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YEAR 2000 COMPUTING CRISIS

Medicare and the Delivery of Health Services Are at Risk

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GAO/T-AIMD-99-89

Mr. Chairman and Members of the Committee:

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 to provide accurate benefits and 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.

In a report issued last year, we concluded that the progress made by the Department of Health and Human Services' (HHS) Health Care Financing Administration (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 which we found to be lacking or inadequate. This morning 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 HCFA stands today.

Beyond Medicare, the level of information on a national level concerning Year 2000 compliance throughout the health care sector—including providers, insurers, manufacturers, and suppliers—is limited. As we reported last fall, this was true of biomedical equipment routinely used in the delivery of health care.[2] Such equipment includes medical devices such as cardiac defibrillators and monitoring systems that can record, process, analyze, display, and/or transmit data. Today, I would like to share information in this area with you as well.

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

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

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 Year 2000 compliant could be enormous. We originally highlighted this concern in May 1997, making several recommendations for improvement.[3] 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 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 and 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.

The Office of Management and Budget (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.

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

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 can 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,
- 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

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).

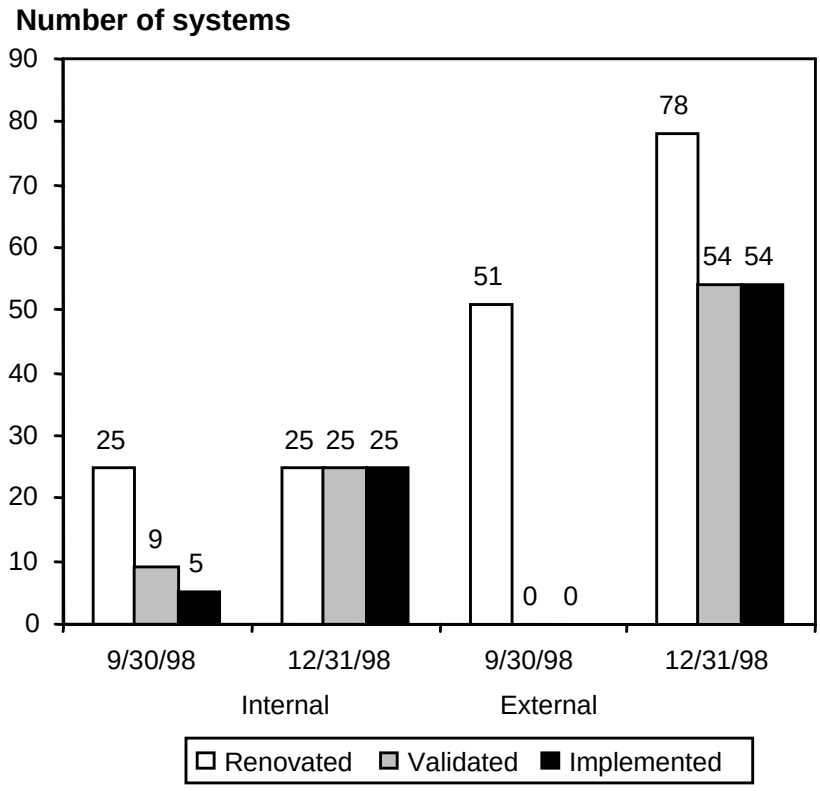
The final area in which HCFA has demonstrated progress is developing business continuity and contingency plans to ensure that, no matter what, beneficiaries will receive care and providers will be paid. HCFA has established cross-organizational workgroups to develop contingency plans for the following 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; it also relies on 78 external mission-critical systems 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 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 work 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



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 have 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; it 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, these 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 too late to them 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 system 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 compliant.[5] 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.

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

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

[5]On 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.

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 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 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 the interruption of Medicare claims processing next year.

Y2K Readiness of the Health Care Sector: Information Is Limited

At this point, I would like to broaden our discussion to the Year 2000-readiness status of the health care sector, including biomedical equipment used in the delivery of health care. While it is undeniably important that Medicare 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 Year 2000 compliant.

However, the level of information currently available on such compliance 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, ventilation, and air conditioning), and biomedical equipment to ensure their continued operation at the turn of the century. Similarly, pharmaceutical manufacturers and suppliers that rely heavily on computer systems for the manufacturing 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 carriers, and patients/consumers—the availability and sharing of Y2K readiness information is vital to safe, efficient, and effective health care delivery.

Readiness information is limited throughout the health care sector. Specifically, the amount of data available to consumers on the Y2K readiness of health care providers, private insurers, and pharmaceutical manufacturers and suppliers is scant. This past June, for example, the American Hospital Association sent a Y2K readiness survey to about 4,700 hospitals. However, only about 17 percent of its members responded.

In May 1998, the President's Council on Year 2000 Conversion established a Health Care Working Group[6] chaired by HCFA to conduct outreach activities of the health care sector. In response to an October 1998 request from the Chair of the President's Council to gauge the Year 2000 readiness of the health sector, several professional health care associations surveyed their membership, requesting information on the status of work completed in the Y2K assessment, renovation, validation, and implementation phases. For example, the Association of State and Territorial Health Officials and the Centers for Disease Control and Prevention (CDC) sent a Year 2000 readiness-assessment survey to 57 state and territorial health officials.

[6]Members include federal health care agencies and professional health care associations such as the American Ambulance Association, American Hospital Association, American Medical Association, Health Industry Manufacturers Association, Joint Commission on the Accreditation of Health Care Organizations, National Association of Community Health Centers, and National Association of Rural Health Clinics.

According to CDC, officials of 27 states responded as of February 19, 1999, and the results are still under review. Similarly, the Generic Pharmaceutical Industry Association sent a survey to its members last December; it plans to discuss the results at a March 8, 1999, meeting of the Year 2000 Pharmaceuticals Acquisition and Distribution Committee (comprised of federal and pharmaceutical representatives). Finally, HHS' Office of the Inspector General sent a Y2K readiness survey last December to a sample of Medicare providers; it is not known at this time when the results will be available. The working group plans to gather Y2K readiness information from this sector throughout 1999, especially among smaller health care organizations.

Until such survey results are known to consumers, the Y2K readiness of key components of the health sector will remain in doubt. Because of the potential impact of the Year 2000 problem on patient care, it is critical that such readiness information be obtained and publicized. In this way consumers will have access to data that can offer some assurance that the information systems, equipment, and products used in the delivery of health care services will operate as expected when needed after the turn of the century. Conversely, the lack of such information can contribute to consumer doubt, misinformation, or even panic. It can also foster unnecessary stockpiling of drugs and the attendant drain on pharmaceutical product inventories.

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, it is vulnerable to the Y2K problem.[7] 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.

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

As we reported last September,[8] FDA--which provides information from biomedical equipment manufacturers to the public through an Internet World Wide Web site--had a disappointing response rate from biomedical equipment manufacturers to its request for compliance information. The FDA biomedical equipment database also 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.

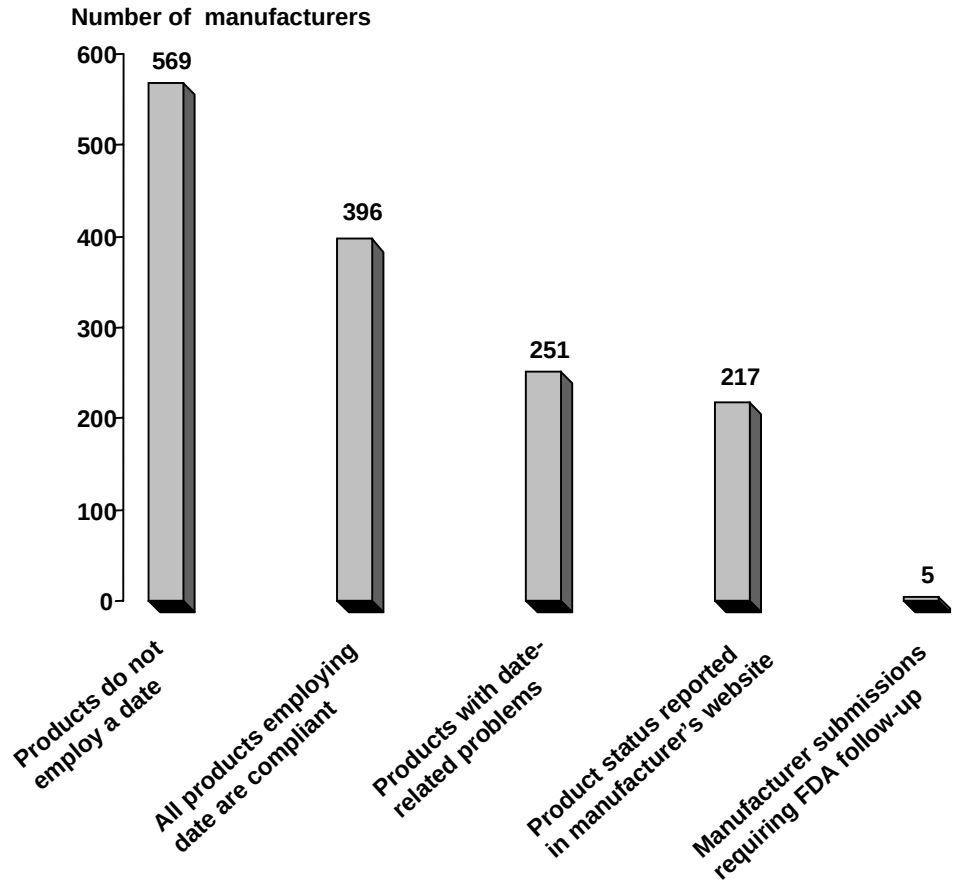
To address these issues, we made recommendations to the Secretaries of HHS and Veterans Affairs (VA)--a key stakeholder in determining the potential effects of the century change on biomedical equipment--to determine what actions, if any, should be taken regarding manufacturers that have not provided 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 a 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 2, about 40 percent of the manufacturers have products that do not employ a date, while about 17 percent reported equipment having date-related problems.

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

Figure 2: 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 reported that most manufacturers citing noncompliant products listed incorrect display of date and/or time as the Y2K problem.[9] 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 incorrect. One

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

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.[10]

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.

In summary, there is great need for much more information available on the Y2K readiness of the health care sector. Until this information is obtained and publicized, consumers will remain in doubt as to the Y2K readiness of key health care components. In addition, while compliance status information is available for some biomedical equipment through the FDA clearinghouse, FDA has not reviewed test results supporting manufacturers' certifications to provide the American public with a higher level of confidence that biomedical equipment will work as intended.

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

[10] Year 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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