United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations and the Subcommittee on Health and Environment, Committee on Commerce, House of Representatives

For Release on Delivery
Expected at
1 p.m.
Tuesday,
April 27, 1999

YEAR 2000 COMPUTING CRISIS

Readiness of Medicare and the Health Care Sector

Statement of Joel C. Willemssen
Director, Civil Agencies Information Systems
Accounting and Information Management Division

Messrs. Chairmen and Members of the Subcommittees:

We appreciate the opportunity to join in today's hearing and share information on the readiness of automated systems that support the nation's delivery of health benefits and services to function reliably without interruption through the turn of the century. This includes the ability of Medicare and Medicaid to pay for services to millions of Americans and the overall readiness of the health care sector, including such key elements as biomedical equipment used in the delivery of health services. Successful Year 2000--or Y2K--conversion is critical to these efforts.

We reported in February that while some progress by the Department of Health and Human Services' (HHS) Health Care Financing Administration (HCFA)—and its contractors—had been made in addressing the numerous recommendations we made last year [1] to improve key HCFA management practices associated with its Y2K program, many significant challenges remained. [2] At the time, we also reported that while some progress had been achieved, many states' Medicaid systems were at risk, and much work remained. [3]

Beyond Medicare and Medicaid, the information available on the national level concerning Y2K readiness throughout the health care sector—including providers, insurers, manufacturers, and suppliers—indicates much work remains in renovating, testing, and implementing compliant systems. Also, as we recently testified, while information on the compliance status of biomedical equipment is available through a clearinghouse maintained by the Food and Drug Administration (FDA), the test results for this equipment are not reviewed. [4] Finally, information on the Y2K readiness of pharmaceutical and medical-surgical manufacturers is incomplete.

[1] Medicare Computer Systems: Year 2000 Challenges Put Benefits and Services in Jeopardy (GAO/AIMD-98-284, September 28, 1998).

[2] Year 2000 Computing Crisis: Medicare and the Delivery of Health Services Are at Risk (GAO/T-AIMD-99-89, February 24, 1999).

[3] Year 2000 Computing Crisis: Readiness of State Automated Systems That Support Federal Human Services Programs (GAO/T-AIMD-99-91, February 24, 1999).

[4] See Year 2000 Computing Crisis: Action Needed to Ensure Continued Delivery of Veterans Benefits and Health Care Services (GAO/T-AIMD-99-136, April 15, 1999).

HCFA's Ability to Process Medicare Claims Into the Next Century

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 Y2K compliant could be enormous. We originally highlighted this concern in May 1997 and made several recommendations for improvement. [5] Our report of last September warned that although HCFA had made improvements in its Y2K management, the agency and its contractors were severely behind schedule in making their computers that process Medicare claims Y2K compliant. In February, we testified that although HCFA had been responsive to our recommendations and that its top management was actively engaged in its Y2K program, its reported progress was highly overstated. We testified that none of HCFA's 54 external mission-critical systems reported compliant by HHS as of December 31, 1998, was Y2K ready, based on serious qualifications identified by the independent verification and validation (IV&V) contractor. Further, we reported that HCFA continued to face serious Y2K challenges. Specifically, HCFA

- lacked an overall schedule and critical path to identify and rank Y2K tasks to help ensure that they could be completed in a timely manner;
- needed a formal risk management process to highlight potential technical and managerial weaknesses that could impair project success;
- continued to have thousands of electronic data exchanges that were not Y2K compliant;
- faced a significant amount of testing in 1999, especially since changes will continue to be made to its mission-critical systems to make them compliant; and
- needed to sustain its efforts to complete and test business continuity and contingency plans to ensure that Medicare claims will be processed next year.

The Office of Management and Budget (OMB) also continues to be concerned about HCFA's progress. In its March 18, 1999, summary of Y2K progress reports of all agencies for the reporting quarter ending February 12, 1999, it concluded that HCFA remains a serious concern due to external systems testing, implementation schedules, and the qualified compliance of a number of external mission-critical systems. OMB further stated that although Medicare contractors had been making an intensive effort to

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

complete validation and implementation by the governmentwide deadline of March 31, 1999, some external contractors may not succeed. Due in large part to HCFA's status, OMB designated HHS as a tier 1 agency on its three-tiered rating scale, meaning it had made insufficient progress in addressing the Y2K problem.

HCFA's Actions to Achieve Compliance and Bolster Outreach Efforts to Medicare Providers

HCFA has been responsive to our recommendations. To more effectively identify and manage risks, HCFA is relying on multiple sources of information, including test reports, reports from its 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 and to identify problems.

HCFA also is more effectively managing its electronic data exchanges. It issued instructions to its contractors (fiscal intermediaries and carriers) to inform providers and suppliers that they had to begin submitting Medicare claims in Y2K-compliant data exchange format by April 5 of this year. HCFA now reports that 93 percent of the fiscal intermediaries and 99 percent of the carriers are complying. HCFA also established new instructions for contractors to report on data exchanges, and created a new database to track status.

HCFA continues to further define its testing procedures. It required that existing qualifications be addressed and tested by March 31, 1999. It also issued instructions—on January 11, 1999—for all contractors to recertify their systems from July 1 to November 1, 1999. To more clearly define this testing, HCFA issued additional recertification and end-to-end testing guidance on March 10, 1999.

HCFA has also begun to use several Y2K-analysis tools to measure testing thoroughness, and its IV&V contractor is assessing test adequacy of the external systems (e.g., test coverage and documentation). In addition to the IV&V contractors' efforts, HCFA has engaged a separate contractor to conduct independent tests on some of its mission-critical systems. HCFA further plans to perform end-to-end testing with its Y2K-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.

Another 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 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 fourth and final iteration of this plan was issued on April 1, 1999, and the plan is expected to be tested by June 30.

HCFA has continued to strengthen its outreach efforts to the providers of Medicare services. On January 12, 1999, the Administrator sent individual letters to over 1.3 million Medicare providers in the United States, alerting them to take prompt Y2K 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, is holding a series of conferences throughout the country, and has established a toll-free information hotline.

Reported Status of HCFA's Mission-Critical Systems

HCFA operates and maintains 25 internal mission-critical systems; it also relies on 75 external mission-critical systems operated by contractors throughout the country who 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 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.

In HHS' latest Y2K quarterly progress report to OMB, dated February 10, it reported that as of December 31, 1998, all 25 of HCFA's internal mission-critical systems were reported to be compliant, as were 54 of the external systems. Yet as we testified in February, none of these 54 systems was Y2K ready because all had important associated qualifications (exceptions), some of them significant. [6] HCFA issued a memorandum in early January requesting Medicare carriers and fiscal intermediaries to resolve these qualifications by March 31, the federal target date for Y2K compliance. HCFA reported to us on April 19, 1999, that most of these qualifications

[6]GAO/T-AIMD-99-89, February 24, 1999.

have been resolved and that 73 of 75 external systems are now compliant (the total number of external mission-critical systems decreased from 78 to 75 because three contractors plan to leave the Medicare program before the end of the year).

HCFA's IV&V contractor's analysis of the qualifications was consistent with what HCFA reported to us. Specifically, the IV&V contractor's analysis of the 53 external systems concluded that 19 had no remaining qualifications, 33 had qualifications it deemed "low impact" (i.e., could be addressed within the next 3 months or would have a minor impact on the site's ability to meet Medicare requirements), and 1 had qualifications deemed critical. The IV&V contractor recommended that all qualifications be resolved by June 28, 1999, so that HCFA's final testing of its mission-critical systems could begin on July 1, 1999, with no open qualifications.

Despite Reported Compliance, HCFA's Mission-Critical Systems Still Require Additional Y2K Renovation and Testing

The HCFA mission-critical systems that have been characterized as Y2K compliant are not, however, the final systems that will be processing Medicare claims on January 1, 2000. These systems will undergo a significant amount of change between now and July 1, 1999, for both Y2K and other reasons. These changes will require a complete retest to ensure that the systems have not been contaminated by the changes and that they still are indeed Y2K compliant.

Specifically, these changes will address (1) outstanding qualifications, (2) additional Y2K changes, (3) a critical software release of the Common Working File, and (4) legislative mandates. [7] In addition to the changes required to address outstanding qualifications, changes are also occurring because of other compliance issues not listed as qualifications. For example, three standard system maintainers are currently updating their systems because the earlier renovation was performed with noncompliant compilers.[8] Each of these three upgrades is scheduled to be completed by July 1999. In addition, analyses using tools that determine the Y2K readiness of software code are uncovering additional Y2K programming errors. For example, 28 programming errors were recently identified using a Y2K tool on the Florida standard system. These errors are to be

[7] These legislative mandates include software changes required to implement new policies for the Balanced Budget Act of 1997, such as hospice updates and Medicare+Choice.

[8] A compiler is a computer program that converts human-readable source code into a sequence of machine instructions that the computer can run.

corrected and tested by June 1999. According to HCFA officials, such errors were uncovered based on an inspection of only about one-seventh of the software code associated with the Florida standard system. If time permits, HCFA is considering using this Y2K tool on 100 percent of the code on all of the standard systems.

In addition to these Y2K-related changes, HCFA is planning a major software release of the Common Working File in late June, and legislatively mandated changes are to occur through June. HCFA plans to conduct 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 Y2K compliant. The late 1999 time frames associated with this testing represent a high degree of risk.

Other Critical Risks and Challenges Remain

Testing is a critical area in which HCFA faces significant challenges. Complete and thorough testing is essential to providing reasonable assurance that new or modified systems will process dates correctly and will not jeopardize an organization's ability to perform core business operations. Because the Y2K problem is so pervasive, potentially affecting an organization's systems software, applications software, databases, hardware, firmware, embedded processors, telecommunications, and interfaces, the requisite testing can be extensive and expensive. Experience is showing that Y2K testing is consuming between 50 and 70 percent of a Y2K project's time and resources. According to our guide, to be done effectively, testing should be planned and conducted in a structured and disciplined fashion. [9]

To date, HCFA's testing of its external systems has not been rigorous. HCFA's IV&V contractor has reported concerns with test documentation, readiness, and coverage associated with HCFA's external mission-critical systems. Specifically, the IV&V contractor reported that the quality of test documentation has been found to be incomplete and inadequate during a significant number of site visits. In addition, the results of using a Y2K tool to assess renovation quality and test readiness on each of the standard systems revealed that both indicators are primarily rated in the low to medium ranges, meaning that errors exist that could cause Y2K-related system failures.

[9] Year 2000 Computing Crisis: A Testing Guide (GAO/AIMD-10.1.21, November 1998).

The IV&V contractor also reported that HCFA's contractors have no satisfactory mechanism for determining the quality of test coverage (e.g., systems functionality, HCFA-mandated dates, interface coverage) associated with the self-certification testing. Because of this, HCFA issued instructions on April 9, 1999, that required contractors to submit information on the functionality covered by their test cases. Until test coverage is determined and testing is fully executed, the quality of the testing conducted will remain unknown.

In addition, two standard system maintainers did not test with the Common Working File, rather, they used a system that simulates the functions performed by the Common Working File. Testing with a system that simulates the Common Working File is less than ideal since the simulated system is not identical to the actual system. HCFA has acknowledged this and plans to have these two standard system maintainers test with the Common Working File during the recertification testing.

Further, testing has not been completed in the optimal sequence to ensure compliance of all systems. Since each contractor relies on one of the six standard systems to process its claims, ideally each of these six standard systems should have been completely tested before the contractors tested their front-end and back-end processing systems with their respective standard systems. However, only the Florida standard system maintainer completed future-date testing before the system was provided to its 29 contractors. Thus, more than half of the contractors tested with standard systems that had not completed Y2K testing. Managing multiple testing baselines and ensuring that corrections to one system's testing errors does not lead to problems in another system is a major challenge.

In September 1998 we recommended that HCFA rank its remaining Y2K work 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.[10] Such a schedule is extremely important because of the number of systems, their complexity, and interdependencies among them. However, HCFA still lacks an integrated schedule. The complexity and required sequencing of the 75 external and 25 internal systems associated with the recertification requires an integrated testing schedule to avoid scheduling constraints. For example, the Common Working File and standard systems should be

[10] GAO/AIMD-98-284, September 28, 1998.

tested initially so that the contractors can test with fully compliant systems. Without an integrated schedule, HCFA cannot effectively prioritize remaining work or ensure that all Y2K testing will be completed on time.

HCFA's late start and the limited time remaining raises risks that the recertification testing will likewise not be as rigorous as necessary. Two areas already have us concerned—testing overlap and a decrease in the number of future dates that will be tested. HCFA officials told us that contractors will begin to test with the Common Working File before it is completely Y2K-tested. Ideally, these tests should be done sequentially so that each contractor can test with a fully Y2K-tested Common Working File. Also, although HCFA's recertification will test four future dates, two more than the self-certification testing, this total is fewer than what HCFA had originally planned. Initially, HCFA planned to test with nine future dates.

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 Y2K-test sites. These tests are to include all internal systems and contractor systems, but will not include testing with banks and providers. HCFA has required its contractors to future-date 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. HCFA expects this testing to be completed by August 31. This contractor currently plans to test eight internal systems and the six external standard systems. Originally, all 25 internal mission-critical systems were to be tested. In addition, because of the changing nature of the Medicare systems and the limited remaining time, the independent testing will be conducted with systems that were available January 1999, not with the exact systems that will be operating on January 1, 2000.

HCFA also faces risks because it has thousands of data exchanges that are not yet compliant. 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. HCFA's total number of data exchanges dropped significantly since February 10, 1999. The number of internal data exchanges declined from 7,968 to 3,209, while the number of external data exchanges dropped from 255,383 to 141,866. HCFA officials attributed this decrease to "performing a major cleanup of the data." As of April 9, 1999, HCFA reported that only four of its 3,209 internal data exchanges were still not compliant, and that over 3,000 of its 141,866 external data exchanges were not compliant. To ensure that HCFA's internal and external systems are capable of exchanging data between 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.

Given the magnitude of HCFA's Y2K 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 Y2K challenge are planned October 1, 1999, and January 1, 2000, provider payment updates; 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. We have requested detailed information on the specific changes that the October 1 and January 1 updates will require to determine the amount of testing that will be necessary after these changes are made. HCFA already is faced with too much to test in too little time, and these updates further contribute to already monumental testing challenges.

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 of this after June. If this were to occur, the workload would have to be transferred to another contractor whose Y2K-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 is transitioning the work of the three contractors that are leaving the program.

HCFA required the 386 managed care organizations currently serving 6.6 million Medicare beneficiaries to certify their systems as Y2K compliant by April 15. As of April 21, 1999, HCFA had received certifications from 315 of the organizations. Similar to fee-for-service contractors, 271 of the 315 certifications contained qualifications. We plan to review these certifications as part of our ongoing work for the Senate Special Committee on Aging to determine whether the managed care organizations' systems are Y2K compliant and whether a formal recertification would have to be performed later this year.

Medicaid Systems Are at Risk

Similar to Medicare, the systems supporting the Medicaid program also face Y2K challenges and 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' Y2K status last summer, [11] 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.

In response, HCFA administered two state self-reported surveys and conducted several on-site visits and found that overall state Medicaid systems status had improved little. To obtain more reliable Y2K state Medicaid status information, HCFA also hired a contractor to conduct independent verification and validation of states' systems.

[11] Year 2000 Computing Crisis: Readiness of State Automation 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 1 of the 54 entities surveyed responded.

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 in July/August 1998 had already slipped, underscoring the need for on-site visits to secure more accurate information. In addition, according to HCFA, while four states appeared to have made some progress in the 6 months since our survey, three states' status remained the same. Further, HCFA found that one state's Medicaid eligibility system was not as far along as the state had reported in our survey. To assist states with their effort, HCFA's IV&V contractor plans 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 1999. The later visits will emphasize contingency planning to help the states ensure continuity of program operations in the event of systems failures.

Y2K Readiness of the Health Care Sector: Much Work Remains

At this point, I would like to broaden our discussion to the Y2K-readiness status of the health care sector, including biomedical equipment [12] and pharmaceutical and medical-surgical products used in the delivery of health care. While it is undeniably important that Medicare and Medicaid systems be compliant so that the claims of health care providers and beneficiaries can be paid, it is also critical that the services and products associated with health care delivery itself be Y2K compliant. However, with just over 8 months until the turn of the century, the level of progress to date is not reassuring.

Virtually everything in today's hospital is automated—from the scheduling of procedures such as surgery, to the ordering of medication such as insulin for a diabetic patient, to the use of portable devices as diverse as heart defibrillators and thermometers. It, therefore, becomes increasingly important for health care providers such as doctors and hospitals to assess their health information systems, facility systems (such as heating, ventilating, and air conditioning equipment), and biomedical equipment to ensure their continued operation on January 1, 2000. Similarly, pharmaceutical manufacturers and suppliers that rely heavily on computer systems for the manufacture and distribution of drugs must assess their processes for compliance. Given the large degree of interdependence among components of the health sector—providers, suppliers, insurance

[12] Biomedical equipment refers to both medical devices regulated by the Food and Drug Administration (FDA), and scientific and research instruments, which are not subject to FDA regulation.

carriers, and patients/consumers—the availability and sharing of Y2K readiness information is vital to safe, efficient, and effective health care delivery.

In response to an October 1998 request from the Chair of the President's Council on Year 2000 Conversion, several federal agencies and professional health care associations surveyed key components of the health care sector. Accordingly, the amount of readiness information on this sector has increased in recent months. The survey results, however, indicate that much work still remains in renovating, testing, and implementing compliant systems. Further, readiness information on the health sector is still incomplete because a significant number of sector members did not respond to the surveys.

According to a survey that the American Hospital Association (AHA) sent to 2,000 of its members in February 1999, much work remains. For example, based on the 583 responses received as of March 1, 1999, the hospitals reported that only about 6 percent of the medical devices, 13 percent of information systems, and 24 percent of physical plant/ infrastructure are compliant. However, most hospitals indicated that they expect to be compliant by the end of the year. [13]

The American Medical Association's (AMA) survey to 7,000 physicians showed that approximately 47 percent of the 522 physicians that responded by mail or telephone indicated that they do not have a good understanding of Y2K conversion, and have practices that are not Y2K ready. Almost all of these physicians reported that they would be ready by the end of the year. The survey disclosed no difference between the Y2K preparedness of large physician groups and solo or small physician groups (10 physicians or fewer). However, AMA stated that caution should be taken in interpreting the survey results due to the low response rate.

According to responses received to a December 1998 survey sent by HHS' Office of the Inspector General to a sample of 5,000 Medicare providers—1,000 each to hospitals, nursing homes, durable medical device manufacturers, physicians, and home health agencies—except for hospitals, providers reported making limited progress in assessing their biomedical equipment for Y2K compliance. All providers reported making

[13]Compliance refers to the hospitals' information systems, medical devices, and physical plant/ infrastructure.

limited progress in testing data exchanges between their computers and external vendors, and developing emergency backup plans in case of computer failures. Further, many Medicare providers did not respond to this survey. For example, the response rates for medical device manufacturers, physicians, and home health agencies were less than 30 percent.

A survey sent by the Association of State and Territorial Health Officials and the Centers for Disease Control and Prevention (CDC) to 57 state and territorial health officials in December 1998 showed that two thirds of the 29 respondents did not have contingency plans. CDC is also concerned about the lack of readiness information on local public health agencies.

Finally, according to the second quarterly report by the President's Council on Year 2000 Conversion, the health care sector has not made adequate progress in addressing the Y2K problem. [14] The report stated that while recent surveys indicate that health care providers have a high level of confidence that they will complete much of the work on mission-critical systems before the end of the year, the actual number of systems made compliant to date is relatively low in areas from recordkeeping to infrastructure. The report noted that recordkeeping systems are "of great concern" because they play an essential role in processing payment claims to insurance companies and government health agencies.

Biomedical Equipment: Status Information Available for Many Items, but Test Results Not Reviewed

The question of whether medical devices such as magnetic resonance imaging (MRI) systems, x-ray machines, pacemakers, and cardiac monitors can be counted on to work reliably on and after January 1, 2000, is critical to medical care delivery. To the extent that biomedical equipment uses embedded computer chips, it is vulnerable to the Y2K problem.

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 adversely affect the patient. The degree of risk depends in large part on the role the equipment plays in a patient's care.

[14] The President's Council on Year 2000 Conversion: Second Summary of Assessment Information, April 21, 1999.

Responsibility for oversight and regulation of medical devices, including the impact of the Y2K problem, lies with FDA. Last September we testified that FDA, like the Veterans Health Administration (VHA)—a key federal health care provider—was trying to determine the Y2K compliance status of biomedical equipment. [15] FDA's goal was to provide a comprehensive, centralized source of information on the Y2K compliance status of biomedical equipment used in the United States and to make this information publicly available on a web site. However, at the time, FDA had a disappointing response rate from manufacturers to its letter requesting compliance information. And, while FDA made this information available to the public, it was not detailed enough to be useful. Specifically, FDA's list of compliant equipment lacked information relating to the particular make and model of the equipment.

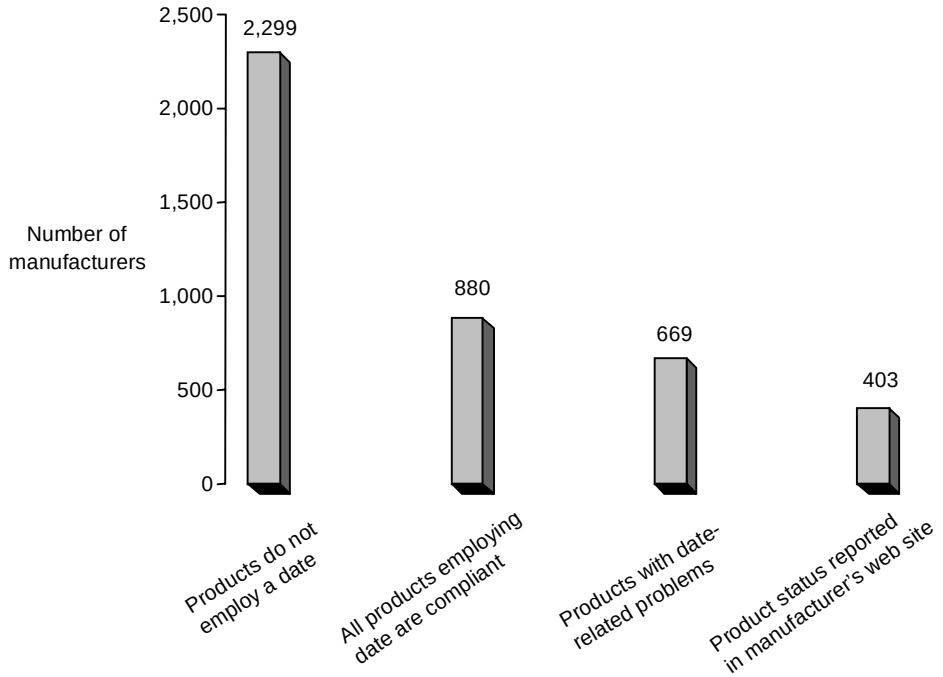
To provide more detailed information on the compliance status of biomedical equipment, as well as to integrate more detailed compliance information gathered by VHA, we recommended that VA and HHS jointly develop a single data clearinghouse that provides such information to all users. We said development of the clearinghouse should involve representatives from the health care industry, such as the Department of Defense's Health Affairs and the Health Industry Manufacturers Association. In addition, we recommended that the clearinghouse contain such information as (1) the compliance status of all biomedical equipment by make and model, and (2) the identity of manufacturers that are no longer in business. We also recommended that VHA and FDA determine what actions should be taken regarding biomedical equipment manufacturers that have not provided compliance information.

In response to our recommendation, FDA—in conjunction with VHA—has established the Federal Year 2000 Biomedical Equipment Clearinghouse. With the assistance of VHA, the Department of Defense, and the Health Industry Manufacturers Association, FDA has made progress in obtaining compliance-status information from manufacturers. For example, according to FDA, 4,251 biomedical equipment manufacturers had submitted data to the clearinghouse as of April 5, 1999. As shown in figure 1, about 54 percent of the manufacturers reported having products that do not employ a date, while about 16 percent reported having date-related

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

problems such as incorrect display of date/time. FDA is still awaiting responses from 399 manufacturers.

Figure 1: Biomedical Equipment Compliance-Status Information Reported to FDA by Manufacturers as of April 5, 1999



Note: Total number of manufacturers = 4,251.

Source: FDA.

FDA has also expanded the information in the clearinghouse. For example, users can now find information on manufacturers that have merged with or have been bought out by other firms.

In collaboration with the National Patient Safety Partnership, [16] FDA is in the process of obtaining more detailed information from manufacturers on noncompliant products, such as make and model and descriptions of the

[16]The National Patient Safety Partnership is a coalition of public and private health care providers, including VA, the American Medical Association, the American Hospital Association, the American Nurses Association, and the Joint Commission on Accreditation of Healthcare Organizations.

impact of the Y2K problem on products left uncorrected. For example, FDA sent a March 29, 1999, letter requesting that medical device manufacturers submit to the clearinghouse a complete list of individual product models that are Y2K compliant.

We reported last September that VHA and FDA relied on manufacturers to validate, test, and certify that equipment is Y2K compliant. [17] We also reported that there was no assurance that the manufacturers adequately addressed the Y2K problem for noncompliant equipment, because FDA did not require medical device manufacturers to submit test results to it certifying compliance. Accordingly, we recommended that VA and HHS take prudent steps to jointly review manufacturers' compliance test results for critical care/life support biomedical equipment. We were especially concerned that VA and FDA review test results for equipment previously determined to be noncompliant but now deemed by manufacturers to be compliant, or equipment for which concerns about compliance remain. We also recommended that VA and HHS determine what legislative, regulatory, or other changes were necessary to obtain assurances that the manufacturers' equipment was compliant, including the need to perform independent verification and validation of the manufacturers' certifications.

At the time, VA stated that it had no legislative or regulatory authority to implement the recommendation to review test results from manufacturers. In its response, HHS stated that it did not concur with our recommendation to review test results supporting medical device equipment manufacturers' certifications that their equipment is compliant. It said that the submission of appropriate certifications of compliance was sufficient to ensure that the certifying manufacturers' equipment was compliant. HHS also stated that it did not have the resources to undertake such a review, yet we are not aware of HHS' requesting resources from the Congress for this purpose.

More recently, VHA's Chief Biomedical Engineer told us that VHA medical facilities are not requesting test results for critical care/life support biomedical equipment; they also are not currently reviewing the test results available on manufacturers' web sites. He said that VHA's priority is determining the compliance status of its biomedical equipment inventory and replacing noncompliant equipment. The director of FDA's Division of

[17] GAO/AIMD-98-240, September 18, 1998.

Electronics and Computer Science likewise said FDA sees no need to question manufacturers' certifications.

In contrast to VHA's and FDA's positions, some hospitals in the private sector believe that testing biomedical equipment is necessary to prove that they have exercised due diligence in the protection of patient health and safety. Officials at three hospitals told us that their biomedical engineers established their own test programs for biomedical equipment, and in many cases contacted the manufacturers for their test protocols. Several of these engineers informed us that their testing identified some noncompliant equipment that the manufacturers had previously certified as compliant. According to these engineers, to date, the equipment found to be noncompliant all had display problems and was not critical care/life support equipment. We were told that equipment found to be incorrectly certified as compliant included a cardiac catheterization unit, a pulse oxymeter, medical imaging equipment, and ultrasound equipment.

VHA, FDA, and the Emergency Care Research Institute [18] continue to believe that manufacturers are best qualified to analyze embedded systems or software to determine Y2K compliance. They further believe that manufacturers are the ones with full access to all design and operating parameters contained in the internal software or embedded chips in the equipment. VHA believes that such testing can potentially cause irreparable damage to expensive health care equipment, causing it to lock up or otherwise cease functioning. Further, a number of manufacturers also have recommended that users not conduct verification and validation testing.

We continue to believe that, rather than relying solely on manufacturers' certifications, organizations such as VHA or FDA can provide users of biomedical equipment with a greater level of confidence that the equipment is Y2K compliant through independent reviews of manufacturers' compliance test results. The question of whether to independently verify and validate biomedical equipment that manufacturers have certified as compliant is one that must be addressed jointly by medical facilities' clinical staff, biomedical engineers, and corporate management. The overriding criterion should be ensuring patient health and safety.

[18] An international, nonprofit health services research agency. This organization believes that superficial testing of biomedical equipment by users may provide false assurances, as well as create legal liability exposure for health care institutions.

Y2K-Readiness Information on Pharmaceutical and Medical-Surgical Manufacturers Is Incomplete

Another question critical to the delivery of health care is knowing whether there will be sufficient supplies of pharmaceutical and medical-surgical products available for consumers at the turn of the century. As the largest centrally directed civilian health care system in the United States, VHA has taken a leadership role in the federal government in determining whether manufacturers supplying these products are Y2K-ready. This information is essential to VHA's medical operations because of its "just-in-time" [19] inventory policy. Accordingly, VHA must know whether its manufacturers' processes, which are highly automated, [20] are at risk, as well as whether the rest of the supply chain will function properly.

To determine the Y2K readiness of its suppliers, VA's National Acquisition Center (NAC) [21] sent a survey on January 8, 1999, to 384 pharmaceutical firms and 459 medical-surgical firms with which it does business. The survey contained questions on the firms' overall Y2K status and inquired about actions taken to assess, inventory, and plan for any perceived impact that the century turnover would have on their ability to operate at normal levels. In addition, the firms were requested to provide status information on progress made to become Y2K compliant and a reliable estimated date when compliance will be achieved for business processes such as (1) ordering and receipt of raw materials, (2) mixing and processing product, (3) completing final product processing, (4) packaging and labeling product, and (5) distributing finished product to distributors/ wholesalers and end customers.

According to NAC officials, of the 455 firms that responded to the survey as of March 31, 1999, about 55 percent completed all or part of the survey. The remainder provided either general information on their Y2K readiness status or literature [22] on their efforts. As shown in table 1, more than half of the pharmaceutical firms surveyed responded (52 percent), with just less than one third (32 percent) of those respondents reporting that they are

[19] This term refers to maintaining a limited inventory on hand.

[20] Pharmaceutical manufacturers rely on automated systems for production, packaging, and distribution of their products, as well as for ordering raw materials and supplies.

[21] This organization is responsible for supporting VHA's health care delivery system by providing an acquisition program for items such as medical, dental, and surgical supplies and equipment; pharmaceuticals; and chemicals. NAC is part of VA's Office of Acquisition and Materiel Management.

[22] This includes annual and quarterly financial reports required by the Securities and Exchange Commission for companies listed on the New York Stock Exchange.

compliant. The table also shows that 54 percent of the medical-surgical firms surveyed responded, with about two-thirds of them (166) reporting that they are Y2K compliant.

Table 1: Status of Companies Surveyed by VHA as of March 31, 1999

Responses	Pharmaceutical	Medical-surgical
Y2K compliant	65	166
Will be compliant by 1/1/2000 or earlier[a]	90	70
Provided no compliant date	50	14
Total number of responses	**205**	**250**
Non-responses	179	209
Total number of firms surveyed	**384**	**459**

[a]Estimated compliance status ranged from 3/31/99 through 1/1/2000; about 71 percent of pharmaceutical firms and 80 percent of medical-surgical firms estimated they will be compliant by 7/31/99. One firm responded that it will be compliant by 1/1/2000.

Source: VA. We did not independently verify these data.

On March 17, 1999, NAC sent a second letter to its pharmaceutical and medical-surgical firms, informing them of VA's plans to make Y2K readiness information previously provided to VA available to the public through a web site (**www.va.gov/oa&mm/nac/y2k**). VA made the survey results available on its web site on April 13, 1999. The letter also requested that manufacturers that had not previously responded provide information on their readiness. NAC's Executive Director said that he would personally contact any major VA supplier that does not respond.

On a broader level, VHA has taken a leadership role in obtaining and sharing information on the Y2K readiness of the pharmaceutical industry. Specifically, VHA chairs the Year 2000 Pharmaceuticals Acquisitions and Distributions Subcommittee, which reports to the Chair of the President's Council on Year 2000 Conversion. The purpose of this subcommittee is to bring together federal and pharmaceutical representatives to address issues concerning supply and distribution as it relates to the year 2000. The subcommittee consists of FDA; federal health care providers; industry trade associations such as the Pharmaceutical Research and Manufacturers of America (PhRMA), Generic Pharmaceutical Industry Association, the National Association of Chain Drug Stores, and the National Wholesale Druggists' Association; and consumer advocates.

In response to the Chair's request for Y2K-readiness information on the pharmaceutical industry, several of these trade associations, representing both brand name and generic pharmaceutical manufacturers, have surveyed their members on this issue. Table 2 summarizes the survey results available to date.

Table 2: Summary of Y2K Readiness Survey Results From Pharmaceutical Manufacturers

Industry trade association	Number of members surveyed	Number of responses	Summary of results
Pharmaceutical Research and Manufacturers of America (PhRMA)	25	24 [a]	All respondents have Y2K plans and are developing contingency plans to ensure continuous supply of medicines to patients. Respondents expect to collectively spend $1.75 billion to address the Y2K problem. Most repair work is expected to be completed in early to mid-1999.
Generic Pharmaceutical Industry Association (GPIA)	16[b]	14	All respondents have Y2K plans and individually expect to spend no more than $1.5 million on the Y2K problem. Most repair work is expected to be completed in June or July 1999.
National Association of Pharmaceutical Manufacturers (NAPM)	12	7	Most respondents have Y2K plans.
Association of Military Surgeons of the U.S. (AMSUS)	41[c]	41	All respondents have Y2K plans. Respondents are spending from $2 million to $70 million on the Y2K problem. All repair work is expected to be completed by June 30, 1999.

[a]These members constitute more than 90 percent of the industry capacity represented by PhRMA, which represents more than 95 percent of the research-based pharmaceutical manufacturers in the United States.

[b]This number only represents those members that are generic pharmaceutical manufacturers.

[c]Of the members surveyed, 24 are also members of PhRMA and 22 of these participated in the PhRMA survey.

Source: Associations listed. We did not independently verify these data.

In addition, the National Wholesale Druggists' Association sent a survey to 240 of its associate members that are pharmaceutical manufacturers requesting information on patient stockpiling of pharmaceutical products. Three quarters of the 77 members responding as of November 1998 said

they could currently fill orders which will provide patients with a 3-month supply. Less than 20 percent of the respondents said they could provide a 1-year supply. Finally, in January 1999, the National Association of Chain Drug Stores sent a survey to over 130 of its members and received responses from about 25 percent. These respondents indicated that they will finish Y2K renovations by September 30, 1999, and two-thirds of the respondents have developed contingency plans.

Based on their survey results, these industry trade associations believe that computer systems and software application problems will not substantially impede the ability of the supply chain to maintain an uninterrupted flow of medicines. However, in contrast to VHA's survey, the associations' surveys were provided in summary format and did not contain detailed information on the Y2K readiness of specific manufacturers or members of the supply chain. This information is necessary if consumers are to have confidence that there will be a sufficient supply of medications on hand at the turn of the century.

FDA's Y2K Efforts for Pharmaceutical and Biological Products Industries Focused Initially on Awareness

FDA's oversight and regulatory responsibility for pharmaceutical and biological products [23] is to ensure that they are safe and effective for their intended uses. Because of its concern about the Y2K impact on manufacturers of these products, FDA has taken several actions to raise the Y2K awareness of the pharmaceutical and biological products industries. In addition, it is thinking about conducting a survey to determine the industry's Y2K readiness.

One of FDA's actions to raise industry awareness was the January 1998 issuance of industry guidance by the Center for Biologics Evaluation and Research (CBER) on the Y2K impact of computer systems and software applications used in the manufacture of blood products. In addition, as shown in table 3, FDA has issued several letters to pharmaceutical and biological trade associations and sole-source drug manufacturers.

[23] Biological products include vaccines, blood, and blood products.

Table 3: FDA Letters to Manufacturers Regarding Y2K

Date	FDA source	Recipient	Purpose
October 1998	Center for Drug Evaluation and Research	Pharmaceutical manufacturer trade associations	To relay to members FDA's expectation that the pharmaceutical industry would (1) make resolution of Y2K a high priority, (2) ensure that production systems were fixed and tested prior to January 1, 2000, and (3) urge manufacturers to develop Y2K contingency plans.
October 1998	Center for Biologics Evaluation and Research	Biologics manufacturer trade associations	Same as above.
January 1999	Center for Drug Evaluation and Research	Sole-source drug manufacturers	Same as above. Also (1) noted that the impact of Y2K on pharmaceutical safety, efficacy, and availability merits special attention for firms which are the sole manufacturers of drug components, bulk ingredients, and finished products, and (2) stated that pharmaceutical industry suppliers must have Y2K-compliant systems to protect against disruption in the flow of product components, packaging materials, and equipment to pharmaceutical manufacturers.

Source: FDA.

Further, on February 11, 1999, FDA's director of emergency and investigation operations sent a memorandum on FDA's interim inspection policy for the Y2K issue to the directors of FDA's field investigations. The policy emphasizes FDA's Y2K awareness efforts for manufacturers. It states that FDA inspectors are to (1) inform firms of FDA's Y2K web page (URL **http://www.fda.gov/cdrh/yr2000/year2000.html**), (2) provide firms with copies of the appropriate FDA Y2K awareness letter, (3) explain that Y2K problems could potentially affect aspects of the firms' operations, including some areas not regulated by FDA, and that FDA anticipates that firms will take prudent steps to ensure that they are not adversely affected by Y2K, and (4) provide firms with a copy of FDA's compliance policy guide "Year 2000 (Y2K) Computer Compliance."

In addition, on February 22, 1999, FDA and PhRMA jointly held a government/industry forum on the Y2K preparedness of the

pharmaceutical and biotech industries. The objectives of this forum were to (1) share information on Y2K programs conducted by health care providers, pharmaceutical companies, FDA, and other federal agencies, (2) provide a vehicle for networking, and (3) raise awareness.

On March 29, 1999, FDA revised its February 11, 1999, interim inspection policy. The revision states that field inspectors are now to inquire about manufacturers' efforts to ensure that their computer-controlled or date-sensitive manufacturing processes and distribution systems are Y2K compliant. Inspectors are to include this information in their reports, along with a determination of activities that firms have completed or started to ensure that they will be Y2K compliant.

Further, FDA inspectors may review documentation in cases in which firms have made changes to their regulated computerized production or process control systems to address Y2K issues. The purpose of this review is to ensure that the changes were made in accordance with firms' procedures and applicable regulations. If inspectors determine that a firm has not taken steps to ensure Y2K compliance, they are to notify their district managers and the responsible FDA center.

FDA's interim policy describes steps inspectors are to take in reviewing manufacturers' Y2K compliance. However, FDA stated that the primary focus of its inspections for the remainder of 1999 will be to ensure that products sold in the United States are safe and effective for their intended use and comply with federal statutes and regulations, including current "good manufacturing practice" requirements. [24] FDA officials explained that the agency does not have sufficient resources to perform both regulatory oversight of the manufacturers and in-depth evaluations of firms' Y2K compliance activities.

Nevertheless, according to the March 29, 1999, memorandum, field inspectors are to note, in the administrative remarks section of their inspection reports, any concerns they may have with a firm's Y2K readiness. These reports are to be reviewed by FDA district managers. According to FDA, if a Y2K-related concern affects the identity, strength, quality, purity, and potency, as well as safety, effectiveness, or reliability of a drug product, the district manager can discuss this issue with FDA's

[24] These include federal standards for ensuring that products are high in quality and produced under sanitary conditions (21 CFR parts 210, 211).

Office of Regulatory Affairs and determine a course of action, including product correction or removal.

Like VHA, FDA is interested in the impact of Y2K readiness of pharmaceutical and biological products on the availability of products for health care facilities and individual patients. FDA's Acting Deputy Commissioner for Policy informed us on March 24, 1999, that the agency is thinking about surveying pharmaceutical and biological products manufacturers, distributors, product repackagers, and others in the drug dispensing chain, on their Y2K readiness and contingency planning. In anticipation of a possible survey, the agency published a notice in the March 22, 1999, Federal Register, regarding this matter. The Acting Deputy Commissioner said that potential survey questions on contingency planning would include steps the manufacturers are taking to ensure an adequate supply of bulk manufacturing materials from overseas suppliers. This is a key issue because, as we reported in March 1998,[25] according to FDA, as much as 80 percent of the bulk pharmaceutical chemicals used by U.S. manufacturers to produce prescription drugs is imported.

In summary, HCFA and its contractors have made progress in addressing Medicare Y2K issues that we have raised. However, until HCFA completes its planned recertification between July and November, the final status of the agency's Y2K 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 to avoid the interruption of Medicare claims processing next year. Also, because many states' Medicaid systems are at risk, business continuity and contingency plans will become increasingly critical for these states in an effort to ensure continued timely and accurate delivery of benefits to needy Americans.

Regarding the health sector overall, while additional readiness information is available, much work remains in renovating, testing, and implementing compliant systems. Aggressive action is needed in obtaining information on the Y2K readiness of hospitals, physicians, Medicare providers, and public health agencies. Until this information is obtained and publicized, consumers will remain in doubt as to the Y2K readiness of key health care

[25] Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program (GAO/HEHS-98-21, March 17, 1998).

components. In addition, while compliance status information is available for biomedical equipment through the FDA clearinghouse, FDA has not reviewed test results supporting manufacturers' certifications; such review would provide the American public with a higher level of confidence that biomedical equipment will work as intended. The public also needs readiness information on specific pharmaceutical manufacturers to address concerns about the stockpiling of drugs and medications.

Messrs. Chairmen, this concludes my statement. I would be pleased to respond to any questions that you or other members of the Subcommittees may have at this time.

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary, VISA and MasterCard credit cards are accepted, also.

Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 37050
Washington, DC 20013

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000
or by using fax number (202) 512-6061, or TDD (202) 512-2537.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (202) 512-6000 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

For information on how to access GAO reports on the INTERNET, send an e-mail message with "info" in the body to:

info@www.gao.gov

or visit GAO's World Wide Web Home Page at:

http://www.gao.gov

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

Official Business
Penalty for Private Use $300

Address Correction Requested

Bulk Mail
Postage & Fees Paid
GAO
Permit No. GI00