicare carrier and fiscal intermediary program integrity performance standards that measure quality and desired outcomes; (2) implement a fully functioning program safeguard contractor with implementation of three operational models (functional model, data analysis model, and benefit model) and award a contract for the fourth program safeguard contractor operational model (full program safeguard contractor model); (3) implement Balanced Budget Act program safeguards (establish a national database of state statutes concerning nonphysician practitioner licensure requirements; establish a process to measure the nonphysician error rate, fully implementing a national database of state licensure requirements for nonphysician practitioners and paying 90% of nonphysician practitioner claims correctly; and create a therapy service program safeguard contractor, developing an error rate for therapy service claims); (4) improve the provider enrollment process, reducing the rate of return by 30 percentage points to 40 percent; (5) ensure millenium contingency planning (goal met in 1999); (6) reduce the payment error rate for inpatient hospital claims 25% from baseline (not developed); (7) develop a data exchange and analysis strategy to monitor the services provided to Medicare and Medicaid beneficiaries in congregate care settings, developing and completing a data exchange analysis project with Medicare contractors and Medicaid state agencies to allow the coordinated monitoring of services provided to Medicare and Medicaid beneficiaries in congregate care settings; (8) create additional contractors for managed care, fully implementing the enrollment certification contractor and the managed care program safeguard contractors; (9) reduce the payment error rate for Community Mental Health Center partial hospitalization claims by 39%; and (10) implement nursing home quality goals and measures (see key agency outcome pertaining to high-quality nursing home outcomes).

Goals and Measures Dropped

- Increase Medicare Secondary Payer liability and no-fault dollar recoveries (target: 5%).
- Reduce the percentage of Medicare home health services for which improper payment was made in California, Illinois, New York, and Texas (target: 10%).
- Review additional claims to improve the efficiency of the medical review (target: 10%).

Goal and Measure Changed

- Increase the ratio of recoveries identified through the audit process to audit dollars spent (target: increase ratio by at least 5% over FY 1997).

GAO Observations on the FY 2001 Performance Plan for This Key Outcome

HCFA did not always give specific reasons why variations in its performance goals occurred. For example, HCFA does not provide any explanation in its FY 2001 performance plan as to why the performance goal, "increase Medicare Secondary Payer liability and no-fault dollar recoveries" was dropped. The only explanation provided for dropping the goal, "review additional claims to improve the efficiency of the medical review," is the statement that it was subsumed into the new FY 2001 Comprehensive Plan for Program Integrity goal. In its comments, HCFA explained that given the long time to resolve some Medicare Secondary Payer cases, it made sense to track both increased recovery leads and recoveries, which is why it broadened its Medicare Secondary Payer goal. HCFA also explained that it dropped its goal of reviewing additional claims to improve efficiency of medical review because the agency decided it was more important to focus on the quality of its medical review—part of its goal to implement the Comprehensive Plan for Program Integrity.

However, HCFA did explain why it dropped the goal, "reduce the percentage of Medicare home health services for which improper payment was made" in the FY 2000 plan. Further, the FY 2001 plan indicates that if the FY 2000 target is not met, this goal may be reintroduced. Additionally, HCFA introduced several new goals that appear to address some of the program integrity concerns raised by GAO and HHS' IG.

Because many of the baselines and measures for the new and revised FY 2001 goals are currently in development, HCFA's intended performance regarding them is unclear. HCFA has not provided a succinct or concrete statement of expected performance for subsequent comparison with actual performance in all cases. Further, while HCFA discusses the need to coordinate with other agencies in meeting new and revised goals, it does so in a cursory manner, such as in the statement "we will continue to work with our partners in conducting our everyday business of ensuring that Medicare claims are paid properly."

Two key weaknesses that GAO identified in prior years' HCFA performance plans are that goals were not consistently measurable and that the strategies and resources needed to achieve the goals were not adequately addressed. These problems continue in the FY 2001 plan. In some instances, this is because HCFA is still developing the baselines and appropriate measures. In other instances, HCFA states generally that the accomplishment of the goal is the target and does not explain in sufficient detail what its strategies are to ensure goal accomplishment.

HCFA's procedures to verify and validate its performance data or identify actions to compensate for low quality data also continue to be inadequately described. For example, for its new 10-part performance goal, "improve the effectiveness of program integrity activity through successful implementation of the Comprehensive Plan for Program Integrity initiatives," the verification and validation section is only two sentences long, one of which states, "verification and validation methods will vary with each initiative's measures." There is no indication as to what these methods actually are in the performance plan. Part of the implementation involves developing an inpatient claim Payment Error Prevention program, but HCFA does not discuss how this program will measure error and how these measures will be verified and validated. These data verification and validation weaknesses may lead to questions about the reliability of current and future performance reports. In its comments, HCFA explained that some aspects of its Comprehensive Plan for Program Integrity, such as the nursing home initiatives, stand alone with their own discussion of verification and validation and others are error rate measures that will be verified and validated through the methods used to measure the Medicare fee-for-service error rate.

Finally, in GAO's review of HCFA's FY 1999 performance plan on this key agency outcome, we noted that it did not adequately address the need for crosscutting efforts. While we highlighted the fact that HCFA's FY 2000 performance plan more consistently stated its intention to coordinate, we noted that merely stating intention to coordinate was insufficient. Performance plans are more useful if specific details about planned coordination strategies are included. It appears that HCFA did not correct this deficiency in its FY 2001 performance plan.

Key Agency Outcome: Beneficiaries Receive High-Quality Nursing Home Services

Table I-2 shows HCFA's performance goal and measure that relates to HHS' key agency outcome of beneficiaries receiving high-quality nursing home services and whether or not these goals were met in FY 1999, as reported in HHS' FY 1999 performance report.

Table I-2: Goal and Measure to Have Beneficiaries Receive High-Quality Nursing Home Services and Its FY 1999 Status, as Reported by HHS

Goal/measure	FY 1999 status
Decrease the prevalence of restraints in long-term care facilities to 14%.	Target met (11.9% prevalence)

GAO Observations on HHS' FY 1999 Goals and Measures to Have Beneficiaries Receive High-Quality Nursing Home Services and HHS' Performance Report on This Key Outcome

HCFA's performance goal of reducing the prevalence of restraints is outcome-oriented, objective, measurable, and quantifiable. While GAO's analysis of HCFA's 1999 annual performance plan recognized that decreasing the use of restraints was an important goal, it also raised concerns that the plan presented no other goals directed at improving the overall quality of care for individuals in long-term care facilities. HCFA has since added two new performance goals directly linked to the quality of care provided by such facilities.

In its FY 1999 plan, HCFA established a baseline of 17.2% use of restraints for FY 1996 against which future performance would be judged. It also provided a well-reasoned discussion on its rationale for selecting this goal. For example, HCFA noted that the prevalence of the use of physical restraints is a proxy for measuring the quality of life for nursing home residents. The agency also discussed concerns about the use of psychoactive drugs to manage resident behavior in place of using physical restraint and noted that it is difficult to distinguish between appropriate and inappropriate use of such drugs and that there is no routinely available data to allow it to do so.

HCFA's performance report clearly indicates progress toward restraint reduction. It is difficult, however, to determine the extent to which agency actions have played a key role in decreasing the use of restraints in long-term care facilities because many other outside groups have sponsored a large number of provider and consumer education projects to demonstrate ways in which nursing homes may remove residents' restraints. HCFA, however, recognizes the role that others have played in restraint reduction.

HCFA discusses performance measures that are related to program evaluations performed by HCFA and others, including GAO. However, the performance report does not include the required summary of findings and recommendations in evaluations completed during the fiscal year covered by the report or state that no related evaluations were done.

HCFA provides information on the source of its performance data and briefly notes that data are checked during annual surveys. However, it does not discuss the process that surveyors use to verify data or recognize data concerns. For example, HCFA does not discuss the variability in reported data resulting from the extent to which facilities count (or do not count) bedside rails when they are functioning as restraints. HCFA states that, in the future, data from another source, the minimum data set—which is based on the ongoing measurement of the status of residents in all facilities in the country—will be used to further refine its restraint measure. However, HCFA also recognizes that it must exercise caution in using data from the minimum data set until it has assessed its accuracy and completeness.

Unmet FY 1999 Performance Goals and Measures for This Key Outcome

HHS had no unmet FY 1999 performance goals and measures for this outcome.

HHS' FY 2000 Performance Goals and Measures to Have Beneficiaries Receive High-Quality Nursing Home Services

Goal and Measure Added

- Decrease the prevalence of pressure ulcers in residents in long-term care facilities.

Goal and Measure Changed

- Decrease the use of physical restraints 10% (from 13%).

GAO Observations on the FY 2000 Performance Plan for This Key Outcome

HCFA added a new goal for FY 2000 to enhance coverage of Medicaid issues and because GAO had criticized HCFA's ability to detect and prevent pressure ulcers in residents. However, HCFA did not have baseline information related to this developmental goal and, therefore, did not set future-year performance targets. HCFA plans to establish a baseline in FY 2000 to be used in setting the FY 2001 target. It will use data from the minimum data set database, such as quality indicator reports, to measure changes in prevalence. In discussing data verification and validation issues related to this goal, however, HCFA provides information on data sources but does not provide detailed information on data concerns or limitations or on ongoing efforts to ensure data accuracy.

HCFA revised its original FY 2000 target for physical restraints because interim data indicated that a more aggressive 10% target was feasible.

HHS' FY 2001 Performance Goals and Measures to Have Beneficiaries Receive High-Quality Nursing Home Services

Goal and Measure Added

- Improve the management of the survey and certification budget development and execution process.

GAO Observations on the FY 2001 Performance Plan for This Key Outcome

HCFA added this new goal for FY 2001 because the agency is responsible for maximizing the use of available funding for survey and certification activities. States' survey and certification programs help ensure that institutions, including nursing homes, providing

health care services to Medicare and Medicaid beneficiaries meet federal health, safety, and quality standards.

The agency provides a detailed discussion of its planned strategic approach for achieving this multiyear goal. For example, HCFA states that, in future years, it plans on developing and implementing survey performance measures to assess the quality of survey work that states perform. However, the critical step of assessing states' performance could begin sooner if HCFA were to use available data. For example, one HCFA regional office has used survey data to evaluate the performance of state agencies in its region in areas such as survey predictability. The regional office plans to issue quarterly management reports, which will include these evaluations, to document state agencies' performance over time and to make it easier to identify patterns of poor state performance.

The agency's FY 2001 performance plan's presentation of this performance goal addresses some weaknesses that GAO identified in the agency's FY 1999 and 2000 performance plans. For example, the agency established a clearer link between budget accounts and program activities than it has in prior plans. In addition, by adding this goal, HCFA has more fully addressed this important aspect of HCFA's mission. However, GAO questions whether the goals in HCFA's plan sufficiently address the agency's overall performance in implementing about 30 ongoing nursing home initiatives, including preventing dehydration and malnutrition and combating resident abuse. In its comments on this letter, HCFA noted that the state survey and certification process already evaluates malnutrition and dehydration in nursing homes. However, the performance plan does not measure HCFA's performance on nursing home initiatives or provide an indication on how well HCFA is doing to improve quality care in nursing homes.

Last year, GAO raised concerns about HCFA's performance plan because it did not include measures to assess progress for over one-third of the plan's performance goals. This year's plan continues to track progress for decreasing the presence of restraints in long-term care and proposes completing by October 2000 a methodology for allocating survey and certification appropriations with phased implementation beginning in FY 2001. Nevertheless, the agency has not yet developed performance measures and baselines to track progress in two other key areas—decreasing the prevalence of pressure ulcers in long-term care facilities and assessing the quality of states' survey work.

Key Agency Outcome: Poor and Disadvantaged Families and Individuals Become Self-Sufficient

Table I-3 shows HHS' 25 performance goals and measures that relate to the key agency outcome of having poor and disadvantaged families and individuals become self-sufficient and whether or not these goals were met in FY 1999, as reported in HHS' FY 1999 performance report.

Table I-3: Goals and Measures to Have Poor and Disadvantaged Families and Individuals Become Self-Sufficient and Their FY 1999 Status, as Reported by HHS

Goal/measure	FY 1999 status
Increase employment (Administration for Children and Families)	
• **Temporary Assistance for Needy Families program**	
All states meet TANF work participation rates for both all families (35% participation) and two-parent families (90% participation).	Data not available; expected Dec. 2000
Increase from FY 1998 baseline year the number of adult TANF recipients who become newly employed (no target set).	Data not available; expected Dec. 2000
Increase from FY 1998 baseline year the number of adult TANF recipients/former recipients employed in one quarter of the year who continue to be employed in the subsequent quarter (no target set).	Data not available; expected Dec. 2000
Increase from FY 1998 baseline year the average quarterly earnings received by employed TANF recipients/former recipients over a previous quarter (no target set).	Data not available; expected Dec. 2000
• **Developmental Disabilities (Employment) program**	
Increase to 9,517 the number of adults with developmental disabilities who obtain integrated jobs as a result of Developmental Disabilities program intervention.	Data not available; expected Mar. 2000
Increase to 4,353 the number of businesses/employers that employ and support people with developmental disabilities as a result of Developmental Disabilities program intervention.	Data not available; expected Mar. 2000
Increase to $4 million the dollars leveraged from ADD's federal partners in support of positive outcomes for people with developmental disabilities in terms of employment, housing, education, health, and community support as a result of ADD intervention.	Target not met ($2.1 million leveraged)
• **Refugee Resettlement program**	
Increase the number of refugees entering employment through ACF-funded refugee employment services by at least 5% annually to 51,597 in FY 1999.	Data not available; expected Apr. 2000
Increase the number of entered employments with health benefits available as a subset of full-time job placements by 5% annually to 27,767 in FY 1999.	Data not available; expected Apr. 2000
Increase the number of refugee cash assistance cases closed due to employment by at least 5% annually as a subset of all entered employments to 16,480 in FY 1999.	Data not available; expected Apr. 2000
Increase the number of 90-day job retentions as a subset of all entered employments by at least 5% annually to 37,936 in FY 1999.	Data not available; expected Apr. 2000
Increase the number of refugees who enter employment through the Matching Grant program as a percentage of all Matching Grant employable adults by at least 5% annually to 8,620 in CY 1999.	Data not available; expected May 2000
Increase the number of refugee families (cases) that are self-sufficient (not dependent on any cash assistance) within the first 4 months after arrival by at least 4% annually to 5,710 in CY 1999.	Data not available; expected May 2000

Goal/measure	FY 1999 status
Increase independent living (Administration for Children and Families)	
• **Developmental Disabilities (Employment) program**	
Increase to 2,079 the number of people with developmental disabilities owning or renting their own homes as a result of Developmental Disabilities program intervention.	Data not available; expected Mar. 2000
Increase parental responsibility (Administration for Children and Families)	
• **Child Support Enforcement program (title IV-D of the Social Security Act)**	
Increase the paternity-establishment percentage among children born out-of-wedlock to 96%.	Data not available; expected Mar. 2000
Increase the percentage of IV-D cases having support orders to 74%.	Data not available; expected Mar. 2000
Increase the IV-D collection rate for current support to 70%.	Data not available; expected Mar. 2000
Increase the percentage of paying cases among IV-D arrearage cases to 46%.	Data not available; expected Mar. 2000
Increase the cost-effectiveness ratio—total dollars collected per $1 of expenditures—to $5.	Data not available; expected Mar. 2000
Increase affordable child care (Administration for Children and Families)	
Increase the number of children receiving subsidized child care from 1997 baseline average of 1.25 million served per month (no target set).	Data not available; expected Apr. 2000 for revised goal
Annually increase the number of states that establish family copayment at 10% or less of family income (no target set).	Data not available; expected Apr. 2000 for revised goal
Increase nondiscriminatory access to and participation in HHS programs (Office for Civil Rights)	
Increase the number of HHS grantees and providers found to be in compliance with title VI in limited English proficient reviews/investigations.	
• Increase the number of corrective actions and no violation findings to 125.	Target met (146)
• Increase the number of limited English Proficient reviews to 117.	Target met (132)
Increase the number of state and local TANF agencies and service providers found to be in compliance with title VI, sec. 504, and the Americans With Disabilities Act.	
• Increase the number of corrective actions and no violation findings to 16.	Target met (23)
• Increase the number of TANF reviews to 14.	Target met (19)

GAO Observations on HHS' FY 1999 Goals and Measures to Have Poor and Disadvantaged Families and Individuals Become Self-Sufficient and HHS' Performance Report on This Key Outcome

HHS' FY 1999 performance goals and measures are generally objective; measurable; quantifiable; and, where plausible, outcome-oriented. However, 5 of the 25 performance measures had no targets for FY 1999 (3 in the TANF program and 2 in the child care program). HHS indicated in its FY 1999 performance plan that these measures did not have targets because the agency was still consulting with state partners on these

measures and collecting baseline data. HHS remedied this shortcoming almost completely in its FY 2000 revised final performance plan.

The extent to which HHS accomplished its FY 1999 goals cannot be determined because data generally are not available for the performance measures associated with these goals. FY 1999 data are available for only 5 of the 20 performance measures that had targets (and for none of the measures without targets). HHS met the targets for four of these five performance measures—the measures under the goal of increasing nondiscriminatory access to and participation in HHS programs. HHS did not meet the target for increasing the dollars leveraged from federal partners in support of positive outcomes for people with developmental disabilities.

HHS' summary of its performance success in the FY 1999 performance report acknowledges that time lags in receiving and validating data reports make it difficult to provide a comprehensive summary of FY 1999 performance until later in FY 2000. The summary notes that HHS relies on state administrative data systems for performance reporting and that final reports are due 90 to 120 days after the fiscal year ends. HHS' FY 1999 performance report does provide the approximate dates by which FY 1999 data will be available for the performance measures that lack data. Data for TANF-related performance measures are expected to be available by December 2000, and data for the other performance measures are expected by dates ranging from March to May 2000. Time lags in obtaining data for measures pertaining to helping individuals and families become self-sufficient will likely present a problem every year in assessing HHS' performance in achieving this outcome. However, HHS' performance report does not indicate how the agency plans to address this problem.

In its comments on our report, HHS acknowledged that FY 1999 data were not available for a significant number of performance measures but cited several measures for which the FY 1999 performance report included data for earlier years and maintained that these data indicate progress in achieving objectives. For example, HHS cited FY 1997 and 1998 data on the number of 90-day job retentions for refugees that indicate that FY 1998 performance exceeded the target for FY 1999.

HHS' FY 1999 performance report notes that program evaluations are playing an increasingly important role in program improvement as the agency continues to focus on results-oriented management. However, the report does not list the program evaluations completed, or scheduled to have been completed, in FY 1999 or summarize the findings of these evaluations in assessing the agency's FY 1999 performance.

Unmet FY 1999 Performance Goals and Measures for This Key Outcome

HHS' performance fell short of its target for one goal: Increase to $4 million the dollars leveraged from ADD federal partners in support of positive outcomes for people with developmental disabilities in terms of employment, housing, education, health, and community support as a result of ADD intervention. The dollars leveraged increased to only $2.1 million. HHS did not provide a clear explanation of the reasons for not

achieving this target. The FY 1999 performance report explains that unforeseen challenges in identifying mutual opportunities with federal partners delayed achievement of the target. However, the performance report neither specifies these challenges nor agency actions and time frames for achieving this performance measure in the future. In its comments, HHS noted that it has efforts under way to work more closely with various grantee partners to assist them in identifying and leveraging other federal resources.

HHS' FY 2000 Performance Goals and Measures to Have Poor and Disadvantaged Families and Individuals Become Self-Sufficient

Goals and Measures Added

Four new goals and measures were added for FY 2000 that replace the goals for ACF to increase affordable child care:

- Increase the number of children served by Child Care and Development Fund (CCDF) subsidies from FY 1998 baseline average of 1.5 million served per month to 1.92 million.
- Increase the percentage of potentially eligible children who receive CCDF subsidies from FY 1998 baseline of 10% to 11%.
- Decrease the average percentage of family income spent in assessed child care copay among families receiving CCDF subsidies from FY 1998 baseline of 6.2% to 5.8%.
- Increase the number of families working and/or pursuing training/education with support of CCDF subsidies from FY 1998 baseline of 802,000 to 1 million.

Goals and Measures Changed

- Goals to increase from FY 1998 baseline year (1) the number of adult TANF recipients who become newly employed, (2) the number of adult TANF recipients/former recipients employed in one quarter of the year who continue to be employed in the subsequent quarter, and (3) the average quarterly earnings received by employed TANF recipients/former recipients over a previous quarter were revised slightly and expressed in terms of percentages rather than numeric changes; targets have been established.
- Goal to increase to $4.5 million the dollars leveraged from ADD federal partners in support of positive outcomes for people with developmental disabilities was lowered to $2.4 million.
- Targets under the goal of increasing nondiscriminatory access to and participation in HHS programs were revised: the number of corrective actions and no violation findings was increased to 151 (from 140); the number of limited English proficient reviews was increased to 136 (from 131); the number of corrective actions and no violation findings was increased to 29 (from 18); and the number of TANF reviews was increased to 24 (from 16).

GAO Observations on the FY 2000 Performance Plan for This Key Outcome

HHS provided reasonable explanations of the changes in performance measures from FY 1999. The agency explained that the TANF performance measures were revised because (1) given the continuing decline in the size of the TANF caseload, it would be unrealistic to use numeric changes for these measures, and (2) in light of evidence that the remaining TANF population has more barriers to employment, it is not clear that substantial increased performance is achievable. HHS explained that new performance measures for child care were established as a result of completing the process of building consensus with the states on appropriate measures. We believe that these new measures should provide a more precise and comprehensive indication of HHS' progress in increasing affordable child care than the measures contained in the FY 1999 performance plan.

HHS lowered the target level for the goal in the Developmental Disabilities program of increasing the dollars leveraged from federal partners in response to challenges it experienced in working with federal partners. However, the FY 1999 performance report does not discuss any revisions to the means and strategies section of the FY 2000 performance plan to better achieve this target.

HHS increased the FY 2000 target levels for each of the four measures under the goal of increasing nondiscriminatory access to and participation in HHS programs in response to its performance in exceeding the FY 1999 targets for each of these measures. As a result of this revision, the targets in the revised FY 2000 plan for each measure are now higher than those achieved in FY 1999.

HHS' FY 2001 Performance Goals and Measures to Have Poor and Disadvantaged Families and Individuals Become Self-Sufficient

Goals and Measures Added

HHS added five goals and measures for FY 2001 for the Social Services Block Grant (SSBG):

- Maintain the number of child recipients of day care services that are funded in whole or in part by SSBG funds at FY 1998 baseline of 2,364,852.
- Maintain the number of adult recipients of home-based services that are funded in whole or part by SSBG funds at FY 1998 baseline of 252,275.
- Increase the number of adult recipients of special services for the disabled that are funded in whole or part by SSBG funds by 5% annually from FY 1998 baseline to 338,200.
- Maintain the number of recipients of child protective services that are funded in whole or part by SSBG funds at FY 1998 baseline of 1,264,365.
- Increase the number of recipients of information and referral services funded in whole or part by SSBG funds by 2% annually from FY 1998 baseline to 1,223,545.

HHS added one goal and measure for the child care program:

- Increase the number of slots in state-regulated child care settings from FY 2000 baseline.

GAO Observations on the FY 2001 Performance Plan for This Key Outcome

States have considerable flexibility to use SSBG funds for a broad array of services. The FY 1999 and FY 2000 performance plans included a section on SSBG but had no performance goals or measures for this program. Citing congressional intent that SSBG funding be directed at one or more of five national goals, HHS developed SSBG performance goals and measures in the FY 2001 plan that address the national goals. Each of the five performance measures provides a succinct and concrete statement of expected performance for subsequent comparison with actual performance. However, since the FY 2001 performance plan contains no discussion of strategies the agency will use for meeting these performance targets, such as coordination with other agencies, it is unclear whether HHS plans to take any steps to facilitate meeting these targets. In its comments on this letter, HHS said it will continue to review and assess shifts in funding priorities to project accomplishments of performance targets as well as discuss with states problems that arise and provide technical assistance where practical.

HHS added a new child care performance measure for FY 2001 as a result of the completion of the consensus-building process with states mentioned above. However, no target has been established for this measure.

HHS' FY 2001 performance plan reflects progress in addressing key weaknesses GAO previously identified in the agency's FY 2000 plan. For example, while several performance measures in the FY 2000 plan associated with helping families become self-sufficient had no targets, all but one of the related performance measures in the FY 2001 plan have targets. In addition, our assessment of HHS' FY 2000 plan noted that the agency had not established baseline data for three performance measures pertaining to the employment progress of TANF recipients; this shortcoming has been remedied in the FY 2001 plan.

However, not all of the problems we previously identified have been addressed. Our assessment of HHS' FY 2000 performance plan noted that the plan did not adequately identify actions to compensate for unavailable or poor quality data in the area of child support enforcement. In particular, our assessment highlighted the statement in HHS' plan that not all states have certified statewide automated systems and that some states still maintain data manually. Our assessment also cited a report from the agency's Office of Child Support Enforcement (OCSE) that noted that where automated systems are not in place, problems of duplication and missing information could result. As was the case with the FY 2000 plan, the FY 2001 plan does not discuss the actions HHS will take to compensate for possibly unreliable data in this area or the implications of these data limitations.

Key Agency Outcome: Improved Prevention of Diseases and Disabilities

Table I-4 shows HHS' 42 performance goals and measures that relate to the key agency outcome of improving prevention of diseases and disabilities and whether or not these goals were met in FY 1999, as reported in HHS' FY 1999 performance report.

Table I-4: Goals and Measures to Improve Prevention of Diseases and Disabilities and Their FY 1999 Status, as Reported by HHS

Goal/measure	FY 1999 status
Centers for Disease Control and Prevention	
Reduce the tuberculosis (TB) case rate (targets: (1) 85% of TB patients will complete a course of curative TB treatment within 12 months of initiation of treatment, (2) 92% of TB patients with initial positive cultures will also have drug susceptibility results, (3) 75% of contacts of infectious cases who are placed on therapy for latent TB infections will complete a treatment regimen, (4) 70% of other high-risk infected persons who are placed on therapy for latent TB infection will complete a treatment regimen, and (5) states will report information to CDC on identified priority variables).	Data not available; expected between mid-2000 and late 2001.
Reduce the rate of heterosexually acquired AIDS cases, as well as AIDS cases related to injecting drug use and male homosexual contact, through the implementation of HIV-prevention programs as part of a community planning process, and reduce the rate of perinatally acquired HIV/AIDS cases (targets: (1) 10% decrease in the number of diagnosed heterosexually acquired AIDS cases from 1995 baseline of 9,300, (2) 15% decrease in the number of AIDS cases related to injecting drug use from 1995 baseline of 17,800, (3) 20% decrease in the number of AIDS cases related to male homosexual contact from 1995 baseline of 28,600, and (4) 50% decrease in the number of diagnosed perinatally acquired HIV/AIDS cases from 1993 baseline of 865).	Data not available; expected June 2000
Among persons counseled and tested for HIV infection in CDC-supported sites, improve the percentage of persons who return for their results and post-test counseling (target: 10% relative increase in the percentage of persons who return from 61% in 1996 to 67%).	Data not available; expected June 2000
Reduce the percentage of HIV/AIDS-related risk behaviors among school-aged youth through dissemination of HIV-prevention education programs (target: at least 90% of high school students taught about HIV/AIDS prevention in school).	Data not available; expected summer 2000
Reduce sexually transmitted disease (STD) rates by providing chlamydia and gonorrhea screening, treatment, and partner treatment to 50% of women in publicly funded family planning and STD clinics nationwide (targets: (1) less than 8% prevalence of *Chlamydia trachomatis* among high-risk women under 25, (2) less than 6% prevalence of *Chlamydia trachomatis* among women under 25 in publicly funded family clinics, (3) less than 250 per 100,000 incidence of gonorrhea in women aged 15 to 44 in publicly funded family planning and STD clinics, (4) less than 125 per 100,000 incidence of pelvic inflammatory disease (PID), as measured by a reduction in hospitalizations for PID, in women aged 15 to 44 in publicly funded family planning and STD clinics, and (5) less than 225,000 initial visits for PID to physicians in publicly funded family planning or STD clinics).	Data not available; expected between June 2000 and end of 2001
Reduce the incidence of congenital syphilis (target: incidence of less than 20 cases of congenital syphilis in the general population per 100,000 live births).	Data not available; expected June 2000

Goal/measure	FY 1999 status
Reduce the incidence of primary and secondary syphilis through the development of syphilis elimination action plans for each state that had a primary and secondary syphilis rate in 1995 of greater than or equal to 4 per 100,000 population and an HIV prevalence in childbearing women of greater than 1 per 1,000 (target: at least 85% of U.S. counties will have an incidence of primary and secondary syphilis in the general population of less than or equal to 4 per 100,000).	Data not available; expected June 2000
Reduce the number of cases of vaccine-preventable diseases (targets: maintain at or reduce to 0 the number of cases of paralytic polio, rubella, measles, *Haemophilus influenzae* invasive disease in children under 5, diphtheria, congenital rubella syndrome, and tetanus; reduce to 500 the number of mumps cases; and reduce to 2,000 the number of pertussis cases among children under 7).	Data not available; expected Sept. 2000
Ensure that 2-year olds are appropriately vaccinated (target: at least 90% of children 2 years of age have specified immunization coverage for each vaccine).	Data not available; expected Aug. 2000
Increase pneumococcal pneumonia and influenza vaccination among persons age 65 and older (targets: 60% and 54% rates of vaccination for influenza and pneumococcal pneumonia, respectively, among noninstitutionalized high-risk populations).	Data not available; expected summer 2000
Collaborate with domestic and international partners to help achieve the World Health Organization's (WHO) goal of global polio eradication by Dec. 31, 2000 (targets: 445 million doses of oral polio vaccine purchased as needed to assist in conducting mass immunization campaigns in Asia, Africa, and Europe; 67 persons in the network of CDC and CDC-funded staff, virologists, epidemiologists, technical and scientific officers on long-term assignments in WHO country and regional offices; and 50 trained public health professionals in a special program to prepare a cadre throughout CDC to complete short-term assignments with WHO).	Target met (450 million doses purchased, 75 staff on assignment, and 100 trained professionals in special program)
Reduce morbidity and mortality attributable to behavioral risk factors by building nationwide programs in chronic disease prevention and health promotion and intervening in selected diseases and risk factors (targets: reduce to 34% the percentage of teenagers smoking, and 85% of states participating in the Behavioral Risk Factor Surveillance System).	Data not available; expected Apr. 2000
Increase early detection of breast and cervical cancer by building nationwide programs in breast and cervical cancer prevention (targets: 67% of women age 40 and older diagnosed at localized stage, excluding breast cancers diagnosed on an initial screen in the National Breast and Cervical Cancer Early Detection Program; and no more than 22 invasive cervical cancers per 100,000 Pap tests provided in women aged 20 and older, excluding invasive cervical cancers diagnosed on an initial screen in the early detection program).	Data not available; expected Mar. 2000
Reduce the prevalence of chronic and disabling conditions and improve the quality of life for those already affected by these conditions by building nationwide programs in chronic disease prevention and health promotion and intervening in selected diseases and risk factors (targets: five prevention research studies conducted to better understand how to apply diabetes scientific findings in clinical and public health practice and the results published in peer-reviewed journals, and at least 75% of the 58 state diabetes programs having core capacities).	Target met (7 prevention research studies, and 75% of state programs)
Reduce the incidence of youth violence (target: develop best practices protocols for implementation and evaluation of youth violence prevention programs).	Target met
Reduce the incidence of intimate partner violence (target: 31 state and community-based intimate partner violence and sexual assault projects).	Target met

Goal/measure	FY 1999 status
Reduce the number and severity of injuries related to bicycle-related head injuries by increasing the use of bicycle helmets by children in CDC-funded projects (targets: 5% per year reduction in the number of bicycle-related emergency department visits, and increase the use of bicycle helmets by child bicyclists in CDC-funded project areas to 30%).	Data not available; expected between Apr. and June 2000
Reduce the incidence of fire-related injuries by increasing the percent of residential dwellings that have at least one functional smoke alarm on each habitable floor in CDC-funded projects (targets: 1.3 per 100,000 incidence of residential fire-related deaths, 88% of homes with at least one smoke detector, and develop recommendations for conducting and evaluating smoke detector promotion programs).	Third target met; data for first two targets expected by Sept. 2000
Increase by 25% the number of toxic substances that can be measured by CDC's environmental health laboratory by 2002 from a baseline of 200 in 1997, so state-of-the-art laboratory methods can be employed to prevent avoidable environmental diseases (target: six new methods to measure human exposure to toxic substances).	Target met
Increase the number of women who consume 400 micrograms of folic acid from a baseline of 25% in 1996 to 50% by 2002 (target: 35% of women of reproductive age will consume 400 micrograms of folic acid).	Data not available; none expected
Reduce the incidence of childhood asthma attacks through implementation of comprehensive asthma prevention programs in states (target: six states having implemented core asthma programs).	Target not met (two states do not have programs)
By 2011, there will be virtually no children with blood lead levels that exceed 10 micrograms per deciliter (the level at which children's health may be damaged) (target: 25% reduction in the number of children with elevated blood lead levels).	Data not available; none expected
Conduct a targeted program of research to reduce morbidity, injuries, and mortality among workers in high-priority areas and high-risk sectors (targets: determine current levels of National Institute of Occupational Safety and Health (NIOSH) and other federal agencies' research funding in National Occupational Research Agenda areas as a baseline, and establish protocol on the use of bibliometrics and other research proxy measures).	Target met
Ensure safe and healthful work conditions by developing a surveillance system for major occupational illnesses, injuries, exposures, and health hazards (targets: undertake a comprehensive surveillance planning process; and implement recommendations and collect, analyze, and disseminate surveillance information on occupational illnesses, injuries, and hazards).	Target met
Promote safe and healthful work conditions by increasing occupational disease and injury prevention activities through workplace evaluations, intervention, and NIOSH recommendations (targets: establish baseline of annual performance in conducting workplace evaluations and technical assistance visits, and prepare policy and technical documents that define policy and/or make other recommendations and evaluate the extent to which recommendations are being implemented).	Target met (baseline of 334 health hazard evaluations established and evaluation initiated)
Foster safe and healthful work conditions by providing workers, employers, the public, and the occupational safety and health community with information, training, and capacity to prevent occupational diseases and injuries (targets: review training materials for ease of understanding, and design and implement two model information dissemination and training programs).	First target met; second unmet (programs developed but not implemented)

Goal/measure	FY 1999 status
Achieve meaningful improvement in the lives of racial and ethnic populations who now suffer disproportionately from the burden of disease and disability, and develop the necessary tools and strategies that will enable the nation to meet the far more challenging goal of eliminating these health disparities by the year 2010 (target: fund a selected community to implement interventions based on community planning activities to eliminate racial and ethnic health disparities for selected focus areas).	Target met (32 community coalitions funded)
Health Care Financing Administration	
Increase the prevalence of Medicare beneficiaries age 65 years and older who receive an influenza vaccination (target: 60%).	Data not available
Increase the percentage of Medicare beneficiaries age 65 years and older who receive a mammogram in a 2-year period (target: 60%).	Data not available
Health Resources and Services Administration	
Continue to ensure access to preventive and primary care for low-income individuals (target: 86% of patients are at or below 200% of poverty level).	Data not available; expected May 2000
Continue to ensure access to preventive and primary care for minority individuals (target: 65% of patients are racial minorities or Hispanic).	Data not available; expected May 2000
Increase the number of uninsured and underserved persons served by health centers (target: 8.9 million persons in underserved areas).	Data not available; expected May 2000
Increase proportion of users with diabetes with up-to-date testing of glycohemoglobin (target: 20%).	Data not available; expected June 2000
Increase proportion of health center women receiving age-appropriate screening for cervical and breast cancer (targets: 85% Pap tests, 60% mammograms, and 60% clinical breast exams).	Data not available; expected May 2000
Increase proportion of health center adults with hypertension who report their blood pressure is under control (target: 50%).	Data not available; expected May 2000
Decrease percentage of health center users who are hospitalized for potentially avoidable conditions (no target set).	Data not available; expected Sept. 2001
Increase the number of enrolled female (AIDS) clients provided comprehensive services, including appropriate services before or during pregnancy, to reduce perinatal transmission (target: 13,900).	Data not available; expected Jan. 2001
Decrease by 39% the number of newly reported AIDS cases in children as a result of perinatal transmission (target: 415).	Data not available; expected Jan. 2001
Indian Health Service	
Increase by 3% the proportion of American Indian and Alaskan Native children who have completed all recommended immunizations by age 2 over the FY 1998 rate (target: 91%).	Target not met (87%)
Reduce deaths by unintentional injuries for American Indian and Alaskan Native people to no more than 93 per 100,000 people (target: 93 per 100,000).	Data not available; expected Dec. 2002
Identify the area-specific prevalence of obesity in American Indians and Alaskan Natives both in the Head Start population (3- to 5-year-olds) and in third grade children (8- to10-year-olds), and develop a multidisciplinary and multidimensional intervention plan for one or both age groups to address this problem (target: develop approach and baselines).	Target met
National Institutes of Health	
Develop new or improved approaches for preventing or delaying the onset or progression of disease and disability (target: research yields such approaches, and the findings are published and/or disseminated).	Target met

GAO Observations on HHS' FY 1999 Goals and Measures to Improve Prevention of Diseases and Disabilities and HHS' Performance Report on This Key Outcome

Several HHS agencies have performance goals and measures that contribute to the outcome of improved prevention of diseases and disabilities. CDC has lead responsibility for prevention and is responsible for the majority of HHS' prevention-related goals. The agencies have a mix of outcome goals, evidence-based intermediate outcome goals, and output goals.

By and large, individual HHS agencies articulate the degree to which their goals were achieved on an explicit, goal-by-goal basis. Most of HHS' prevention goals are objective and measurable. While, in general, measures can indicate progress toward goal attainment, in some cases the measure toward an outcome goal is an output or process measure. For example, CDC has a goal of reducing the prevalence of chronic and disabling conditions and improving the quality of life for those already affected by these conditions. Two of the goal's performance measures are conducting a targeted number of prevention research studies and having a targeted percentage of state diabetes programs with certain core capacities, such as surveillance. In some cases, the measure is not the most appropriate way to assess goal attainment. For example, one HRSA goal is to ensure access to preventive and primary care for low-income individuals. The measure for that goal is the proportion of health center patients with income at or below 200% of the poverty level. A truer measure of the extent to which the health center program accomplishes this goal would be data on the proportion of low-income people in health centers' communities who receive services at the centers. NIH's method of assessing whether it met its prevention goal was not an objective measure; a group of experts assessed whether published research funded by NIH yielded new or improved approaches for preventing or delaying the onset or progression of disease and disability.

HHS has provided only limited evidence as to whether it accomplished its FY 1999 prevention goals. Of 74 measures HHS linked with its prevention goals, 19 had targets that were met, 3 had targets that were unmet, and 4 had no target set. The performance report did not provide performance data on the remaining 48 but indicated data would be available by a specified future date, typically during 2000. However, in some instances HHS provided earlier trend data that it believes indicates progress in achieving goals. Furthermore, HHS does not discuss how it used program evaluations to identify ways to improve program performance for this outcome. (HHS' performance report states that it incorporates by reference the Department's annual report to the Congress on HHS evaluation activities.)

The individual HHS agencies with prevention goals differ in the extent to which they offer assurance that the performance information they present is credible. Some examples follow:

- For each of its goals, CDC discusses the verification and validation of its performance measures. In some instances, these processes are electronic checks, possibly

involving multiple data systems; but in others, verification and validation is monitored manually by epidemiologists and program officers. CDC's measures related to prevention are derived, for the most part, from its own health data systems, including those of the National Center for Health Statistics. However, CDC is also dependent upon reports of health events as submitted by state public health laboratories. The agency provides a discussion of the strengths and weaknesses of its data. Foremost among the latter are the delays in data availability currently experienced and the fact that as the health system changes, historical data series may no longer produce the data needed to evaluate historical trends.

- IHS' measures related to prevention are derived from its Resource and Patient Management System, public health nursing records, the CDC Pediatric Nutrition Surveillance System, the National Center for Health Statistics, and state Vital Events Offices, among other sources. IHS reports on the extensive edits, both automated and by hand, that are part of its Resource and Patient Management System, and thereby determine the quality of that system's data. There is no information in the performance report on the quality of the data from the other systems used. In general, IHS does provide baseline information, notes trends over time, and addresses weaknesses in its data and methods. Further, it discusses any data that are preliminary, estimated, or missing.
- HRSA's Uniform Data System collects information from health centers, and HRSA relies on these data to measure achievement of some of its primary care goals. The performance report states that the Uniform Data System is validated through edit checks and onsite reviews. However, GAO recently reported that the edit checks have not always been effective and that onsite reviews do not occur frequently enough to ensure timely data validation.[3]

Unmet FY 1999 Performance Goals and Measures for This Key Outcome

Three of HHS' FY 1999 goals for improving prevention of diseases and disabilities were not met:

- CDC did not meet its goal of reducing the incidence of childhood asthma attacks through implementation of comprehensive asthma prevention programs in states. CDC's brief explanation for not reaching its asthma prevention program target cited funding constraints.
- CDC also did not meet its goal of implementing two model information dissemination and training programs on safe and healthful work conditions; it did not discuss why its dissemination and training programs were not implemented.
- IHS did not meet its goal of increasing the percentage of American Indian and Alaskan Native children having completed all recommended immunizations by age 2 to 91%. IHS provided a reasonable and detailed explanation for not reaching its immunization target, including a discussion of external factors such as the continued

[3]Community Health Centers: Adapting to Changing Health Care Environment Key to Continued Success (GAO/HEHS-00-39, Mar. 10, 2000).

growth of new recommended vaccines. It also described its attempts to resolve those issues over which it has some control (for example, recruitment of needed staff).

For 27 of the goals and measures for this key outcome, HHS could not provide data.

HHS' FY 2000 Performance Goals and Measures to Improve Prevention of Diseases and Disabilities

Goals and Measures Added

Centers for Disease Control and Prevention

- Measure HIV incidence in selected high-risk populations (target: continue to conduct 14 studies in approximately 53 sites).
- Reduce the annual incidence of new HIV infections (target: 40,000 new infections).
- Increase the number of states with five of the seven core cardiovascular disease prevention capacities (target: 11 states).
- Reduce the prevalence of chronic and disabling conditions and improve the quality of life for those already affected by increasing the percentage of CDC-funded state diabetes control programs that will adopt new diabetes-related guidelines and increasing the percentage of diabetics who receive annual eye and foot exams (targets: 100% of programs; 72% eye exams and 62% foot exams).
- Reduce the onset and consequences of arthritis by expanding preventive services and community programs (target: 30 states using the Behavioral Risk Factor Surveillance System modules on arthritis).

Health Care Financing Administration

- Decrease the prevalence of pressure ulcers in long-term care facilities (target: establish baseline and (future) target prevalences and additional (future) interventions).
- Increase the percentage of Medicaid 2-year-old children who are fully immunized (target: establish several groups of states at different stages in the process of baseline development).

Health Resources and Services Administration

- Increase the percentage of diabetic users who have had annual dilated eye exams (target 80%).
- Increase the number of specific environmental services provided to 32,600.
- Achieve state-set rates for reducing the incidence of youths 15 to 19 years old who have contracted selected sexually transmitted diseases in 50% of the participating states (target: obtain baseline data).

Indian Health Service

- Ensure that the total number of public health nursing services provided to individuals in all settings and the total number of home visits are increased by 7% in FY 2000 over the FY 1997 workload baselines.
- Increase overall pneumococcal and influenza vaccination levels among diabetics and adults aged 65 years and older to 65%.
- Determine prevalence rates for the usage of tobacco products.
- Determine prevalence rates of HIV/AIDS infection in American Indian and Alaskan Natives at IHS treatment facilities.
- Develop and implement an environmental health surveillance system.

Goals and Measures Changed

Centers for Disease Control and Prevention

- Targets for reducing the TB case rate: 93% (from 92%) of TB patients with initial positive culture will also have drug susceptibility results; 95% of states will report essential TB-related surveillance variables to CDC.
- Targets for reducing the rate of acquired AIDS: decrease the number of diagnosed heterosexually acquired AIDS cases by 10% from 1997 (not 1995) baseline; decrease the number of AIDS cases related to injecting drug use by 10% (from 15%) from 1997 (not 1995) baseline; decrease the number of AIDS cases related to male homosexual contact by 10% (from 20%) from 1997 (not 1995) baseline; and decrease by 203 cases the number of perinatally acquired HIV/AIDS cases (from 50% decrease from 1993 baseline of 865).
- Target for increasing the percentage of persons who return for AIDS-related results and post-test counseling: 65% (from 67%).
- Target for reducing the incidence of congenital syphilis in the general population: less than 19 (from 20) cases per 100,000 live births.
- Target for percentage of U.S. counties with incidences of syphilis of less than or equal to 4 per 100,000: more than 90% (from 85%) of U.S. counties.
- Target to ensuring that at least 90% of 2-year-olds are appropriately vaccinated was revised to at least 90% of children 19- to 35-months of age have specified immunization coverage for each vaccine.
- Targets for increasing pneumococcal pneumonia and influenza vaccination rates among persons age 65 and older: 60% and 70%, respectively (from to 54% and 60%).
- Targets for collaborating with domestic and international partners to help achieve WHO's goal of global polio eradication by December 31, 2000: 526 million (from 445 million) doses of oral polio vaccine purchased, 82 (from 67) persons in the network of CDC and CDC-funded staff, and 60 (from 50) trained public health professionals in a special program to prepare a cadre for completing short-term assignments.
- Target for increasing the percentage of women age 40 and older diagnosed at localized stage of breast cancer: 72% (from 67%).

- Targets for reducing the prevalence of chronic and disabling conditions: seven (from five) prevention research studies conducted, and at least 85% (from 75%) of the 58 state diabetes programs having core capacities.
- Goal for reducing the incidence of youth violence was revised to include targets: 30% reduction in number of students reporting fighting in CDC-funded violence projects, dissemination of best practices protocols, and eight best practices workshops held.
- Goal for reducing the incidence of intimate partner violence was revised to read "violence against women" and to include targets: begin development of a survey instrument, implement and begin evaluation of two innovative programs, develop a violence against women research plan and identify institutions committed to such research, identify sources of entire state data on intimate partner violence, and increase at least one of three options for increasing knowledge about this topic.
- Target for increasing by 30% the use of bicycle helmets by children in CDC-funded projects was increased for use by an additional 25%.
- Targets for reducing the incidence of fire-related injuries by increasing the percent of residential dwellings that have at least one functional smoke alarm on each habitable floor in CDC-funded projects: 1.1 (from 1.3) per 100,000 incidence of residential fire-related deaths, 60% (from 88%) of homes with at least one smoke detector on each habitable floor, and publish recommendations for conducting and evaluating smoke detector promotion programs.
- Target for increasing by 25% the number of toxic substances that can be measured by CDC's environmental health laboratory to 40 new substances by the year 2002 from a baseline of 200 in 1997 was decreased to measure 8 new substances.
- Target for increasing the percentage of women of reproductive age who consume 400 micrograms of folic acid: 40% (from 35%).
- Target for reducing the incidence of childhood asthma attacks through implementation of comprehensive asthma prevention programs in states was increased to eight (from six) states having implemented core asthma programs.
- Target for conducting a targeted program of research to reduce morbidity, injuries, and mortality among workers in high-priority areas and high-risk sectors: increase levels of NIOSH and other federal agencies' research funding in National Occupational Research Agenda areas, and establish baseline amounts on the use of bibliometrics and other research proxy measures.
- Target for ensuring safe and healthful work conditions by developing a system for surveillance for major occupational illnesses, injuries, exposures, and health hazards: finalize a comprehensive surveillance planning process.
- Targets for promoting safe and healthful work conditions by increasing occupational disease and injury prevention activities through workplace evaluations, intervention, and NIOSH recommendations: begin an evaluation of the extent to which recommendations are being implemented, and continue and report evaluation studies.
- Target for fostering safe and healthful work conditions by providing workers, employers, the public, and the occupational safety and health community with information, training, and capacity to prevent occupational diseases and injuries: complete model information dissemination and training programs.

- Target for achieving meaningful improvement in the lives of racial and ethnic populations and of developing the necessary tools and strategies that will enable the nation to meet the far more challenging goal of eliminating these health disparities by the year 2010: fund selected communities.

Health Resources and Services Administration

- Target for increasing the number of uninsured and underserved persons served by health centers: 9.6 million (from 8.9 million) persons.
- Target for increasing the proportion of users with diabetes with up-to-date testing of glycohemoglobin: 80% (from 20%).
- Goal for decreasing the percentage of health center users who are hospitalized for potentially avoidable conditions was revised to include target: 13.5%.
- Target for increasing the number of enrolled female (AIDS) clients provided comprehensive services, including appropriate services before or during pregnancy, to reduce perinatal transmission: 14,470 (from 13,900) clients.
- Target for decreasing the number of newly reported AIDS cases in children as a result of perinatal transmission was revised to refer to a 5% annual decrease; 2000 target: 203 cases (from 415).

Indian Health Service

- Goal for increasing the proportion of American Indian and Alaskan Native children who have completed all recommended immunizations by age 2: 89% (from 91%).
- Goal for reducing the number of deaths from unintentional injuries of American Indian and Alaskan Native people to 93 per 100,000: no more than 71.5 hospitalizations from unintentional injuries per 10,000 people.
- Goal for identifying the prevalence of obesity in American Indian and Alaskan Native children: develop at least five pilot sites to test intervention strategies for reducing childhood obesity for the Head Start population and/or third grade children.

GAO Observations on the FY 2000 Performance Plan for This Key Outcome

In general, the HHS agencies that have prevention goals discussed reasons for revising FY 1999 goals or adding new goals for FY 2000. However, they did not present information linking the effect of their FY 1999 performance on their estimated performance levels for FY 2000. HRSA included discussions of the influences of other agencies, such as CDC, and external factors, such as markets, in explaining its changes. HCFA cited the influence of external agencies, such as GAO. IHS revised some of its targets in response to its FY 2000 appropriation.

HHS' FY 2001 Performance Goals and Measures to Improve Prevention of Diseases and Disabilities

Goals and Measures Changed

Centers for Disease Control and Prevention

- Targets for reducing the TB case rate: percent of TB patients who will complete a course of curative TB treatment within 12 months of initiation of treatment was increased to 88% (from 85%); percent of TB patients with initial positive cultures who will also have drug susceptibility results was increased to 95% (from 93% for FY 2000); percent of infectious cases placed on therapy for latent TB infections who will complete a treatment regimen was increased to 78% (from 75%); and the percent of other high-risk infected persons placed on therapy for latent TB infections who will complete a treatment regimen was increased to 72% (from 70%).
- Targets for reducing the rate of acquired AIDS cases: decrease the number of diagnosed heterosexually acquired AIDS cases by 10% from the FY 2000 target of 10,350 cases; decrease the number of cases related to injecting drug use by 10% from the FY 2000 target of 14,130 cases; decrease the number of AIDS cases related to male homosexual contact by 10% from the FY 2000 target of 19,170 cases; and reduce the annual incidence of new HIV by 5% from FY 2000 estimate.
- Target for increasing the number of enrolled female (AIDS) clients provided comprehensive services to reduce perinatal transmission: 15,000 clients (from 14,470 in FY 2000).
- Target for decreasing by 5% annually the number of perinatally acquired HIV/AIDS cases: 193 cases (from 203 for FY 2000).
- Target for increasing the number of uninsured and underserved persons served by health centers: 9.7 million (from 9.6 million in FY 2000).
- Target for increasing the percentage of persons who return for AIDS-related results and post-test counseling: 70% (from 60% for FY 2000).
- Target for reducing the incidence of congenital syphilis in the general population: less than 18 cases per 100,000 live births (from 19 per 100,000 live births).
- Target for increasing pneumococcal pneumonia and influenza vaccination rates among persons age 65 and older: rates of 63% and 72%, respectively (from 60% and 70% for FY 2000).
- Target of reducing morbidity and mortality attributable to behavioral risk factors by building nationwide programs in chronic disease prevention and health promotion and intervening in selected diseases and risk factors: 35.9% of teenagers smoking (from 34% for FY 1999).
- Target for increasing the number of states with five of the seven core cardiovascular disease prevention capacities: 18 states (from 11 states for FY 2000).
- Targets for collaborating with domestic and international partners to help achieve WHO's goal of global polio eradication by December 31, 2000: 450 million doses of oral polio vaccine purchased (from 526 for FY 2000), 90 persons in the network of CDC and CDC-funded staff (from 82 for FY 2000), and 100 trained public health

professionals in a special program to prepare a cadre for completing short-term assignments (from 60 for FY 2000).

- Target for increasing the percentage of women age 40 and older diagnosed at localized stage of breast cancer: 73% (from 72% for FY 2000).
- Target for reducing the onset and consequences of arthritis by expanding preventive services and community programs: 35 states using the Behavioral Risk Factor Surveillance System modules on arthritis and 2 to 3 states addressing arthritis with CDC support (from 30 states for FY 2000).
- Targets for reducing the incidence of youth violence: technical assistance to at least five communities using best practices protocols, and develop and test new mechanisms for disseminating best practices.
- Targets for reducing violence against women: pilot test survey instrument, develop progress report on funded programs, address at least two understudied aspects of violence against women, develop and pilot the surveillance system on intimate partner violence, and increase at least two of three options for increasing knowledge about this topic.
- Target for increasing the use of bicycle helmets by children in CDC-funded projects: increase use by an additional 25% over FY 2000.
- Targets for reducing the incidence of fire-related injuries by increasing the percent of residential dwellings that have at least one functional smoke alarm on each habitable floor in CDC-funded projects: 65% of homes (from 60% for FY 2000), and publishing and disseminating recommendations for conducting and evaluating smoke detector promotion programs.
- Targets for increasing the number of toxic substances that can be measured by CDC's environmental health laboratory: 12 new methods to measure human exposure to toxic substances.
- Target for increasing the number of women of reproductive age who consume 400 micrograms of folic acid: 45% of women (from 40% for FY 2000).
- Target for reducing the incidence of childhood asthma attacks through implementation of comprehensive asthma prevention programs in states: 12 states having implemented core asthma programs (from 8 states in FY 2000).
- Targets for conducting a targeted program of research to reduce morbidity, injuries, and mortality among workers in high-priority areas and high-risk sectors: increase further the levels of NIOSH and other federal agencies' research funding in National Occupational Research Agenda areas, and increase further the use of bibliometrics and other research proxy measures.
- Target for ensuring safe and healthful work conditions by developing a system for surveillance for major occupational illnesses, injuries, exposures, and health hazards: continue implementation of surveillance planning process.
- Targets for promoting safe and healthful work conditions by increasing occupational disease and injury prevention activities through workplace evaluations, intervention, and NIOSH recommendations: report on and analyze the extent to which recommendations are being implemented, and begin applications of lessons learned.
- Target for fostering safe and healthful work conditions by providing workers, employers, the public, and the occupational safety and health community with

information, training, and capacity to prevent occupational diseases and injuries: report on and analyze model information dissemination and training programs.
- Target for achieving meaningful improvement in the lives of racial and ethnic populations and of developing the necessary tools and strategies that will enable the nation to meet the far more challenging goal of eliminating these health disparities by the year 2010: announce availability of continuation funding.

Health Resources and Services Administration

- Target for increasing the number of uninsured and underserved persons served by health centers: 45% of uninsured and underserved persons.
- Target for increasing the proportion of users with diabetes with up-to-date testing of glycohemoglobin: 90% (from 80% for FY 2000).
- Target for decreasing the percentage of health center users who are hospitalized for potentially avoidable conditions: 13% (from 13.5% for FY 2000).
- Target for increasing the number of enrolled female (AIDS) clients provided comprehensive services, including appropriate services before or during pregnancy, to reduce perinatal transmission: 15,000 clients (from 14,700 for FY 2000).
- Target for decreasing the number of newly reported AIDS cases in children as a result of perinatal transmission: 193 cases (from 203 for FY 2000).

Indian Health Service

- FY 2000 goal of 89% of American Indian and Alaskan Native children having completed all recommended immunizations by age 2 was increased to 91%.
- FY 2000 goal of 71.5 hospitalizations from unintentional injuries per 10,000 American Indian and Alaskan Native people was increased to no more than 70 hospitalizations per 10,000 people.
- FY 2000 goal of developing at least five pilot intervention sites was revised: reduce childhood obesity rates by maintaining ongoing body mass index assessments for both intervention pilot sites and nonintervention comparison sites, as part of an overall assessment of the ongoing childhood obesity prevention project's effectiveness.
- Target for ensuring that the total number of public health nursing services provided to individuals in all settings and the total number of home visits are increased by 7% over the FY 1997 workload baselines: 7% increase over FY 2000 levels in total services and in home visits.
- Target for increasing overall pneumococcal and influenza vaccination levels among diabetics and adults age 65 years and older: 67% (from 65% for FY 2000).
- Goal for determining area prevalence rates for the usage of tobacco products: develop five regional tobacco control centers to assist American Indian and Alaskan Native health facilities and organizations with tobacco prevention and cessation activities.
- Goal for determining prevalence rates of HIV/AIDS infection in American Indian an Alaskan Natives at IHS treatment facilities: implement local needs assessment to address HIV/AIDS infection in communities.

- Goal for developing and implementing an environmental health surveillance system to provide the information needed to identify environmental health issues, establish local and regional priorities, and develop and evaluate environmental interventions and programs: assess 90% of communities.

GAO Observations on the FY 2001 Performance Plan for This Key Outcome

The HHS agencies with prevention goals generally do not discuss the reasons for changes in their goals. However, for the most part the changes are not alterations to the basic goal but, instead, represent a progression of targets reflecting successively higher levels of goal attainment, such as when CDC sets progressively lower targets for disease incidence rates. HRSA provides reasons for more substantial goal variations.

The HHS agencies provide succinct and concrete statements of their expected performance with respect to their goals. They also discuss the need to coordinate with other agencies and nonfederal entities on particular activities or projects, specifying, in most cases, the nature of the cooperation. For example CDC reports efforts to work with state and local education agencies to implement HIV-prevention education in schools and with SAMHSA and the National Institute on Drug Abuse on issues related to HIV/AIDS transmission in the injecting drug using population. CDC and IHS also provide rich information on their strategies for achieving their goals. For example, both agencies include informative discussions of their strategies for meeting their goals to reduce morbidity and disability related to diabetes.

Some key weaknesses noted in past GAO work remain. Although prevention goals are now usually consistently measurable, the strategies and resources to be used to achieve these goals are not always adequately discussed. For example, while CDC and IHS link their targets to specific budgetary resources, NIH and HRSA do not.

The agencies discuss procedures to verify and validate their performance data. For example, CDC provides detailed information about its data sources. HRSA includes an extensive discussion of its varied data sources and their strengths and limitations, and the agency's attempts to compensate for these limitations. As we discussed above, however, HRSA needs to take additional actions to deal with problems in its data sources.

Key Agency Outcome: Reduced Use of Illegal Drugs

Table I-5 shows SAMHSA's seven performance goals and measures that relate to HHS' key agency outcome of reducing use of illegal drugs and whether or not these goals were met in FY 1999, as reported in HHS' FY 1999 performance report.

Table I-5: Goals and Measures to Reduce Use of Illegal Drugs and Their FY 1999 Status, as Reported by HHS

Goal/measure	FY 1999 status
Expand and enhance substance abuse prevention services by increasing percent of states that use block grant funds in each of six prevention strategy areas to 80%.	Target met (90%)
Increase community involvement in dealing with problems of substance abuse and its effects; specifically, promote the development of infrastructure in communities for initiating and facilitating prevention activities by increasing the mean number of organizations participating in coalition activities to 40% greater than 1995 baseline and by increasing prevention services that promote coalition efforts by 100%.	Target met (more than 300% greater and 100% greater, respectively)
Generate new knowledge about effective prevention models by implementing effective intervention models and by decreasing use of alcohol, tobacco, and drugs for children 9 years old and older.	(Targets not developed)
Examine the impact of integrated services systems on services to homeless and seriously mentally ill persons by having client outcomes for days of drug use show greater improvement than comparison group.	Target met
Enhance knowledge about treating adult marijuana users by submitting two clinical intervention manuals with "lessons learned" from multisite study.	Target met
Enhance knowledge about the effects on outcomes of providing wrap-around services, such as child care and transportation, in addition to drug treatment (study coordinating centers will develop and apply statistical models; 100% of reports with findings submitted and results validated).	(Targets not developed)
Raise public awareness about substance abuse prevention issues and promote healthy changes in individual and group attitudes and behavior by increasing media placements and media access by 5% over base year.	Target met

GAO Observations on HHS' FY 1999 Goals and Measures to Reduce Use of Illegal Drugs and HHS' Performance Report on This Key Outcome

The 1999 performance goals and measures directly related to the selected key outcome were both outcome- and output-oriented. Some output measures ultimately could influence clinical outcomes. For example, a measure for the goal of enhancing knowledge about treating adult marijuana users was the submission of two clinical intervention manuals with lessons learned. It is expected that intervention models resulting from this project can be disseminated to clinicians as effective treatment approaches. The performance goals and measures were measurable and quantifiable, and the measures indicated a level of progress towards the goal.

The agency met or exceeded most of the targets it set for FY 1999. The performance report shows that SAMHSA far exceeded the performance target of 40% for increasing

the mean number of organizations participating in coalition activities. An analysis of the data, however, revealed that coalition participation in FY 1997 had already exceeded the FY 1995 base year number by more than 300%. It is not clear why SAMHSA set the FY 1999 target at 40% above the base year. According to agency officials, the target should have been adjusted upward. In most instances, the agency provided reasonable assurance that the performance information was credible. However, for the measure of increasing the percentage of states that will use grant funds for activities in six prevention areas, SAMHSA relied on states to validate the information reported in their block grant applications. In our September 1998 report, we found that some data states reported in block grant applications were incomplete and of questionable quality.

The agency's FY 1999 performance report notes that an evaluation policy has been implemented that defines an integrated model of evaluation and planning, and that results from completed and ongoing evaluations continue to provide useful information for program planning and policy development. The performance report describes the one evaluation completed in FY 1999 and lists seven evaluation projects that were ongoing during the period. SAMHSA completed the National Evaluation Data and Technical Assistance Center evaluation. The center provided a variety of evaluation technical assistance and training services to SAMHSA staff and grantees. There was no discussion of the findings and recommendations of the completed evaluation or how results were used to assess program performance.

Unmet FY 1999 Performance Goals and Measures for This Key Outcome

There were no unmet goals and measures where performance targets were established for FY 1999.

HHS' FY 2000 Performance Goals and Measures to Reduce Use of Illegal Drugs

Goals and Measures Added

- Enhance knowledge about treating teen marijuana users; clients treated with five intervention models will have significantly reduced marijuana use.
- Help states coordinate, leverage, and/or redirect substance abuse prevention resources, and develop strategy to reduce youth drug use by (1) increasing state collaboration rating (target: 25% above FY 1999 baseline) and (2) decreasing past month substance use for youth ages 12 to 17 (target: 15% from FY 1998 baseline).
- Prevent or reduce substance abuse by improving school bonding and academic performance, family bonding and functioning, and life-management skills by decreasing substance abuse and related violence for treatment clients relative to similar populations without prevention programming (target: 5%); study sites will document models that are determined to be effective and replicable.
- Increase the number of scientifically defensible programs, practices, and policies adapted and sustained by the state incentive grantees and their subrecipients by (1) increasing the number of prevention technologies introduced to all state grantees and

subrecipients (target: 25% above FY 1999 baseline) and (2) decreasing past month substance use among youth 12 to 17 years old (target: 15% from FY 1997 baseline).

- Support substance abuse prevention and treatment services by (1) increasing percent of adults receiving treatment services who were employed, had a permanent residence, and had reduced criminal involvement (establish baseline in FY 2000); (2) decreasing percent of alcohol and drug use (establish baseline in FY 2000); (3) implementing voluntary performance outcome measures through its Treatment Outcome Pilot Projects II program for block grant reporting (target: 19 states); and (4) increasing the number of states and territories voluntarily reporting performance measures in block grant applications (target: 19 states).
- Address gaps in substance abuse treatment capacity by (1) increasing the number of clients served (target: 23,000); (2) increasing the percent of adults receiving services who had reduced criminal involvement (target: 2 days in jail), were employed, had a permanent residence, and experienced reduced drug-related health, behavioral, or social consequences; and (3) increasing the percent of all clients who had no past month substance use (target: 30%).
- Enhance knowledge about treating adult marijuana users; clients provided 12 weeks of treatment will have better outcomes than those provided 6 weeks.
- Enhance knowledge about the effects on outcomes of providing wrap-around services, such as child care and transportation; clients receiving wrap-around services will have better outcomes, such as reduced substance use and improved employment, than clients who receive substance abuse treatment alone (according to study results).

Goals and Measures Dropped

- Enhance knowledge about the effects on outcomes of providing wrap-around services, such as child care and transportation; study coordinating centers will develop and apply statistical models (target met).
- Increase community involvement in dealing with problems of substance abuse and its effects; specifically, promote the development of infrastructure in communities for initiating and facilitating prevention activities (target met).

GAO Observations on the FY 2000 Performance Plan for This Key Outcome

Most of the variation between the FY 1999 and the FY 2000 plans was the addition of new goals and measures. In all cases, the agency clearly described the rationale for the goals and the means by which the measures will be accomplished. Although there was a discussion in the 2001 performance plan of progress made in FY 1999, there was no clear discussion of the effect FY 1999 performance had on estimated performance levels for FY 2000. In the cases where measures were dropped, the agency had completed the measure or expected to complete it during FY 2000.

HHS' FY 2001 Performance Goals and Measures to Reduce Use of Illegal Drugs

Goals and Measures Added

- Support substance abuse prevention and treatment services through new measure: number of clients served (target: 1.6 million).
- Develop strategy to reduce drug use by youth through new measure: maintain the number of science-based programs being implemented by local subrecipients in states receiving state incentive grants.
- Test effectiveness of integrating mental health and substance abuse prevention and treatment services for children and their families by having all members of families who are identified as substance abusers be offered treatment (target: 50% of family members provided treatment will have reduced substance use at 1-year follow-up).

Goals and Measures Dropped

- Enhance knowledge about treating adult marijuana users by submit two clinical intervention manuals with lessons learned (target met).
- Enhance knowledge about the effects on outcomes of providing wrap-around services, such as child care and transportation, with final reports submitted and results validated (target met).

GAO Observations on the FY 2001 Performance Plan for This Key Outcome

Most of the variation in 2001 goals and measures compared to FY 1999 and FY 2000 was the adding of new goals and measures. In all cases, the agency clearly described the rationale for the goals and the means by which the measures will be accomplished. In the cases where measures were dropped, the agency had completed the measure or expected to complete it during FY 2001.

The 2001 performance plan has a discussion of changes and improvements over the previous year. One improvement discussed was the agency's positioning to begin reporting measurement data from its block grant programs. SAMHSA received approval from the Office of Management and Budget to collect client outcome data from states on a voluntary basis in their substance abuse prevention and treatment block grant application. SAMHSA has established specific measures and targets for assessing progress towards achieving better outcomes for clients served, such as reduced substance use and involvement in criminal activity and increased employment. SAMHSA is relying on states to validate the outcome data they collect and report. However, as we observed in our review of the agency's FY 2000 performance plan, there is no indication that SAMHSA plans to verify the quality of the data that states report.

SAMHSA's 2001 performance plan also notes that some of the performance goals, measures, and targets for the agencies' programs including the block grant, were developed in collaboration with many partners and stakeholders. Among some of the

partners listed were states, CDC, National Institute on Drug Abuse, the Office of National Drug Control Policy, and the Department of Justice.

Key Agency Outcome: The Public Has Prompt Access to Safe and Effective Medical Drugs and Devices

Table I-6 shows FDA's 19 performance goals and measures that relate to HHS' key agency outcome of ensuring the public has prompt access to safe and effective medical drugs and devices and whether or not these goals were met in FY 1999, as reported in HHS' FY 1999 performance report.

Table I-6: Goals and Measures to Ensure the Public Has Prompt Access to Safe and Effective Medical Drugs and Devices and Their FY 1999 Status, as Reported by HHS

Goal/measure	FY 1999 status
Human drugs	
Review and act on 90% of standard original new drug application (NDA) submissions within 12 months of receipt (70% within 10 months) and 90% of priority original NDA submissions within 6 months (targets: 90% of standard NDAs in 12 months; 30% of standard NDAs within 10 months; 90% of priority NDAs within 6 months).	Data not available; expected Jan. 2001 for standard, July 2000 for priority
Review and act on original generic drug applications within 6 months after submission date (target: 60% of generic drug applications).	Target not met; expects to review and act on about 40% of applications received within 6 months
Review and act on 90% of resubmitted NDAs within 6 months of receipt (target: 90% of resubmitted NDA applications).	Data not available; expected May 2000 (expects to exceed goal)
Review and act on 90% of standard efficacy supplements within 12 months (30% within 10 months of receipt) and priority efficacy supplements filed within 6 months of receipt (targets: 90% within 12 months; 30% within 10 months; priority within 6 months).	Data not available; expected Oct. 2000 (expects to exceed goal)
Review and act upon 90% of manufacturing supplements within 6 months and act on 30% of manufacturing supplements requiring prior approval within 4 months (targets: 90% within 6 months; 30% within 4 months).	Data not available; expected Apr. 2000 (expects to exceed goal)
Continue to automate NDA and abbreviated NDA submissions and archiving (target: electronic submission and archive capacity for NDAs and abbreviated NDAs).	Target not met (about 40% of NDAs received include electronic submissions)
Improve adverse drug event reporting system (target: implement adverse event reporting system for the electronic receipt of voluntary and mandatory adverse drug event reports).	Data not available; expected by end of FY 1999

Goal/measure	FY 1999 status
Ensure FDA inspections of domestic drug manufacturers and repacking establishments result in a high rate of conformance with FDA requirements (target: at least 90%).	Target met (95%)
FDA will evaluate drug information provided to 75% of individuals receiving new prescriptions.	Target not met
Inspect 28% of registered human drug manufacturers, repackers, relabelers, and medical gas repackers (target: 22% of registered firms).	Target met (26% based on estimate of 2-year coverage data)
FDA will continue to improve the legibility and clarity of over-the-counter drug labels.	Regulation requiring labeling was issued Mar. 1999
Medical devices	
Increase the on-time percentage of first actions on premarket approval applications (within 180 days) and first actions on humanitarian device exemptions (within 75 days) completed to 90% in FY 2001 (target: 65%)	Data not available; expected May 2000 (expects to meet goal)
Review and complete 95% of 510(k) (premarket notification) first actions within 90 days in FY 2001 (targets: 510(k), 90% within 90 days; third-party 510(k), 75% within 30 days).	Data not available; expected Feb. 2000 (expects to exceed goal)
Participate in the development of 20 to 25 application review standards (target: recognize over 415 standards for use in application review and update the list of recognized standards).	Target met (450 recognized standards)
Ensure FDA inspections of domestic medical device manufacturing establishments result in at least 90% conformance.	Target met (95% conformance rate)
Initiate regulatory actions and recalls for 95% of high-risk, noncompliant or defective electronic products within 30 days.	Target met
At least 97% of mammography facilities meet inspection standards, with less than 3% with level 1 problems	Target met
Increase the number of low-risk postmarket reports processed in summary form from 20,000 in FY 1998 to over 25,000 in FY 1999.	Target met (estimated 38,000 reports)
Commit over 75% of inspection resources to high-risk devices.	Target not met (50%)

GAO Observations on HHS' FY 1999 Goals and Measures to Ensure the Public Has Prompt Access to Safe and Effective Medical Drugs and Devices and HHS' Performance Report on This Key Outcome

The majority of FDA's performance goals and targets are meaningful, outcome-oriented, objective, measurable, and clearly defined. However, some goals and targets are not concrete statements of expected performance and, thus, cannot be compared to actual performance. Measurable goals and targets were not established for the Human Drug program's goals on automating NDA and abbreviated NDA submissions and archiving, improving the adverse event reporting system, evaluating drug information to consumers

receiving new prescriptions, and improving the legibility and clarity of over-the-counter drug labels. Targets for three of these goals merely restate the performance goal.

We identified a total of 12 goals and measures in FDA's final FY 1999 performance plan that were not included in the human drugs and medical devices sections of the FY 1999 performance report. FDA indicated that it dropped most of these goals in order to streamline the performance plan for purposes of clarity and that it plans to continue to monitor each goal for internal management. A more detailed explanation would have helped the reader better understand FDA's rationale for not reporting on its performance and its decision to drop these goals.

Outcomes for two goals under the Medical Device program are not clearly defined. One goal seeks to increase the on-time percentage of first actions on premarket approval applications within 180 days and first actions on humanitarian device exemptions within 75 days. The target for FY 1999 is 65% for premarket approval applications and humanitarian device exemptions. However, FDA provides an estimate of 67% performance. Thus, it is unclear whether the outcome is intended to relate to premarket approval applications, humanitarian device exemptions, or both. In its comments, FDA noted that the estimate applies to both premarket applications and humanitarian device exemptions. However, it would be more useful to users of the report if FDA noted that the estimates apply to both measures. Another goal seeks to improve the timeliness of reviewing and completing 95% of 510(k) premarket notifications for first actions within 90 days. The FY 1999 target for 510(k)s is 90% within 90 days and for third-party 510(k)s, 75% within 30 days. FDA shows an estimate of 99.7%, making it unclear whether the outcome relates to one measure or both measures. FDA commented that it had received so few third-party 510(k)s that it addressed them only in a footnote. However, we found no evidence of a footnote in the report that documents the number of third-party 510(k)s received in FY 1999. Nevertheless, we believe FDA should clearly indicate whether the outcome measure relates to 510(k)s, third-party 510(k)s, or both.

Performance data are unavailable for nearly 60% of the performance goals; therefore, it is not possible to assess the extent to which FDA has achieved its FY 1999 performance goals. While FDA reported several meaningful individual program accomplishments in FY 1999, performance data are missing for 7 of the 19 goals and 4 other goals do not have measurable targets.

FDA explained that late reporting of outcomes for the premarket goals of the Medical Device program occurred because final data on how long it took to review certain submissions might not be available for up to a year after the end of the goal year. No explanation was given for the absence of final outcome data on five goals of the Human Drug program. FDA also omitted dates for when actual outcome data will be available on two goals: reviewing and acting on original generic drug applications within 6 months after the submission date, and increasing the number of low-risk postmarket medical device reports processed in summary form. Outcome data are expected to be available on all of the other goals by February 2001. Where final outcome data are missing for goals, FDA frequently provides estimated data or indicates that it believes performance will either meet or exceed the goal; it also provides earlier trend data.

Nine goals had FY 1999 performance data. Targets for seven of these goals were reportedly either met or exceeded. However, only two goals had descriptions of how the performance outcomes affected the agency's strategic goal related to reducing the risk of medical devices on the market. For the third consecutive year, the Medical Device program reported achieving its target (a conformance rate of 97% in FY 1999) of ensuring that mammography facilities meet inspection standards. While the Medical Device program also met its goal to recognize over 415 device review standards—the report does not indicate whether FDA has updated the list of recognized standards, the other element of the FY 1999 target.

FDA does not always provide confidence that performance information is credible. For example, the Human Drugs program noted that it performed a preliminary assessment of the outcome data for completeness, accuracy, consistency, and related quality control practices to determine if the data were of sufficient quality to document performance, appropriate to measure targets, and considered convincing. However, the program does not discuss the major data systems used to track performance data, procedures used to verify and validate data in the systems, strengths and weaknesses of the data systems, or external factors that may effect the integrity of the data.

In contrast, the Medical Device program provides useful descriptions of the data systems used to compile performance results and the procedures used to ensure data integrity for the Mammography Program Reporting and Information System and Center for Devices and Radiological Health field data systems. However, it does not discuss procedures used to verify and validate data in its medical device adverse event reporting system—which we have reported has experienced serious problems, including difficulty handling large volumes of adverse event reports, poor quality data, and processing and reviewing reports in a timely manner.[4]

Unmet FY 1999 Performance Goals and Measures for This Key Outcome

Three goals for this key outcome were not met in FY 1999:

- Review and act on 60% of original generic drug applications within 6 months after submission (actual: about 40%). FDA expects to meet this target.
- FDA will evaluate drug information provided to 75% of individuals receiving new prescriptions (actual: the written national telephone survey is not yet completed; study of gender differences in risk communication completed but not yet published).
- Commit over 75% of medical device inspection resources to high-risk devices (actual: 50%).

FDA did not meet its statutory mandate under the FDA Modernization Act of 1997 (FDAMA) to review and act on original generic drug applications within 6 months after

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

submission. According to FDA, the Human Drug program missed the target because several years ago it began a procedure to reduce approval times by allowing reviewers to use a "facsimile" amendment—requests from FDA reviewers to applicants for the resolution of minor errors in applications. This procedure results in review times that exceed 6 months but shortens overall approval times, which FDA believes is more important than the 6-month target. Existing backlogs of chemistry and microbiology reviews also contributed to the program not meeting the 6-month goal. To address the problem, the Human Drug program has established a plan to improve performance by restructuring the chemistry and microbiology review processes and hiring new staff to review applications. To reflect these changes, FDA revised its target to 40% in FY 1999—about the same level of performance achieved in FY 1995, according to baseline data in the FY 1999 performance plan.

FDA does not acknowledge that the Human Drug program did not meet the goal of evaluating the availability, quality, and usefulness of prescription drug information provided to 75% of individuals receiving new prescriptions. Two studies intended to aid in developing comprehensive drug information are still under way. While a 1998 national telephone survey of consumers who received prescription drug information was completed, the program indicates that some parts of the survey results have yet to be written. The second study, which examines gender differences in risk communication of drug labeling, was reported completed in FY 1999, but publication of the study is not anticipated until early 2000. Consequently, FDA does not consider that the goal not met because all of the data have not been evaluated to determine whether or not the goal was achieved. However, both the goal and measure indicate that FDA was scheduled to complete the evaluation in FY 1999. Therefore, we consider the goal unmet.

The Medical Device program acknowledged that it did not meet the goal to dedicate over 75% of its resources to high-risk device inspections. FDA cited competing priorities within the agency, growth of the medical device industry, and reductions in device and radiological health inspection resources as contributing reasons for not meeting the goal. The goal is being dropped because the Medical Device program believes it is a "basic activity goal" that does not focus on results. However, according to FDA, new inspection processes under development—such as a model to prioritize inspections based on risk and the Quality System Inspection Technique, which focuses on inspections of key manufacturing and quality areas—are expected to improve medical device quality; high-risk inspection coverage; and, ultimately, public health.

HHS' FY 2000 Performance Goals and Measures to Ensure the Public Has Prompt Access to Safe and Effective Medical Drugs and Devices

Goal and Measure Added

- Review 50 medical device standards for continued applicability and review 50 medical device standards for recognition.

Goal and Measure Dropped

- Participate in the development of 20 to 25 medical device application review standards (goal met).

Goals and Measures Changed

- Targets for reviewing and acting on 90% of standards NDAs filed within 12 months of receipt: 70% (from 50%) within 10 months of receipt, and 90% of priority applications within 6 months.
- Target for improving adverse event reporting system: implement software to make adverse event reporting systems more compatible with International Conference of Harmonization requirements; develop next adverse event reporting system generation to enhance functionality.
- Target for inspecting of registered human drug manufacturers, repackers, relabelers, and medical gas repackers: 22% (from 28%).
- Target for reviewing and acting on fileable original generic drug applications within 6 months of review after submission date: 45% (from 60%).
- Targets for giving consumers and health professionals more easily understandable over-the-counter drug information: make new drug approval information increasingly available via Internet, and develop partnerships with national organizations to disseminate educational information to consumers.
- Target for improving inspection coverage for Class II and Class III domestic medical device manufacturers: 24% (from 28%).
- Target added for developing MedSun Surveillance System based on approximately 75 to 90 user facilities: evaluate pilot and report results to the Congress.

GAO Observations on the FY 2000 Performance Plan for This Key Outcome

FDA provides a brief explanation of changes made to goals and targets in light of reported FY 1999 performance levels for individual performance goals. Several changes to targets were minor in scope, involving slight adjustments to clarify the target, add additional targets, or make corrections to them.

Performance levels of two targets were modified because FDA did not receive an increase in requested funding for inspections of human drug manufacturers and medical device manufacturers in FY 2000. For example, the Human Drug program's target for inspections of 28% of registered human drug manufacturers, repackers, relablelers, and medical gas repackers was reduced from 36% to 22% in FY 2000. FDA noted that a significant investment in training and time is needed to ensure quality and uniformity of inspections among FDA and state contracts or partnership agreements but does not explain the effect of budget reductions on its estimated performance levels for FY 2000 or provide a strategy to achieve the FY 2000 goal. Based on FY 1999 performance, the Human Drug program also revised its target for reviews of generic drug applications—

the revised FY 2000 target of 45% reflects changes in the chemistry and microbiology review processes and increased staff.

FDA merged two goals in the FY 1999 performance plan regarding providing more easily understandable and accessible over-the counter drug information to consumers and health professionals into a single goal. This change more clearly communicates the intended goal and streamlines the plan.

The Medical Device program provides an adequate assessment of the effect of FY 1999 performance on FY 2000 performance. The program noted that because it did not receive an increase in funding for FY 2000, the target for improving inspection coverage for Class II and Class III domestic manufacturers to 39% was decreased to 24%. FDA stated that despite surpassing the FY 1999 goal of inspecting 26% of the medical device firms with a performance of 30%, inspection coverage is expected to decline due to reduced field resources and an increasing number of medical device firms. Implementation of FDAMA requirements, ongoing reengineering, and FDA's commitment to a strong science base have resulted in FDA examining how it conducts inspections. As such, FDA has developed a strategy that involves working with the medical device industry to reengineer the process used for quality system inspections. The new technique is intended to significantly reduce inspection times and increase the effectiveness of the inspections, ultimately helping the agency better cope with declining resources and a growing industry. FDA also believes implementing its Warning Letter Pilot Test initiative will be instrumental in getting device firms to correct problems quickly. Under this initiative, firms will be allowed 15 days to respond to and/or correct problems identified during an inspection. If the problem is corrected, FDA does not issue a warning letter.

HHS' FY 2001 Performance Goals and Measures to Ensure the Public Has Prompt Access to Safe and Effective Medical Drugs and Devices

Goals and Measures Changed

- Initiate all research programs approved by the Product Quality Research Institute's steering committee (target: 50%).
- Implement, evaluate, track, and report on clinical trials FDA is requesting under FDAMA or requiring under the Pediatric Rule (target: implement, evaluate, track, and report on the clinical trials FDA is requesting under the Pediatric Rule).
- Maintain inspection coverage for Class II and Class III foreign medical device manufacturers (target: 9%).
- Review and complete premarket approval application supplement final actions within 180 days (target: 90%).
- Review and complete 510(k) final actions within 90 days in FY 2001 (target: 75%).
- Complete investigational device exemption agreement meetings within 30 days (target: 100%).
- Complete premarket approval application determination meetings within 30 days (target: 95%).

Goal and Measure Changed

- Target for reviewing and acting on fileable original generic drug applications within 6 months of review after submission date: 50% (from 45% for FY 2000).

GAO Observations on the FY 2001 Performance Plan for This Key Outcome

In FY 1999, the Human Drug program revised its target for reviewing and acting on 60% of generic drug applications to 40%. As mentioned earlier, changes to review processes and an increase in review staff are expected to result in performance of 45% in FY 2000 to 50% in FY 2001.

FDA established several new goals for FY 2001; they address collaborative initiatives with the scientific community, FDAMA statutory requirements, activities related to the U.S.-European Union mutual recognition agreements, and initiatives to reinvent medical device premarket processes. Each of the new goals links well with the agency's strategic goals. However, FDA does not always discuss the strategies and resources that will be used to achieve the goals.

The Human Drug program established a goal to initiate all research programs approved by the Product Quality Research Institute's steering committee in FY 2000. The institute is a collaborative effort that FDA is using to leverage resources by using external scientists to identify best practices for the manufacture of quality drug products. Information developed from the steering committee is expected to help identify low- and high-risk product development and manufacturing practices as well as support regulatory policy and guidance for product quality data submitted to FDA in drug approval requests.

Under FDAMA and its new Pediatric Rule, the Human Drug program is also reinventing a critical area of its premarket review process related to drugs that affect children. FDAMA grants drug sponsors additional market exclusivity for performing and submitting pediatric studies during drug development. These additional data are intended to provide doctors with more complete information on how drugs affect children and improve treatment of children. While the goal directly links to the strategic goal of ensuring the availability of safe and effective drugs, it does not discuss strategies and resources that will be used to implement the goal or external factors that may affect performance. Furthermore, the target restates the performance goal and is not measurable. FDA commented that it will better define the goal and measures in the FY 2002 performance plan.

Regarding its FY 2000 goal for inspections of foreign medical device manufacturers, FDA believes the U.S.-European Union mutual recognition agreement provides a strategy that will help reduce its foreign inspection workload associated with medical device review. FDA currently estimates that its overseas workload could increase by as much as 25%. Activities are under way to prepare third parties in the European Union to perform work

in the European Union for FDA and to prepare third parties in the United States to perform reciprocal work in the United States for the European Union. However, FDA does not provide a strategy of how mutual recognition agreement implementation will reduce its overseas workload.

To address FDAMA statutory requirements to reduce premarket review times, FDA established new goals to review and complete premarket approval application supplement final actions within 180 days and 510(k) premarket notification final actions within 90 days. However, the report does not discuss what strategy and resources FDA plans to use to implement these goals.

Three key weaknesses identified by GAO in prior assessments of FDA's performance plans were not addressed in the FY 2001 performance plan. First, in our FY 1999 assessment, we observed that FDA's plan did not mention data limitations related to large volumes of reports and poor quality data in the medical device adverse event reporting system. The FY 2000 plan acknowledged the system weaknesses we identified and noted that improvements in the system were being made by developing a sentinel reporting system of user facilities to report device problems to FDA. However, the FY 2001 plan does not discuss progress made toward improving data integrity in the current system or the proposed sentinel system. Second, the FY 2001 plan does not discuss weaknesses in the FY 1999 plan regarding the Human Drug programs' Operational Administrative System for Import Support (OASIS). To facilitate coordination with the U.S. Customs Service, FDA reported that it planned to use OASIS to ensure that safe imported products reach consumers in the United States. We reported, however, that the agency's data systems cannot be integrated with OASIS to identify imported pharmaceutical products. Third, the FY 2001 plan provides a limited picture of intended performance related to FDA's inspection of foreign pharmaceutical manufacturers. The Human Drug program still has not included a goal in the plan to improve the inspection of foreign pharmaceutical facilities, even though product safety is one of FDA's strategic goals. This same observation was made in our assessment of the FY 2000 plan.

ENCLOSURE II

OBSERVATIONS ON THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' EFFORTS TO ADDRESS ITS MAJOR MANAGEMENT CHALLENGES

The table on the following pages identifies the major management challenges confronting HHS. The first column lists the major management challenges identified by GAO and those identified by HHS' IG. The second column summarizes the progress, as discussed in its FY 1999 performance report, HHS has made in resolving these major management challenges. The third column discusses the extent to which HHS' FY 2001 performance plan includes performance goals and measures to address these management challenges.

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
Scope and complexity of HHS programs create coordination, oversight, and performance measurement challenges. To manage their wide-ranging programs effectively and efficiently, HHS agencies must coordinate with one another, other federal agencies, and state and local government and private program partners. Balancing program flexibility with oversight responsibilities and the challenge of measuring program outcomes make it difficult for HHS to ensure accountability for results.	HHS reported that it is investing evaluation funds to develop and improve performance measurement systems and the quality of the data that support those systems. For example, the Office of the Assistant Secretary for Planning and Evaluation assessed the "state-of-the-art" in performance measurement for HHS' public health, substance abuse, and mental health block grant programs. HHS also reported that it modified its budget formulation processes specifically to better bring together information and leaders from throughout HHS to define program initiatives to help HHS accomplish its mission and coordinate program improvement. Selected examples of individual agency progress in meeting this challenge in FY 1999 follow. SAMHSA: To help develop a core set of outcome measures of effectiveness for substance abuse prevention and treatment block grant programs and to help 19 selected states develop the infrastructure to collect and report performance information, SAMHSA funded the Treatment Outcome Pilot	HHS does not have departmentwide performance goals related to this challenge. However, some of its component agencies have such goals and measures in their FY 2001 plans; selected examples follow. SAMHSA: The target for SAMHSA's performance goal and measure to increase the number of states and territories reporting performance measures in substance abuse prevention and treatment block grant applications increased from 19 in FY 2000 to 48 in FY 2001. While data collection and reporting is fundamental for ensuring accountability for the effective use of federal resources—part of the agency's mission—SAMHSA's FY 2001 plan identifies this as a major challenge because many states may not be able to report these data. SAMHSA's plan does not explain how the agency expects to meet its FY 2001 target of getting 48 states and territories to report performance data. ACF: No ACF-wide goals exist that

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	Projects II. SAMHSA reported in its FY 2001 plan that all 19 states will have adopted the measures developed during the pilot and is asking all 19 states to voluntarily report performance data in their FY 2000 block grant applications. ACF: In its FY 1999 performance report ACF, states that it has involved internal as well as many external partners (such as states, tribes, and grantees) in the development of its goals, measures, and targets, and almost all of ACF's 14 program plans discuss how input was obtained from them. ACF indicates a strong commitment to continually working collaboratively with its partners to refine performance measures and identify annual targets. As evidence of its cross-program efforts, ACF listed three reports that provide broader indicators of child well-being for use by multiple programs. In 1997, the Assistant Secretary for Children and Families created seven agencywide priorities for welfare reform, child support, child care, infants and toddlers, Head Start, child welfare, and increasing capacity to work with ACF	directly address coordination and ensuring flexibility, but the plan cites these issues as challenges and discusses how ACF programs have worked with various partners to develop the many program-specific goals, measures, and targets in the plan. A few program-specific goals and measures address coordination, such as the following: • Youth Programs: Maintain with nine states and youth services grantees a collaboration that supports a youth development approach to services to young people…and fund an additional state. • Developmental Disabilities (Health): Increase to 5,000 the number of health care providers trained to meet the health needs of people with developmental disabilities as a result of program interventions. • Native American Programs: Increase to 1,500 the number of technical assistance visits per year to Native American populations, with emphasis on urban and rural tribes and nonfederally recognized

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	partners. However, as ACF acknowledges, neither the FY 1999 performance plan nor report explicitly describe ACF's progress towards addressing these priorities but, instead, rely on program-specific narrative and goals to track progress. In its comments on our report, ACF stated that each of the seven priority areas has an operational plan that provides specific activities related to the goals, measures, and targets in the performance plan. CDC: CDC's report discusses its efforts to work with states to develop a means for accountability under the Preventive Health and Health Services Block Grant. States are responsible for reporting on a complete range of program data. Beginning in FY 1999, this uniform data set will also contain GPRA performance measures for those programs that have such measures. Much of CDC's work involves assisting its state partners to enhance their capacities to prevent and detect disease. For example, in 1999 CDC assisted several state health departments develop and implement plans for comprehensive information networks.	tribes. • Community Services Block Grant: Increase by 1% over the previous year the amount of nonfederal resources brought into low-income communities by the Community Services Network. HCFA: HCFA noted in its FY 2001 plan that it continues to increase coordination with states in the performance plan process, particularly with respect to Medicaid-related performance goals. As the planned collaborative process proceeds, HCFA expects to add goals in additional areas of concern in future performance plans. Some performance goals in HCFA's FY 2001 plan are related to improving state coordination and oversight, including the following: • Improve the management of the survey and certification budget. • Provide states with linked Medicare and Medicaid data files for dually eligible beneficiaries. • Assist states in conducting Medicaid payment accuracy studies for the purpose of measuring and

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
		ultimately reducing Medicaid payment error rates. HCFA completely revised one oversight-related performance goal from FY 2000, "develop a performance standard concerning the Health Insurance Portability and Accountability Act's (HIPAA) effectiveness in resolving complaints against insurers, states, or plans." It noted that after a few years' experience with HIPAA, the prior goal, which focused on complaints, would not be meaningful. According to HCFA, the new goal, "ensure compliance with HIPAA requirements through the use of policy form reviews," directly measures the result it wants: compliance with HIPAA by insurers, especially in states where HCFA has enforcement authority. Finally, to improve the exchange and flow of management information, HCFA established the goal to "improve internal communications in HCFA." The FY 2001 target is developmental, but HCFA noted that GAO cited internal communication and

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
		coordination difficulties as a factor hampering HCFA's performance. HCFA plans to gather information and develop recommendations regarding interventions that will remedy current problems and improve its ongoing capability to successfully communicate and coordinate business activities. CDC: CDC has numerous goals and measures that relate to this management challenge; key examples follow: • Reduce preventable morbidity and mortality and improve quality of life of people within the framework of Healthy People 2000 by improving the assessment capacity of prevention programs (measure: at least 85% of total required data from all programs funded by the Preventive Health and Health Services Block Grant will be reported to CDC annually). • Regional population-based emerging infections programs will conduct early warning investigations of agents of infectious diseases (measure: 10

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
		regional programs). HRSA: All states will have implemented performance outcome measurement indicators and reported a summary of their outcomes for state offices of rural health (measure: 50 states).
HHS needs reliable data and data systems to manage programs and assess results. Data needed to manage and evaluate HHS' programs are often unavailable, inaccurate, or inconsistent, and obtaining comparable data from programs carried out by state and local partners is difficult. Year 2000 challenges will compound these problems and could put benefits and services at risk.	HHS notes in its report the continuing data challenges it faces with regard to its reliance on data from its program partners and timeliness of data. These challenges are underscored by the absence of performance data for a substantial number of FY 1999 performance goals. HHS indicates that it is working to resolve issues such as data consistency and the use of appropriate data to measure desired outcomes. HHS reported that all of its information systems functioned properly while transitioning to the year 2000. Also, HHS reported that all information technology investments approved by its Information Technology Investment Review Board met its review criteria. Selected examples of individual agency progress in meeting this challenge in FY 1999 follow.	HHS' FY 2001 goal is that 100% of its information technology investments approved by its Information Technology Investment Review Board meet its review criteria. Selected examples of individual agency FY 2001 goals and measures that should help meet this challenge follow. SAMHSA: SAMHSA's 2001 plan includes a performance measure that states with the capacity will voluntarily report performance outcome data for clients receiving substance abuse treatment supported with block grant funds. The agency expects that for FY 2001, the states' data will show a 40% increase in treatment clients who were employed, had a permanent residence, and had reduced criminal involvement, as well as a 40% decrease in alcohol

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	IHS: IHS reported that it met its goal of beginning the implementation of managerial cost accounting systems by establishing cost center accounting practices at its health facilities, area offices, and headquarters. NIH: As part of its goal to implement the Director's strategy to improve information technology management, NIH reported that it met its FY 1999 performance target of completing information technology organizational, investment, and vision activities by appointing a chief information officer and establishing a new information technology organizational structure. ACF: Improving automated data and management systems is an objective of one of ACF's strategic goals. To achieve this objective, ACF made this area a key priority. Its FY 1999 performance report indicates that ACF • completed replacement of 37 individual automated grant systems with GATES (grants administration, tracking, and evaluation system) to	and drug use. Historically, the reliability of client outcome data for drug treatment programs has been questionable. Some surveys have relied on self-reported data, and obtaining high response rates to follow-up surveys has been difficult. Although SAMHSA is planning to monitor states' efforts, the agency is relying on states and territories to validate their performance data. Further, states are at different levels of infrastructure development; thus, their capacity to collect data and report on the specific performance indicators SAMHSA is requesting will vary. Similar challenges with data reliability and consistency exist for SAMHSA in its effort to collect performance data for the mental health block grant program. ACF: ACF's agencywide objective to improve automated data and management systems is evidence of its continued commitment to address, at least in part, the data management and reliability challenges it faces. Though no program-specific goals directly address this management challenge,

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	improve the efficiency and effectiveness of discretionary grants made by nonprofit and tribal entities and • plans to complete the audit resolution tracking portion of this system by April 2000. According to ACF, GATES allowed it to meet agency year 2000 goals by overcoming programming flaws in its old systems. However, because GATES only focuses on the application, evaluation, award, and funding of various ACF grants, it does not fully address other data collection and reliability problems ACF programs encounter. For example, 13 of ACF's 14 programs did not have actual data available (for at least one goal) in time for use in its FY 1999 report. This occurred generally because final state and local data reports are due to ACF 90 to 120 days after the end of the fiscal year. This time lag in receiving and validating data limits the amount of actual data included in the performance report, which greatly affected ACF's ability to report actual data on TANF—it	almost all of the programs clearly discuss in the plan data sources and limitations and the strategies used to ensure data accuracy. For example, in a portion of ACF's FY 2001 plan describing TANF's performance, the section entitled "Data Sources, Verification, and Validation" states that the consistency and validity of state TANF administrative data are assessed through system edits and consistency checks, special computation runs, and trend analyses. Similarly, a section entitled "Data Sources and Issues" notes that state post-expenditure data collected for the SSBG program is regularly validated. If program officials identify any problems, they are discussed with the state; technical assistance is provided, when appropriate. FDA: FDA plans to recruit over 200 more hospitals into a MedSun system that uses improved data format and collection methods to enhance the validity and reliability of data provided, thus affording a high level of public health protection in FY 2001. The plan adequately links the goal and target

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	had no actual performance information because states are given up to 11 months to submit quarterly data. The child support program also could not report actual data for its FY 1999 performance targets. Data reliability remains a persistent problem for other programs as well. For example, data from the Runaway and Homeless Youth Management Information System vary widely from quarter to quarter and could not be used with confidence to assess FY 1999 performance until the second quarter of FY 2000. Moreover, because the universe of grantees submitting data often changes, comparing program data from year to year is methodologically questionable for this program, according to ACF. And while Head Start has begun to systematically collect useful data through its Family and Child Experiences Survey project, which will help to determine how well program goals and targets are being met, data from this longitudinal, pre-/post-test assessment will only be available every 3 years and will not provide information comparable to information collected from a control	with FDA's mission and strategic goal to reduce high-risk devices on the market. However, the plan does not discuss strategies that will be used to encourage user facility participation in the program, how it plans to evaluate the results of its study of the subset user facilities, or steps planned to ensure the credibility of data reported by the subset of user facilities. With respect to its adverse drug event reporting system, FDA plans to implement separate data entry and retrieval functions, pilot test advanced analytical techniques, and develop and implement a special report module. HCFA: HCFA plans to review and update at least two-thirds of the information technology architecture policies and procedures it sets in FY 2000. Also, HCFA plans to implement prospective payment systems for home health agencies and inpatient rehabilitation hospitals. Agency for Healthcare Research and Quality: Release and disseminate

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	group study. In its comments, ACF stated that the Runaway and Homeless Youth Program will use on a pilot basis in FY 2002 data from the National Runaway Switchboard and grantee annual reports to provide a more reasonably reliable indication of program performance to supplement its management information system. ACF also stated that a contract to study the effect of Head Start using a control group design will likely be awarded before the end of FY 2000. ACF added that HHS' Data Council is assessing the data needs for major ACF programs and will begin to more aggressively address data collection and reliability problems. FDA: To improve FDA's ability to process reports and provide an early warning system, FDAMA authorizes FDA to discontinue universal user facility reporting of problems with medical devices and implement a MedSun Surveillance System composed of a network of user facilities that make up a representative profile of user reports. FDA established a goal in FY 2000 to develop this surveillance system for	Medical Expenditure Panel Survey data and information products in timely manner for use by researchers, policymakers, purchasers, and plans (measures: core public use data files available within a year of the end of data collection—except the full-year expenditure file, which will be available 18 months after the end of data collection; and response time for requests received for information, assistance or specific products is as promised 95% of time). HRSA: • Improve accessibility to HRSA data warehouse (measure: 100 users; full utilization of identified HRSA employees—that is, those staff granted authority to access the data). • Reduce the number of security violations that create a major risk to HRSA's technical infrastructure (measure: 10% reduction from the previous year in the number of major security violations to HRSA infrastructure).

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	injury reporting related to medical devices based on about 75 to 90 user facilities and to report the results to the Congress. FDA enhanced the current reporting system with a new alternative summary reporting system to permit summary data elements to be submitted in line-item format. About 38,000 low-risk reports in summary form were received, which helps the agency focus on high-risk device problem reports and reduces the reporting burden on device firms. FDA established a goal to improve its adverse drug event reporting system and planned, in FY 1999, to implement electronic receipt and review processes. FDA reported that it had conducted pilot programs regarding the establishment of such processes and that implementation of selected periodic industry reports was expected by the end of FY 1999. We reported in our assessment of FDA's FY 1999 performance plan that its strategy to collaborate with the U.S. Customs Service to use the Human Drug programs' OASIS did not recognize data limitations in the system. Specifically,	NIH: • Establish a clinical trials database, as required by the FDAMA (measures: implement an outreach program to promote the database as a resource for patients, physicians, researchers, community health groups and others; implement, at least on a pilot basis, toll-free telephone access to information in the clinical trials database). • Implement the Director's overall strategy to improve information technology management at NIH (measure: continue implementation of the Director's overall strategy by developing a strategic information technology vision and a formal information technology investment process).

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	we noted that FDA's data systems cannot be integrated with OASIS to identify imported pharmaceutical products. FDA did not indicate in its FY 1999 report whether it has made progress towards this challenge. HCFA: HCFA worked towards the development and implementation of an information technology architecture, a key component to successfully managing information systems. Also, to address its goal of developing new fee-for-service and Medicare+Choice payment systems, HCFA reported that it met its FY 1999 performance targets by, for example, establishing risk-adjustment methodologies. CDC: CDC's report has numerous discussions about its efforts to improve the nation's disease surveillance systems. For example, CDC reported on an increase last year in the percentage of physicians in the national sentinel physician surveillance system for influenza who used the Internet to report weekly data and a decrease in lag time in 1999 for releasing data from the National	

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	Health Interview Survey. HRSA: HRSA reported on several initiatives to improve its data collection. For example, its HIV/AIDS program is exploring mechanisms to measure the unduplicated number of clients receiving services from Ryan White programs. HRSA also reported that the quality of data in the Maternal and Child Health program improved due to the standardization of definitions and formats imposed through performance partnerships and the new electronic reporting format. One area where problems remain is information on medically underserved areas/populations and health professional shortage areas. In response to GAO concern about how HRSA identifies these areas and measures the unmet need for primary care, the agency developed new regulations and published them in the *Federal Register* in September 1998. However, HRSA has not issued final regulations.	
Program integrity is a continuing challenge. HHS programs are attractive targets for fraud, waste, and mismanagement; Medicare is	HHS' departmentwide FY 1999 financial statements achieved a clean opinion. However, this achievement does not fully address the CFO Act's purpose, which is	HHS' FY 2001 plan indicates that financial and management integrity of the Medicare program remains one of its highest priorities. Moreover, HHS'

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
particularly vulnerable and remains a high-risk area. HHS' FY 1998 financial statements had serious deficiencies. (HHS' IG also identified aspects of program integrity as challenges for HCFA.)	to provide complete, reliable, timely, and consistent financial information for use in the financing, management, and evaluation of federal programs. Serious financial management weaknesses remain that will continue to challenge HHS and its operating divisions. HHS is still not in compliance with the Federal Financial Management Improvement Act (FFMIA) and has material internal control weaknesses and reportable conditions. HHS' performance goals for reducing material weaknesses and achieving substantial compliance with FFMIA should help focus HHS' attention on realizing fundamental improvements in its financial management systems. Selected examples of individual agency progress in meeting this challenge in FY 1999 follow. HCFA: Key to HHS' performance on program integrity is HCFA's stewardship of Medicare and Medicaid. HCFA's performance report and plan includes a generally clear and credible discussion of a number of strategies HCFA is pursuing to strengthen Medicare program	goal for FY 2001 is for all operating divisions to have a clean financial audit opinion. The performance plan for the Program Service Center has a goal to resolve all reportable conditions identified in its financial statements. HHS' departmentwide plan does not, however, provide specifics about either reportable conditions or material internal control weaknesses. HCFA: HCFA's FY 2001 performance plan added many new and important goals for program integrity and a generally clear discussion of them. However, these include initiatives for which there will not be baseline data for at least a year or for which success will be difficult to measure—making agency progress difficult to clearly track. For example, HCFA has set as a goal to develop new methods for measuring erroneous payments that will help pinpoint specific vulnerabilities—such as provider compliance, contractor- and service-specific error rates, and a fraud rate. However, because these measurement systems are not fully implemented, HCFA will generally not have baseline

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	integrity. HCFA's report indicates it has made some progress and has increased commitment to the effort. However, because the Medicare program has many distinct vulnerable areas, the management challenge of ensuring its integrity will continue in the foreseeable future. For example, HCFA made progress in reducing by 35% the percentage of Medicare home health services for which improper payment was made in selected states (FY 1999 actual: 19%.) However, HCFA's discussion of weaknesses it is trying to address through its Comprehensive Plan for Program Integrity indicates more effort is needed to reduce improper payment for other providers, such as community mental health centers, a sample of whose claims had a 90% payment error rate in 1996. Similarly, HCFA reports that the overall rate of improper payments in fee-for-service Medicare was reduced from $23.2 billion in FY 1996 to $13.5 billion or about 8% in FY 1999. However, because the change was mostly attributed to better documentation provided to auditors, rather than substantive reduction in	data to begin to measure its progress until FY 2001 at the earliest. Also new for FY 2001 is the goal of successfully implementing the initiatives in the Comprehensive Plan for Program Integrity, which include reducing the percentage of errors in inpatient hospital and community mental health center claims, and putting into place program safeguard contractors for specific areas, such as therapy services. While some of the discussion of this initiative is clear, other parts are not. For example, while HCFA clearly reports that it is working to improve provider enrollment, its measure for this effort—70% rate of return—is unclear. HCFA has also added an initiative to improve oversight of Medicare contractors as a developmental goal. Many of these initiatives are clearly important, respond to GAO and HHS IG concerns, and have the potential to strengthen program integrity. However, measuring the effectiveness of an agency's performance in implementing an initiative is difficult without independent evaluation.

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	improper payments, it is not clear that meeting this measure signifies progress. One important aspect of program integrity is sound financial management. HCFA achieved a clean opinion on its FY 1999 financial statement and, thus, met its goal subsequent to the issuance of its performance report. In the past, we have been concerned that HCFA focused on the clean opinion, rather than on reducing its underlying financial management weaknesses. HCFA's discussion of its strategies included a number of actions that it was taking to eliminate these weaknesses, including testing its contractors' internal controls and implementing an integrated general ledger accounting system. ACF: ACF's approach for improving its automated data and management systems (an agencywide strategic objective) could address fraud, waste, and abuse, although this was not expressly stated in its FY 1999 performance report. Also, there were no program-specific goals or measures that directly addressed this management challenge in the FY 1999 performance	HCFA has two FY 2001 goals related to weaknesses in financial management and systems security identified in its CFO financial audit. Although HCFA plans to achieve an unqualified opinion on the FY 2001 financial statements, it continues to have material weaknesses relative to reliability and documentation of its financial information. The plan does not specify a target level for material weaknesses and reportable conditions. In addition, the plan does not address goals and targets for compliance with FFMIA. HCFA relies heavily on automated systems for the administration of virtually all aspects of the program. For HCFA and its contractors, information systems security has been a long-standing material weakness, as indicated in the Report of Independent Auditors on Internal Controls. HCFA has an ambitious goal of improving information systems security by (1) achieving no material weaknesses in CFO audits relative to information systems security, (2) increasing the percent of employees receiving security awareness training to 95%, and

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
	plan, even though ACF's grant programs, such as TANF and Head Start, are vulnerable to fraud, waste, and abuse. ACF stated in its comments that even though no information on its efforts to fight fraud, waste, and abuse was included in its performance plan or report, its Federal Managers' Financial Integrity Act program and annual CFO process are addressing these issues.	(3) increasing the proportion of Medicare contractor sites receiving security reviews. The plan does discuss the coordination involved in the systems security improvement effort. However, the plan does not provide specifics about how weaknesses identified at HCFA's central office and at the system maintainer sites will be addressed. Although the plan does not set targets for reducing reportable conditions, continued review through the CFO audit will help track HCFA's progress. In its comments, HCFA explained that it was pursuing a corrective action plan to correct identified financial management material weaknesses and reportable conditions that had been identified in past CFO audits. HCFA has only begun to address program integrity in the Medicaid program through one new goal—to assist states in conducting Medicaid payment accuracy studies for the purpose of measuring and, ultimately, reducing payment errors. However, the FY 2001 target is to establish the feasibility of conducting pilot studies

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
		within states. As a result, measurable progress in reducing payment errors in this program is likely to be several years away. In its comments, HCFA noted that its 2½ -year-old National Fraud and Abuse Initiative has resulted in a variety of activities geared to reducing fraud and abuse in the Medicaid program. ACF: The agencywide performance goal to implement GATES II could be part of a strategy to address this challenge; however, this is not explicitly stated in ACF's FY 2001 performance plan. The goal reads as follows: "Implement GATES II, which will provide more efficient debt collection and reengineering processes to approve and track waivers granted in ACF programs." ACF also discussed the strategy it used to fulfill for FY 1999 the federal full cost accounting requirements. It plans to use this same successful strategy for FY 2001.

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
		IHS: Continue implementation of managerial cost accounting systems across IHS (measure: secure information technology capability). NIH: • Maintain oversight and protection of the public investment in NIH research through increased monitoring of licensee activities (measure: NIH review audits of sales; when indicators show that sales and royalty information may be incorrect, NIH will conduct reviews of up to three licensees during the year). • Ensure that overpayments do not occur in NIH fellowship programs and that bankruptcy statutes are complied with in collecting past overpayments (measure: achieve a 50% reduction in the number of overpayments).

Major management challenge	Progress in resolving major management challenge, as discussed in the FY 1999 performance report	Applicable goals and measures in the FY 2001 performance plan
Other areas identified by HHS' IG		
ACF: Identifying, investigating, and prosecuting violators of the Child Support Recovery Act, which makes it a federal offense for a noncustodial parent residing in a different state from a child to willfully avoid paying his or her court-ordered child support obligation.	This strategy for increasing collections is not discussed specifically in the goals and measures section of OCSE's FY 1999 performance plan or report. Plan targets focus on increasing the rates of collection for both current and past due child support, and preliminary data indicate that $15.5 billion was collected in FY 1999; however, the extent to which enforcement of the act contributed to this total is not discussed. The plan states that collection techniques aimed at increasing child support payment arrearages include seizing the financial assets of parents who owe but does not identify the act directly as a collection tool or strategy.	Similarly, in ACF's FY 2001 performance plan, OCSE collection targets for current and past due child support payments are expressed as rates and do not identify enforcement of the act as a strategy for meeting these targets. Program goal: All children in IV-D cases receive financial and medical support from both parents. • Objective: Increase the collection rate. In FY 2001, maintain the IV-D collection rate for current support at 71% (FY 1999 baseline available in March 2000). • Objective: Increase paying cases. In FY 2001, increase the percentage of paying cases among IV-D arrearage cases to 50% (FY 1999 baseline available in March 2000).
HCFA: Reducing highly questionable payments for mental health services.	HCFA did not have any performance goals specifically aimed at reducing questionable mental health payments in its FY 1999 performance plan; therefore, none were discussed in its FY 1999	HCFA's FY 2001 performance plan has a brief discussion of its specific plans to strengthen oversight of the mental health service benefit. Within the new FY 2001 goal "improve the

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	performance report. However, the FY 1999 goal to reduce the percentage of improper payments made under the Medicare fee-for-service program indirectly addressed this issue, and HCFA met this goal (FY 1999 target: 9%; FY 1999 actual: 8%).	effectiveness of program integrity activities through the successful implementation of the comprehensive plan for program integrity," HCFA has established a goal to reduce the payment error rate for community mental health centers' partial hospitalization claims from 90% in FY 1996 to 39% for FY 2001. HCFA does not discuss how the CMHC payment error rate was defined in FY 1996; therefore, we cannot determine whether this goal will adequately address HHS IG concerns.
HCFA: Manage growth of Medicare managed care.	HCFA's FY 1999 performance report addresses one goal related to this issue of concern: timely processing of clean Medicare+Choice enrollments equal to the effective date on the transaction (FY 1999 target: 98%). However, the performance plan indicates data will not be available until spring 2000, therefore, HCFA's progress towards this goal cannot be determined.	The FY 2001 performance plan continues to include the goal "enroll beneficiaries into managed care plans timely," which was first established for FY 1999. The targets for FY 1999, FY 2000 and FY 2001 are all the same: 98% of "clean" enrollment transactions to be updated with effective dates equal to that on the transaction. However, it is not clear that the measure will indicate timely processing of Medicare+Choice claims because only "clean" enrollment transactions will be subject to measurement. Another related FY 2001 goal is

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		"improve Medicare's administration of the beneficiary appeal process," which was established in FY 2000 in response to HHS IG concerns. The measure for this goal is still being developed.
HCFA: Reduce questionable home health payments.	According to HCFA's FY 1999 performance report, it achieved its target reduction in the improper payment rate for home health for selected states.	The FY 2000 target for this goal is 10%. According to HCFA, the goal has been discontinued for FY 2001 and replaced by other program integrity goals.
HCFA: Implement nursing facility payment reforms and other Balanced Budget Act provisions.	HCFA's FY 1999 performance report and plan details the progress it has made implementing skilled nursing facility payment reforms and establishing a risk-adjusted payment methodology for Medicare+Choice plans. HCFA met its goal to develop the skilled nursing facility prospective payment system, which HCFA started implementing in FY 1998. It reports that it expects to implement a prospective payment system for outpatient hospital services by the end of FY 2000 and for home health agency and rehabilitation facility services by the end of FY 2001. HCFA developed a risk-adjusted payment methodology for Medicare+Choice, with final rates published in March 1999—meeting that portion of its goal.	HCFA's FY 2001 performance plan continues to address the management challenge of implementing many new payment methodologies, with targets to publish its rules for a prospective payment system for inpatient rehabilitation hospitals and to implement the home health agency prospective payment system by October 1, 2000. HCFA is working toward implementing a prospective payment system for hospital outpatient services in FY 2000. HCFA's plan addresses the importance of implementing these new payment systems because, according to the agency, prospective payment is expected to result in more efficient provision of care and slow the growth in Medicare spending. HCFA indicates

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		that it intends to further refine and improve the payment methodologies on a continuous basis to ensure that payments are as appropriate as possible and that payment methodologies serve their intended purposes. As we have reported to the Congress, we have concerns about certain aspects of the proposed payment methodology for skilled nursing facility, home health care, and Medicare+Choice risk adjustment. In each case, HCFA is likely to lack sufficient information to adequately monitor the appropriateness of payments and services rendered.[a]

[a]Medicare: HCFA Faces Challenges to Control Improper Payments (GAO/T-HEHS-00-74, Mar. 9, 2000).

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