

GAO

Testimony

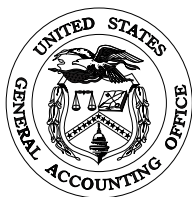
Before the Subcommittee on Government Management,
Information and Technology, Committee on Government
Reform, House of Representatives

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YEAR 2000 COMPUTING CRISIS

Readiness Status of the Department of Health and Human Services

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Mr. Chairman and Members of the Subcommittee:

We appreciate the opportunity to participate in today's hearing focusing on the readiness of the computer systems of the Department of Health and Human Services (HHS) overall and of some of its component organizations to function reliably into the next century. HHS is a vast department; its components face varying challenges in making sure that its programs do not suffer interruption in the delivery of benefits and services upon which millions of Americans depend.

I would like to begin today by summarizing the information contained in HHS' most recent Year 2000 (Y2K) quarterly report to the Office of Management and Budget (OMB), reflecting progress made as of December 31, 1998. I will then offer more specific comments in areas in which we have done work, including the Health Care Financing Administration's (HCFA) Medicare and Medicaid programs, the Administration for Children and Families' (ACF) state human services programs, the Program Support Center's (PSC) Payment Management System (PMS), and the biomedical equipment efforts of the Food and Drug Administration (FDA).

Reported Compliance Status of HHS Systems

As the following table illustrates, HHS reported that as of December 31, 1998, 83 percent of its mission-critical systems were Y2K compliant (243 of 294). Of its 34 systems remaining to be repaired, 99 percent were reported to be renovated, 81 percent validated, and 77 percent implemented.

Table 1: Year 2000 Compliance Status of HHS' Mission-Critical Systems, December 31, 1998, as Reported to OMB on February 10, 1999

HHS agency	Total systems	Number compliant	To be replaced	To be repaired	To be retired
HCFA internal	25	25 ^a	0	0	0
HCFA external	82	54	0	24	4
ACF	45	45	0	0	0
PSC	8	3	1	4	0
FDA	34	30	4	0	0
Other HHS ^b	100	86	5	6	3
Total	294	243	10	34	7

^aIncludes four systems that require additional coordination of internal and external interfaces.

^bIncludes the Administration on Aging, Centers for Disease Control and Prevention, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, Office of Inspector General, and Substance Abuse and Mental Health Services Administration.

Source: Department of Health and Human Services' quarterly report to OMB, February 10, 1999.

In addition to the work that remains to correct its mission-critical systems, HHS has much work left in the embedded systems, facilities, and telecommunications areas. Specifically, according to its February 10, 1999, report to OMB, HHS had (1) assessed about 40 percent of its embedded systems (primarily biomedical equipment) and (2) assessed 20 percent of its facilities. Further, HHS reported that it had two operating divisions with compliant telecommunications systems as well as others in varying stages of assessing and/or remediating their telecommunications systems.

Much Work Remains to Achieve Compliance at HCFA

In a report issued last year, we concluded that the progress made by HCFA—and its contractors—in making its computers that process Medicare claims Year 2000 compliant was severely behind schedule in areas including repair, testing, and implementation.¹ Further, we made numerous recommendations to improve key HCFA management practices that we found to be lacking or inadequate. Today I would like to briefly discuss our findings from that report and our suggestions for strengthening HCFA's Y2K activities, describe actions taken on those recommendations, and provide our perspective on where Medicare claims processing stands today. I will also provide an update on the status of state systems that support HCFA's Medicaid program.

Medicare Systems Remain at High Risk

As the nation's largest health care insurer, Medicare expects to process over a billion claims and pay \$288 billion in benefits annually by 2000. The consequences, then, of its systems' not being Year 2000 compliant could be enormous. We originally highlighted this concern in May 1997, making several recommendations for improvement.² In our report of last September we warned that although HCFA had made improvements in its Year 2000 management, serious challenges remained to be resolved in a short period of time. Specifically, we reported that less than a third of

¹Medicare Transaction System: Success Depends Upon Correcting the Critical Managerial and Technical Weaknesses (GAO/AIMD-99-78, May 16, 1997).

²Medicare Transaction System: Success Depends Upon Correcting Critical Managerial and Technical Weaknesses (GAO/AIMD-97-78, May 16, 1997).

Medicare's mission-critical systems had been fully renovated, and none had been validated or implemented. Further, in terms of the agency's key management practices necessary to adequately direct and monitor its Year 2000 project, HCFA had not

- developed an overall schedule or critical path to identify and rank Y2K tasks to help ensure that they could be completed in a timely manner;
- implemented risk management processes necessary to highlight potential technical and managerial weaknesses that could impair project success;
- planned for or scheduled end-to-end testing to ensure that programwide renovations would work as planned; or
- effectively managed its electronic data exchanges, thereby increasing the risk that Y2K errors would be transferred through data exchanges from one organization's computer systems to those of another.

OMB also had concerns. In its December 8, 1998, summary of Year 2000 progress reports of all agencies for the reporting quarter ending November 13, 1998, it concluded that while HCFA had made significant progress in renovating its internal and external systems, the agency remained a serious concern due to the remediation schedule of its external systems. OMB further stated that Medicare contractors would have to make an intensive, sustained effort to complete validation and implementation of their mission-critical systems by the governmentwide goal of March 31, 1999. OMB designated HHS as a tier 1 agency on its three-tiered rating scale since it had made insufficient progress in addressing the Year 2000 problem.

Our conclusions and recommendations to the HCFA Administrator reflected our concerns about the high level of risk and large number of tasks still facing HCFA. We reported that it was more critical than ever that HCFA have sound business continuity and contingency plans in place that could be implemented should systems failures occur. Our specific recommendations included that HCFA

- rank its remaining Year 2000 work on the basis of an integrated project schedule and ensure that all critical tasks are prioritized and completed in time to prevent unnecessary delays,

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- develop a risk management process,
 - define the scope of an end-to-end test of the claims process and develop plans and a schedule for conducting such a test,
 - ensure that all external and internal systems' data exchanges have been identified and agreements signed among exchange partners, and
 - accelerate the development of business continuity and contingency plans.

HCFA's Actions to Achieve Compliance in its Medicare Systems

HCFA has been responsive to our recommendations, and its top management is actively engaged in its Year 2000 program. HCFA's Administrator has made Year 2000 compliance the agency's top priority and has directed a number of actions to more effectively manage this project. For example, HCFA has established a "war room" for real-time monitoring of Year 2000 renovation, testing, and implementation activities. In addition, the agency established seven contractor oversight teams to monitor progress. HCFA also strengthened its outreach efforts: on January 12, 1999, the Administrator sent individual letters to each of the 1.25 million Medicare providers in the United States, alerting them to take prompt Year 2000 action on their information and billing systems. Three days later the Administrator sent a letter to Congress, with assurances that HCFA is making progress and stressing that physicians, hospitals, and other providers must also meet the Y2K challenge. HCFA also offered to provide speakers in local congressional districts.

To more effectively identify and manage risks, HCFA is relying on multiple sources of information, including test reports, reports from its independent validation and verification (IV&V) contractors, and weekly status reports from its recently established contractor oversight teams. In addition, HCFA has stationed staff at critical contractor sites to assess the data being reported to them and to identify problems.

HCFA is also more effectively managing its electronic data exchanges. HCFA now reports having a complete data exchange inventory of nearly 8,000 internal exchanges and over 255,000 external data exchanges. HCFA also issued instructions to its contractors (carriers and fiscal intermediaries) to inform providers and suppliers that they must submit Medicare claims in Year 2000-compliant data exchange format by April 5 of this year. The status of each of these data exchanges is being tracked by HCFA staff.

HCFA has also more clearly defined its testing procedures. It published additional testing guidance in November 1998 that provided a policy for external systems that requires multiple levels of testing for each system, including:

- Unit level testing: testing of the individual software component using test cases that exercise all component functionality. For the standard claims processing system, this includes full functional testing of claims processing policy and program integrity edits.
- Simulated future date testing: testing of the individual software component using tools to simulate that the date has been rolled forward.
- Compliance testing: testing in a fully Year 2000-compliant environment with real future dates to verify that the system is Year 2000 compliant.

HCFA also plans to perform end-to-end testing with its Year 2000-compliant test sites. These end-to-end tests are to include all internal systems and contractor systems; however, they will not include testing with banks and providers. Finally, HCFA has begun to use a Year 2000 analysis tool to measure testing thoroughness, and its IV&V contractor is assessing test adequacy on the external systems (e.g., test coverage and documentation).

The final area in which HCFA has demonstrated progress is developing business continuity and contingency plans to ensure that, no matter what, beneficiaries will receive care and providers will be paid. HCFA has established cross-organizational workgroups to develop contingency plans for the following core business functions: health plan and provider payment, eligibility and enrollment issues, program integrity, managed care, quality of care, litigation, and telecommunications. HCFA's draft plans document its business impact analysis; the contingency plans are expected to be completed by March 31 of this year, and testing of the plans by June 30.

Reported Status of HCFA's Mission-Critical Systems

HCFA operates and maintains 25 internal mission-critical systems. HCFA also has 78 external mission-critical systems³ operated by contractors throughout the country to process Medicare claims. These external systems include six standard processing systems and the "Common Working File." Each contractor relies on one of these standard systems to

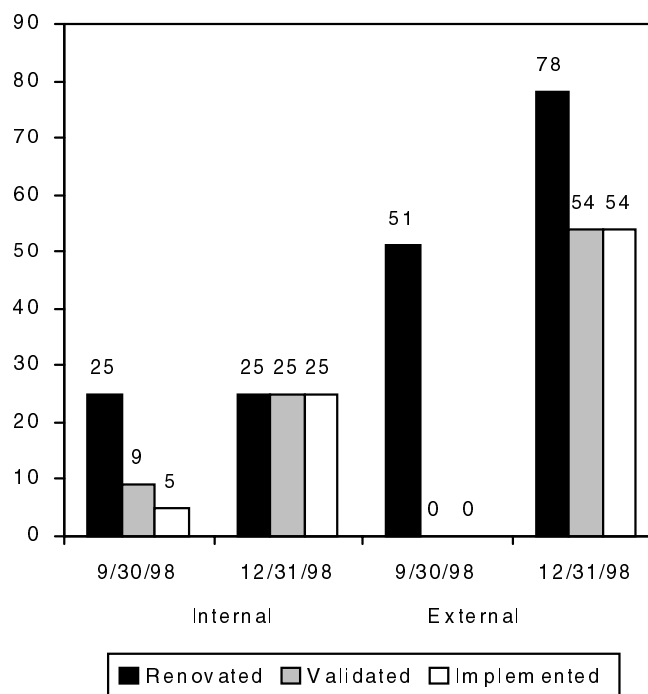
³HHS reported 82 HCFA external mission-critical systems, however, 4 of these are due to be retired.

process its claims, and adds its own front-end and back-end processing systems. The Common Working File is a set of databases located at nine sites that works with internal and external systems to authorize claims payments and determine beneficiary eligibility.

HCFA's reporting of its readiness for next January sounds quite positive as stated in the most recent HHS Y2K quarterly progress report to OMB. According to this report, dated February 10, as of December 31, 1998, all 25 of HCFA's internal mission-critical systems were reported to be compliant, as were 54 of the 78 external systems. Figure 1 shows HCFA's reported status, compared with what it reported on September 30, 1998.

Figure 1: Reported Status of HCFA's Mission-Critical Systems

Number of systems



Source: HCFA quarterly reports to HHS.

Reported Progress Is Highly Overstated

HCFA's reported progress on its external mission-critical systems is considerably overstated. In fact, none of the 54 systems reported compliant by HCFA was Year 2000 ready as of December 31, 1998. All 54 external systems that were reported as compliant had important associated qualifications (exceptions), some of them very significant. Such qualifications included a major standard system that failed to recognize "00" as a valid year, as well as 2000 as a leap year; they also included systems that were not fully future-date tested.

According to HCFA officials, they reported these systems as compliant because these qualifications were "minor problems" that should not take much time to address. This is at variance with the IV&V contractor's interpretation. More specifically, the IV&V contractor found that the qualifications reported by all systems contractors were critical, most requiring a major to moderate level of effort to resolve.

A specific example of a system reported as compliant with qualifications is the Florida standard system, used by 29 contractors. This system had one qualification that consisted of 22 test failures. The IV&V contractor characterized this failure experience as significant. HCFA reports that these failures were corrected with a January 29, 1999, software release. However, in a February 16, 1999, IV&V status report, Blue Cross of California—a user of the Florida standard system—found that date test problems remained. In another example, the EDS MCS standard system that is used by 10 contractors had 25 qualifications; these included 9 problems that were not future-date tested. HCFA now reports that future-date testing of the January software release of the EDS MCS system is 92 percent complete.

As these examples illustrate, the systems are not yet Year 2000 compliant, and the 39 contractors that use these two standard systems likewise cannot be considered compliant. Further, according to the IV&V contractor, two critical qualifications associated with each of the standard systems affect all external contractor systems: (1) HCFA-supplied systems that contractors use in claims processing were delivered to them too late for required testing to be performed and (2) the claims processing data centers' hardware, software, and telecommunications were not completely compliant.

The IV&V contractor acknowledges that Medicare claims processing systems have made progress toward Year 2000 compliance over the past year, yet the various qualifications inevitably mean that some renovation

and a significant amount of retesting still needs to be accomplished before these systems can be considered compliant. To HCFA's credit, it issued a memorandum in early January requesting Medicare carriers and fiscal intermediaries to resolve these qualifications by March 31, the federal target date for Year 2000 compliance. The notice stated that Medicare systems with unresolved Y2K problems affecting claims processing functions must be corrected, tested, and installed in production. As part of our ongoing work for the Senate Special Committee on Aging, we will be monitoring the resolution of these qualifications closely.

Other Critical Risks/Challenges That Remain

The February 16, 1999, report of HCFA's IV&V contractor stated that an integrated schedule that tracks all major internal systems activities needs to be established. It added that system-specific information—including time, test scheduling, and resource considerations—needs to be more fully developed in order to achieve a robust, trackable schedule. We agree. In fact, this is consistent with our previous recommendation that remaining Y2K work be ranked on the basis of a schedule that includes milestones for renovation and testing of all systems, and that it include time for end-to-end testing and development and testing of business continuity and contingency plans.⁴ Such a schedule is even more important for the external systems because of their greater number, complexity, and interdependencies. HCFA still lacks an integrated schedule that identifies a critical path. Without this, it will be difficult for HCFA management to identify important dependencies in this complex environment and to prioritize its remaining work in the time that remains. HCFA also lacks a formal risk management process—something to identify all risks and their interdependencies, assess their impact, establish time frames for mitigation and criteria for successful mitigation, and ensure that the criteria are followed. The one system that was intended to serve as its comprehensive risk management system does not contain current information, according to the IV&V contractor.

HCFA's systems—both internal and external—exchange data, both among themselves and with the Common Working File, other federal agencies, banks, and providers. Accordingly, it is important that HCFA ensure that Y2K-related errors will not be introduced into the Medicare program through these data exchanges. As of February 10, 1999, HCFA reported that over 6,000 of its 7,968 internal data exchanges were still not compliant, and that over 37,000 of its nearly 255,000 external data exchanges were not

⁴GAO/AIMD-98-284, September 28, 1998.

compliant.⁵ To ensure that HCFA's internal and external systems are capable of exchanging data among themselves as well as with other federal agencies, banks, and providers, it is essential that HCFA take steps to resolve the remaining noncompliance of these data exchanges.

In yet another critical area, HCFA faces a significant amount of testing in 1999, since changes will continue to be made to its mission-critical systems to make them compliant. First, changes to resolve the existing qualifications will need to be retested. Second, testing must still take place with full production-level software. For example, the final software release of the Common Working File before 2000 is scheduled for late June; testing will therefore be needed after that. Third, legislatively mandated changes to software that will occur through June will need to be retested as well. HCFA plans to conduct these final tests of its systems between July 1 and November 1, 1999, then recertify all mission-critical systems as compliant without qualification or exception. These final tests will ultimately determine whether HCFA's mission-critical systems are indeed Year 2000 compliant. The late 1999 time frames associated with this testing represent a high degree of risk.

In addition to such individual systems testing, HCFA must also test its systems end-to-end to verify that defined sets of interrelated systems, which collectively support an organizational core business function, will work as intended. As mentioned, HCFA plans to perform this end-to-end testing with its Year 2000 test sites. These tests are to include all internal systems and contractor systems, but will not include testing with banks and providers. HCFA has instructed its contractors that it is their responsibility to test with providers and financial institutions. Even excluding banks and providers, end-to-end testing of HCFA's internal and external systems is a massive undertaking that will need to be effectively planned and carried out. HCFA has not yet, however, developed a detailed end-to-end test plan that explains how these tests will be conducted or that provides a detailed schedule for conducting them.

A final aspect of testing concerns the independent testing contractor. The IV&V contractor's recent assessment of the independent testing contractor concluded that its strategy as currently stated "is high risk for providing

⁵On February 23, 1999, the HCFA Administrator stated that she wanted us to note that the February 10, 1999, HHS quarterly report to OMB had a typographical error, and that the total number of internal data exchanges is 3,418 and that 309 of these are still not compliant.

effective independent testing” because of the limited number of internal systems to actually be independently tested: 8. This number was previously 22. Further, this testing will not be completed until August. The limited number of systems tested and the late completion date are not reassuring.

Given the magnitude of HCFA's Year 2000 problem and the many challenges that continue to face it, the development of contingency plans to ensure continuity of critical operations and business processes is absolutely critical. Therefore, HCFA must sustain its efforts to complete and test its agencywide business continuity and contingency plans by June 30. Another challenge for HCFA is monitoring the progress of the 62 separate business continuity and contingency plans that will be submitted by its contractors. We will continue to monitor progress in this area.

Other issues that further complicate HCFA's Year 2000 challenge are the known and unknown contractor transitions that are to take place before January 1, 2000, and the unknown status of the managed care organizations serving Medicare beneficiaries. As reported in HHS' quarterly submission to OMB, HCFA is concerned about the possibility of Medicare contractors, fiscal intermediaries, and carriers leaving the program and notifying HCFA after June 1999. If this were to occur, the workload would have to be transferred to another contractor whose Year 2000 compliance status may not be known. According to both contractor and HCFA officials, it requires 6-12 months to transfer the claims processing workload from one contractor to another. At present, HCFA must transition the work of three carriers that are leaving the program.

HCFA is requiring the 386 managed care organizations currently serving 6.6 million Medicare beneficiaries to certify their systems as Year 2000 compliant by this April 15. These certifications may be qualified, just as with the fee-for-service contractors. If this were to occur, a formal recertification would have to be performed later this year. Until this initial certification is performed, it will remain unknown whether the managed care organizations' systems are Year 2000 compliant.

To summarize HCFA's Medicare situation, the agency and its contractors have made progress in addressing issues that we have raised. However, their reported progress vastly overstates the facts. Some renovation and a significant amount of testing must still be performed this year. Until HCFA completes its planned recertification between July and November 1999, the final status of the agency's Year 2000 compliance will be unknown. Given

the considerable amount of remaining work that HCFA faces, it is crucial that development and testing of HCFA's business continuity and contingency plans move forward rapidly if we are to avoid interruption of Medicare claims processing next year.

Medicaid Systems Are at Risk

In fiscal year 1997, Medicaid—a joint federal-state program supported by HCFA and administered by the states—provided about \$160 billion to millions of recipients. Medicaid provides health coverage for 36 million low-income people, including over 17 million children. Its beneficiaries also include elderly, blind, and disabled individuals.

In surveying states' Year 2000 status last summer,⁶ we found that many systems were at risk and much work remained to ensure the continuation of services. The states' reported compliance rate for Medicaid systems was only about 16 percent, and 18 states reported that they had completed renovating one quarter or fewer of their Medicaid claims processing systems. These 18 states had Medicaid expenditures of about \$40 billion in fiscal year 1997—one-quarter of total Medicaid expenditures nationwide, covering about 9.5 million recipients.

Since last summer, HCFA has administered two state self-reporting surveys and conducted several on-site visits, finding that overall state Medicaid systems status has improved little. For example, HCFA reported in November 1998 that Medicaid systems had shown some progress in renovation, but that the number of states reporting completion of this phase had actually decreased compared with the July/August 1998 data that were reported to us by the states. It found, further, that 11 states' Medicaid systems were still reported to be 25 percent or less renovated, and about half of the states were 50 percent or less renovated. Only five states—Arkansas, California, Idaho, Illinois, and Iowa—reported their Medicaid systems to be 100 percent renovated. Thus, while OMB guidelines target completion of systems renovation by September 1998, states' self-reported data to HCFA showed that about 90 percent of states had not completed renovation for the Medicaid programs as of November 1998.

⁶Year 2000 Computing Crisis: Readiness of State Automated Systems to Support Federal Welfare Programs (GAO/AIMD-99-28, November 6, 1998). We sent a survey to the 50 states, the District of Columbia, and three territories (Guam, Puerto Rico, and the Virgin Islands). All but one of the 54 entities surveyed responded.

To obtain more reliable Year 2000 state Medicaid status information, HCFA hired a contractor to conduct independent verification and validation of states' systems. As an initial effort, the contractor and HCFA distributed a survey to all states to ascertain background and Year 2000 status information. However, based on more recent information from on-site visits, the IV&V project leader said that the survey data were not as reliable as HCFA had expected because states tended to overstate their progress. As a result, HCFA has instead decided to rely on on-site contractor visits to ascertain accurate Medicaid systems status.

HCFA reported in HHS' February 1999 quarterly report to OMB that based on seven site visits, some of the dates that states had reported to us last July/August had slipped, underscoring the need for on-site visits to secure more accurate information. For example, according to HCFA, while four states appeared to have made some progress in the 6 months since our survey, the status of three states remained the same. Further, HCFA found that one state's Medicaid eligibility system was not as far along as the state had reported. As of February 17, 1999, HCFA told us that it had visited 14 states and that half of those states had shown some improvement. Thus, HCFA and the IV&V contractor plan to make on-site visits to all 50 states and the District of Columbia by the end of this April. For states considered at risk, HCFA will conduct second site visits between May and September 1999 and, if necessary, third visits between October and December. The later visits will emphasize contingency planning to help the states ensure continuity of program operations in the event of systems failures.

Current Status of State Systems Supporting ACF Programs Is Unknown

Key state-administered programs that could be affected by Y2K include Temporary Assistance for Needy Families (TANF), Child Support Enforcement (CSE), Child Care (CC), and Child Welfare (CW) programs; these programs—critical to the health and well being of the needy—are overseen by HHS' ACF. These programs focus on providing benefits to economically needy families with children who lack financial support from one or both parents because of death, absence, incapacity, or unemployment. In fiscal year 1997, federal and state agencies spent just under \$14 billion on cash and work-based assistance. Of this total, almost \$8 billion was federal money, while just over \$6 billion was state-funded. These programs served almost 8 million recipients as of September 1998.

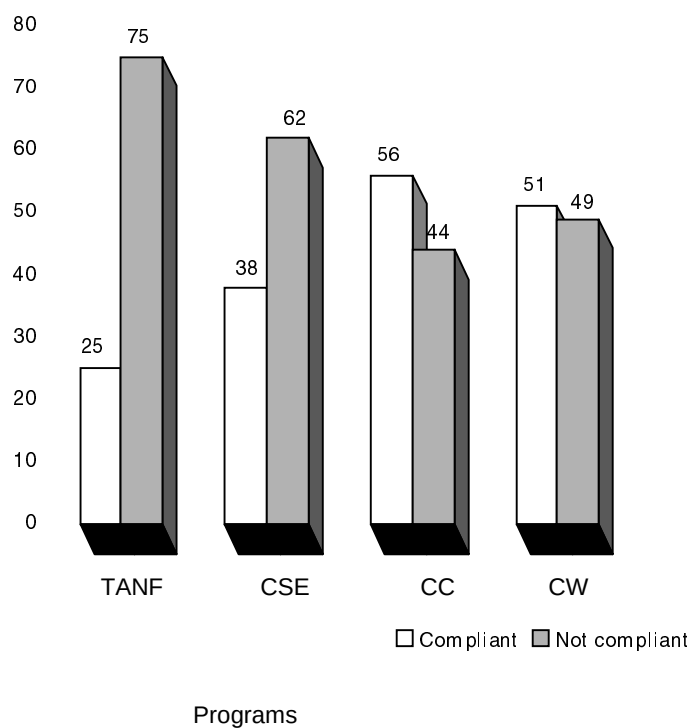
Failure to complete Year 2000 conversion activities for these programs could cause billions of dollars in benefits payments to fail to reach our nation's needy families. Those newly approved for benefits could face an

inability to be automatically added to the recipient file; eligibility for new applicants might not be able to be determined in a timely fashion; eligible recipients could be denied benefits; and payments could be underpaid, overpaid, or delayed.

As figure 2 illustrates, in our November 1998 report on the Year 2000 readiness of state systems that support these programs we found that, although progress varied, many systems were at risk and much work remained to ensure continuation of services.⁷

Figure 2: Percentage of Systems Reported Compliant – July/August 1998

Percentage of systems



⁷GAO/AIMD-99-28, November 6, 1998.

Following our report, OMB implemented a requirement that federal oversight agencies include the status of state human services systems in quarterly Year 2000 progress reports. Specifically, it requested that federal agencies describe actions to help ensure that federally supported, state-run programs will be able to provide services and benefits.⁸ OMB has further asked that agencies report the date when each state's systems will be Year 2000 compliant, and provide information on any significant difficulties that states are encountering.

ACF is currently surveying the states to determine the status of TANF, child support enforcement, child care, and child welfare systems, however, it does not have current information on states' systems. In response to OMB's requirement to provide updated state systems status in the quarterly Y2K progress reports, ACF sent letters and surveys to state chief information officers asking for such information, requesting that states return the survey by January 31, 1999. As of February 16, 1999, ACF had received responses from 27 states. Further, according to HHS' Year 2000 program manager, the information provided by the states raised more questions than answers; some states did not answer all questions or complete the survey for all systems.

ACF is now proposing on-site reviews of state systems for TANF and the child support enforcement, child welfare, and child care programs in all 50 states. ACF sees these reviews as enhancing the available information concerning states' Year 2000 readiness and providing a vehicle through which the agency can provide states with technical assistance. ACF is considering developing a process similar to the one being used by HCFA, or possibly working with HCFA in gathering information.

Status of PSC's Payment Management System

HHS' PSC provides grants payments and cash management services through its Payment Management System (PMS) to all HHS agencies and to 10 other federal agencies on a fee-for-service basis. PSC is organized into three business units, referred to as "services." Each service is responsible for a particular line of business.

⁸OMB Memorandum for the Heads of Selected Agencies, Revised Reporting Guidance on Year 2000 Efforts, January 26, 1999. The state programs included were Food Stamps, Medical Assistance, Unemployment Insurance, TANF, Child Support Enforcement, WIC, Low Income Home Energy Assistance, Child Nutrition, Child Care, and Child Welfare.

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- The Administrative Operations Service's responsibilities include property management, distribution of pharmaceuticals, medical and dental supplies, information systems support, and technical information services.
 - The Financial Management Service is responsible for providing financial services such as grants payments and cash management.
 - The Human Resources Service is responsible for providing a full range of human resources services such as personnel operations and payroll.

A key PSC activity is providing electronic funding and cash management service to organizations receiving HHS grants and contracts, as well as grants from other federal agencies. Its list of federal customers includes the Departments of Agriculture, Energy, Interior, Labor; and the Federal Emergency Management Agency, the Corporation for National Service, the National Aeronautics and Space Administration, the Social Security Administration, the Agency for International Development, and the U.S. Information Agency. According to PSC, its customer environment also includes 12 HHS operating divisions, and about 20,000 recipient organizations:

- 2,900 universities and educational organizations;
- 7,500 hospitals, health, and nonprofit organizations;
- 3,800 state government agencies; and
- 6,300 cross-servicing recipients.

These recipients receive about \$165 billion annually in federal grants payments for a wide range of activities such as school lunch programs, highway construction, and health care.

Delays in Year 2000 Readiness of PMS

PSC has identified eight mission-critical systems spanning the diversity of its administrative, financial, and human resources activities:

- Commissioned Corps Personnel and Payroll System,
- Civilian Payroll and Personnel System,

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- Automated Payment and Adjustment System,
 - Debt Collection System,
 - 5ESS Telephone Switch,
 - PSC LAN Servers,
 - Payment Management System, and the
 - CORE Accounting System.

Of PSC's eight mission-critical systems, the Payment Management System is one of the most critical. However, this system is not yet compliant, and it is unclear when it will be. Developed for the purpose of creating a central system for paying most federal assistance grants, block grants, and contracts, the main purpose of PMS is to serve as a fiscal intermediary between awarding agencies and the recipients of grants and contracts. PSC uses PMS to process billions of dollars in payments to recipient organizations--over half of all federal grant payments. Indeed, it is PMS that makes available to states approximately \$96 billion in Medicaid payments annually.

PMS was originally created 30 years ago, and has been expanded and modified several times since, according to PSC. In 1995, PSC began a project to replace PMS with a new, state-of-the-art automated system known as the "Reengineered Payment Management System." It was anticipated that this new system would be Year 2000 compliant and operational by October 1997.

Since its inception, the planned system replacement has encountered problems and, as a result, is still not operational. For example, according to a December 1997 PSC status report to HHS, the original contractor for the replacement system failed to maintain the agreed-upon schedule and therefore PSC decided to hire another contractor to implement the system. With the new contractor, the estimated date to complete the new system was revised to October 1, 1998, which was not met.

Problems appear to continue to plague the new system replacement effort. For example, in its biweekly status report for the period ending February 12, 1999, the contractor reports that portions of the implementation strategy are in jeopardy due to problems with database

extracts from the existing system. The contractor is concerned that database extracts, if transitioned to the new system, “may contain hidden surprises.”

Despite the new system’s problems, the Director of the Division of Payment Management told us that he expects the new system to be operational and Year 2000 compliant by March 31, 1999. Nevertheless, because PSC was concerned that it was at risk of not having a fully tested compliant system, it contracted in January 1999 for an independent consulting firm to conduct an analysis of whether PSC should rely on the new replacement system as its Year 2000 solution or, instead, rely on remediation and testing of the existing payment management system. According to the Division Director, this analysis was due on February 23. The Division Director stated that, as of this date, he had not received the final report. According to the firm contracted by PSC, whichever option PSC pursues, program management and independent verification and validation support will be required for the successful completion of the project.

Some Biomedical Equipment Status Information Available Through FDA

The question of whether medical devices such as magnetic resonance imaging (MRI) systems, x-ray machines, pacemakers, and cardiac monitoring equipment can be counted on to work reliably on and after January 1, 2000, is critical to our nation’s health care. To the extent that biomedical equipment uses embedded computer chips and software, it is vulnerable to the Y2K problem.⁹ Such vulnerability carries with it possible safety risks. This could range from the more benign—such as incorrect formatting of a printout—to the most serious—such as incorrect operation of equipment with the potential to decrease patient safety. The degree of risk depends on the role the equipment plays in the patient’s care.

Responsibility for oversight and regulation of medical devices, including the impact of the Y2K problem, lies with FDA. It provides information from biomedical equipment manufacturers through an Internet World Wide Web site. Last September,¹⁰ we reported that FDA had a disappointing response rate from biomedical equipment manufacturers to its request for compliance information. The FDA biomedical equipment database also

⁹ Biomedical equipment refers both to medical devices regulated by FDA, and scientific and research instruments, which are not subject to FDA regulation.

¹⁰ Year 2000 Computing Crisis: Compliance Status of Many Biomedical Equipment Items Still Unknown (GAO/AIMD-98-240, September 18, 1998).

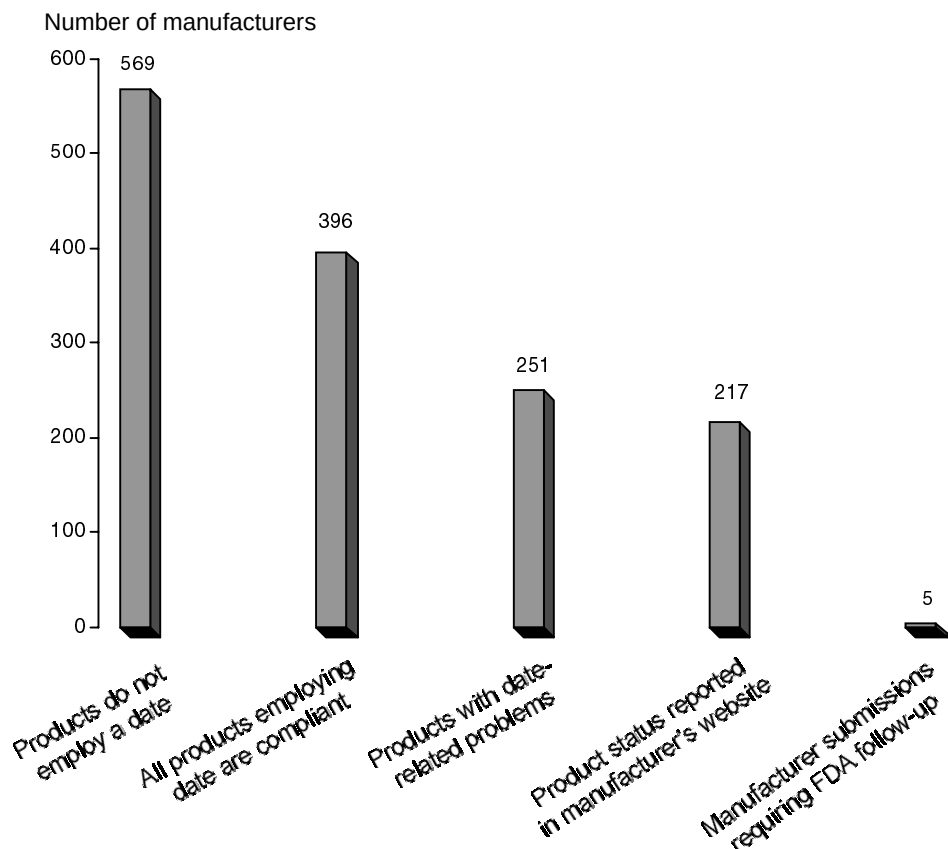
lacked detailed information on the make and model of compliant equipment. Further, FDA did not require manufacturers to submit test results certifying compliance. Therefore, the adequacy of manufacturers' corrections of noncompliant equipment could not be assured.

To address these issues, we made recommendations to the Secretaries of HHS and Veterans Affairs (VA)—a key stakeholder in determining the potential effects of the century change on biomedical equipment—to determine what actions, if any, should be taken regarding manufacturers that have not provided compliance information. We also recommended that the departments (1) work jointly to develop a single data clearinghouse to provide compliance information to all users of biomedical equipment and (2) take prudent steps to review test results for critical care/life support biomedical equipment, especially equipment once determined to be noncompliant but now deemed compliant—and make those results publicly available through FDA's central data clearinghouse.

HHS and VA agreed with our recommendation to develop a single data clearinghouse. FDA, in conjunction with VA, has established the Federal Y2K Biomedical Equipment Clearinghouse; it is publicly accessible through the Internet site and contains information on biomedical equipment compliance submitted to FDA by manufacturers, as well as information gathered by VA and the Department of Defense as part of their Year 2000 compliance projects. FDA also plans to include detailed information on the make and model of equipment reported as compliant.

In its February 10, 1999, quarterly submission to OMB, HHS reported that as of January 12, 1999, about three quarters (1,438) of 1,932 biomedical equipment manufacturers identified by FDA had submitted data to the clearinghouse. As shown in figure 3, about 40 percent of the manufacturers have products that do not employ a date, while about 17 percent reported equipment having date-related problems.

Figure 3: Biomedical Compliance Status Information Reported to FDA by Manufacturers as of January 12, 1999



Note: Total number of manufacturers = 1,438.

Source: Department of Health and Human Services.

Last September we also reported that most manufacturers citing noncompliant products listed incorrect display of date and/or time as the Y2K problem.¹¹ According to VA, these cases may not present a risk to patient safety because health care providers, such as physicians and nurses, can work around the problem. Of more serious concern are situations in which devices depend on date calculations, which can be

¹¹GAO/AIMD-98-240, September 18, 1998.

incorrect. One manufacturer cited an example of a product used for planning delivery of radiation treatment using a radioactive isotope as the source. An error in calculating the strength of the radiation source on the day of treatment could result in a dose that is too high or too low, which could have an adverse effect on the patient.¹²

HHS reports that FDA will continue to explore ways of obtaining compliance information from manufacturers who have not yet replied. In response to our recommendation that FDA and VA review test results of manufacturers' compliance certifications, VA--deferring to HHS--stated that it did not have the legislative or regulatory authority to do this. HHS, for its part, said that it lacked the available resources to undertake such a review and, further, that insufficient time remained to complete such reviews before 2000. We believe that if HHS lacks sufficient resources to review manufacturers' test results, it may want to solicit the help of federal health care providers and professional associations. Finally, HHS stated that submission of appropriate certifications of compliance is sufficient to ensure that the certifying manufacturers are in compliance. We disagree. Through independent reviews of manufacturers' test results, users of medical devices are provided with a greater level of confidence that the devices are indeed Year 2000 compliant.

Mr. Chairman, this completes my statement. I would be pleased to respond to any questions that you or other members of this Subcommittee may have at this time.

¹²Year 2000 Computing Crisis: Leadership Needed to Collect and Disseminate Critical Biomedical Equipment Information (GAO/T-AIMD-98-310, September 24, 1998).

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