YEAR 2000 COMPUTING CRISIS

Leadership Needed to Collect and Disseminate Critical Biomedical Equipment Information

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Accounting and Information Management Division
Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the Year 2000 compliance status of biomedical equipment.\(^1\) 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 obviously of critical importance to our nation’s health care. To the extent that biomedical equipment uses computer chips, it is vulnerable to the Year 2000 problem that we and others have been focusing on for over a year.\(^2\) In the medical arena, such vulnerability carries with it possible safety risks.

The Department of Veterans Affairs (VA)—specifically, the Veterans Health Administration (VHA)—is attempting to determine the Year 2000 compliance status of biomedical equipment in use in its medical centers, outpatient clinics, nursing homes, and domiciliaries. Within the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) oversees and regulates medical devices in the private sector. Both organizations are employing the same strategy: relying on information provided by equipment manufacturers. Our report being released at this hearing details the status of VHA’s and FDA’s biomedical equipment programs.\(^3\)

In brief, VHA has made progress in implementing its Year 2000 strategy for biomedical equipment, but it still does not know how pervasive the problem is. This is because it has not received compliance and cost information from many of the manufacturers on its list of suppliers, as well as from the nearly 100 additional manufacturers no longer in business. Like VHA, FDA has sent letters to biomedical equipment manufacturers, requesting information on products affected by the Year 2000 problem. The response rate to FDA has been disappointing. Failure to obtain timely compliance information from the manufacturers increases the risk to health care providers and biomedical equipment users that such

\(^1\)Biomedical equipment refers both to medical devices regulated by the Food and Drug Administration (FDA), and scientific and research instruments, which are not subject to FDA regulation.

\(^2\)The Year 2000 problem will affect everyone because it is rooted in how dates are recorded and computed. For the past several decades, computer systems have typically used two digits to represent the year, such as “98” for 1998, in order to conserve electronic data storage and reduce operating costs. In this format, however, 2000 is indistinguishable from 1900 because both are represented as “00.” As a result, if not modified, systems or applications that use dates or perform date- or time-sensitive calculations may generate incorrect results beyond 1999. A listing of our publications on the Year 2000 problem is included as an attachment to this statement.

equipment may not operate properly after the turn of the century. It is critical that such information be obtained and publicized; while many reported noncompliant equipment items do not present a risk to patient safety, some could present such risks.

My testimony today will discuss (1) the progress that VHA and FDA have made in determining the compliance status of biomedical equipment and (2) further actions they need to take to minimize associated Year 2000 risks.

Background

Biomedical equipment is indispensable; it plays a central role in virtually all health care. It can be defined as any tool that can record, process, analyze, display, and/or transmit medical data—some of which may even be implanted in patients—and laboratory research instruments, such as blood gas and glucose analyzers. Such equipment may use a computer for calibration or for day-to-day operation. If any type of date or time calculation is performed, susceptibility to a Year 2000 problem exists, whether the computer is a personal computer that connects to the equipment remotely or a microprocessor chip embedded within the equipment. This could range from the more benign—such as incorrect formatting of a printout—to the most serious—incorrect operation of equipment with the potential to decrease patient safety. The degree of risk depends on the role of the equipment in the patient’s care.

As a health care provider, VHA is a key stakeholder in determining the potential effect the Year 2000 computer problem could have on its biomedical equipment. Because VHA, like other health care providers in the private and public sectors, relies on manufacturers to validate, test, and certify that their equipment is compliant, it is critical that manufacturers provide this information so that VHA may take prompt action on noncompliant equipment in its inventory. Another key stakeholder in determining the status of equipment compliance is FDA, which has oversight and regulatory responsibility for domestic and imported medical devices.

VHA: Progress, but Significant Risks Remain

VHA’s strategy for identifying and remedying noncompliant biomedical equipment comprises five steps: (1) increased awareness and continual education of VHA chief information officers (CIO), the Veterans Integrated Service Networks (VISN), 4 and health care facilities on biomedical issues,

4There are 22 VISNs, which encompass 172 VHA medical centers, 376 outpatient clinics, 133 nursing homes, and 30 domiciliaries—a total of 711 facilities.
(2) establishment of an expert working group to provide guidance, (3) development of a database of biomedical equipment manufacturers that supply equipment to VHA, (4) surveying of these manufacturers to identify compliance status and solutions for noncompliant items, and (5) communication of survey results to the field for use in determining the compliance status of biomedical equipment at medical facilities.5

Much of the rationale behind VHA’s reliance on biomedical equipment manufacturers to validate, test, and certify that their equipment is Year 2000 compliant stems from the position taken by some manufacturers that VHA should not attempt to conduct in-depth testing by manipulating the software embedded inside the equipment. According to a VHA official, such testing could void the manufacturer’s certification to FDA that the equipment is safe for use on patients, thereby exposing VHA to legal liability in the event that a patient’s health is harmed by equipment that malfunctions following VHA testing.

As part of VHA’s strategy, its Year 2000 Project Office sent a series of letters to biomedical equipment manufacturers requesting Year 2000 compliance status information. The first letter was sent on September 9, 1997, to approximately 1,600 manufacturers in VHA’s database of suppliers. Follow-up letters were subsequently sent in October and November 1997 and June 1998 to those not previously responding. Upon receipt of responses to these letters, VHA categorized the compliance status provided by the manufacturers for equipment items, as illustrated in table 1.

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5On a monthly basis, each medical facility is expected to report to VHA’s Year 2000 Project Office its strategies for dealing with noncompliant and conditional-compliant equipment in its inventory (see table 1 for definition), and the cost to accomplish this.
### Table 1: VHA Biomedical Equipment Compliance Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant</td>
<td>Equipment will function properly in all aspects upon the change to the year 2000, without any modification or revision.</td>
</tr>
<tr>
<td>Noncompliant</td>
<td>Equipment will not function properly upon the change to the year 2000, and no manufacturer remedy is available. In some cases, improper function involves an incorrect date-time stamp on the output of the equipment, but the equipment’s clinical function is not impaired.</td>
</tr>
<tr>
<td>Conditional-compliant</td>
<td>Equipment requires some form of user intervention to function properly after the year 2000. Such intervention includes the installation of manufacturer-provided software or hardware or a one-time user action (such as turning the equipment on and off after the year 2000).</td>
</tr>
<tr>
<td>Pending</td>
<td>Manufacturers reported to VHA that they have not completed the Year 2000 assessment of their product line.</td>
</tr>
</tbody>
</table>

Source: Veterans Health Administration.

As shown in table 2, manufacturers have provided VHA with compliance information on a wide range of biomedical equipment.
Table 2: Reported Biomedical Equipment Year 2000 Compliance Categories, as of June 1, 1998, With Examples

<table>
<thead>
<tr>
<th>Compliance category</th>
<th>Number of manufacturers</th>
<th>Number of equipment “types” within this category</th>
<th>Examples of equipment “types” within this category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant</td>
<td>694</td>
<td>3,873</td>
<td>Examples: intra-aortic balloon pump, dialysis machine</td>
</tr>
<tr>
<td>Noncompliant</td>
<td>34</td>
<td>182</td>
<td>Examples: defibrillator monitor, cardiology monitor</td>
</tr>
<tr>
<td>Conditional-compliant</td>
<td>102</td>
<td>673</td>
<td>Examples: electrocardiograph machine, defibrillator</td>
</tr>
<tr>
<td>Pending</td>
<td>53</td>
<td>157</td>
<td>Examples: ultrasound system, ventilator</td>
</tr>
<tr>
<td>Manufacturer merged or bought out</td>
<td>187</td>
<td>b</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,070</strong></td>
<td><strong>4,885</strong></td>
<td></td>
</tr>
</tbody>
</table>

aInclusion of a specific type of biomedical equipment in the compliant, noncompliant, conditional-compliant, or pending category does not necessarily mean that all equipment of this type in VHA’s inventory was reported by the manufacturer; similar equipment made by other manufacturers could fall into different categories.

bThe biomedical equipment reported by these manufacturers has already been accounted for in one of the above compliance categories.

Source: Veterans Health Administration. We did not independently verify these data.

Of the nearly 1,600 manufacturers in VHA’s initial mailing over a year ago, about 100 were no longer in business, and a small number responded that the Year 2000 issue did not apply to their products. Accordingly, VHA revised its list of manufacturers to 1,490 as of July 29, 1998; it received compliance status information from about 1,100 (73 percent) of these manufacturers. As shown in table 3, just under half of the 1,490 reported that all of their devices were Year 2000 compliant.
Table 3: Status of Manufacturer Responses as of July 29, 1998

<table>
<thead>
<tr>
<th>Status of response</th>
<th>Number of manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant manufacturers(^a)</td>
<td>701</td>
</tr>
<tr>
<td>Noncompliant manufacturers(^b)</td>
<td>43</td>
</tr>
<tr>
<td>Conditional-compliant manufacturers(^c)</td>
<td>106</td>
</tr>
<tr>
<td>Pending manufacturers(^d)</td>
<td>47</td>
</tr>
<tr>
<td>Manufacturer merged or bought out</td>
<td>195</td>
</tr>
<tr>
<td>Nonresponsive manufacturers(^e)</td>
<td>398</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,490</strong></td>
</tr>
</tbody>
</table>

\(^a\)For inclusion in this category, 100 percent of a manufacturer’s products had to be considered compliant.

\(^b\)For inclusion in this category, only one of a manufacturer’s products had to be considered noncompliant.

\(^c\)For inclusion in this category, the manufacturer had to have no noncompliant equipment, no pending equipment, and at least one conditional-compliant equipment item.

\(^d\)For inclusion in this category, the manufacturer had to have no noncompliant equipment and at least one equipment item pending.

\(^e\)For inclusion in this category, VHA had to have received no compliance information from the manufacturer.

Source: Veterans Health Administration. We did not independently verify these data.

VHA did not receive responses from 398 manufacturers. According to a VHA official, letters sent to 227 of these manufacturers were returned by the U.S. Postal Service marked “no forwarding address.” Further, as noted in table 3, an additional 47 manufacturers that did respond are in the pending category because they reported that they had not completed their assessments and therefore did not yet know if their products were compliant. Among the manufacturers who have yet to respond or complete their assessments is one who supplies high-dollar, high-value equipment, such as radiology systems and electronic imaging systems, to VHA.

According to VHA officials, most of the manufacturers that reported one or more of their biomedical equipment products as noncompliant cited incorrect display of date and/or time as the main problems. For example, a noncompliant electrocardiograph machine, used to monitor heart signals, would print charts with two-digit dates, showing the year 2000 as “00.” According to a VHA official, these cases do not generally lead to the
device's failing to operate and do not present a risk to patient safety because health care providers, such as physicians and nurses, are able to work around such problems.

Conversely, VHA recognizes that incorrect date-time representation or use could pose a risk when the date is used in a calculation or when records generated by the equipment are sorted automatically to present a patient's condition, over a period of time, to a physician for diagnosis and treatment. Specifically, when records are sorted by date of recording, the accuracy of such dates can be critical to a physician's monitoring of patient progress in, for example, the case of blood sugar readings. If readings were taken, for example, on December 25, 27, and 30, 1999, and again on January 1, 2000, the ordering might appear with the last entry first, if it were abbreviated as "00" and read as January 1, 1900. If the physician or other clinician did not pay close attention, a diagnosis or treatment decision could be made based on a misreading of the data trend.

VHA also recognizes that an equipment function that depends on a calculation involving a date, and that is performed incorrectly as a result of a date problem, could present a risk to the patient. One example reported by a manufacturer is a product used for planning the delivery of radiation treatment using a radioactive isotope as the source. An error in the calculation of the radiation source's strength on the day the therapy is to be delivered could result in inappropriate treatment—either too low or too high a dosage — and could have an adverse effect on the patient. Therefore, until VHA receives compliance information from all of its manufacturers, it will be stymied from making decisions as to whether to replace, retire, or continue to use certain biomedical equipment items in its inventory.

Another area of concern is the lack of complete cost information for the replacement or retirement of noncompliant equipment. Last month, VA estimated this cost at $40 million. This estimate, however, was not based on updated cost information from medical facilities, and VHA did not know the replacement and repair cost for biomedical equipment for the manufacturers that have not yet reported compliance and cost information, as well as for the nearly 100 manufacturers no longer in business. VHA has acknowledged the shortcomings of its cost estimate, and just recently began using a new reporting process to capture the cost to replace or repair its noncompliant equipment.

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6We did not independently verify the $40 million cost estimate.
In light of the uncertainties surrounding the compliance status of VHA’s biomedical equipment and the potential effect on patient health and safety, it is crucial that VHA medical facilities develop business continuity and contingency plans to minimize risks associated with the Year 2000 problem. VHA’s medical facilities have not completed plans of this type, and its Year 2000 Project Office has not finalized a contingency plan guidebook to assist the medical facilities in their attempts to come to terms with this risk.

FDA: Limited Progress in Determining Compliance Status of Biomedical Equipment

To assist health care facilities in the public and private sectors, HHS—on behalf of the CIO Council’s Subcommittee on the Year 2000 for Biomedical Equipment and FDA—sent letters to approximately 16,000 biomedical equipment manufacturers in January of this year, requesting information on the Year 2000 compliance of their complete product line. On June 29, FDA sent a second letter to 1,935 medical device manufacturers that had not previously responded to its inquiry and that FDA believed had products that might employ computers or embedded systems. After being provided to FDA, this information was to be made available to the public and to government purchasers and users of these products through an Internet World Wide Web page.

The response rate to these letters has been disappointing; as of July 30, 1998, only about 12 percent (1,975 out of 16,000 letters) had responded. Of the 628 manufacturers reporting that their products do employ a date/time function, about 100 indicated that one or more of their products was not compliant.

According to FDA, it does not perform technical evaluations of manufacturers’ responses to determine their adequacy. Rather, it reviews the responses only to determine whether all questions posed in the letters were answered. This may explain why FDA’s web page includes this disclaimer:

“Inclusion of information in this database indicates that the manufacturer has certified that the data is complete and accurate. The Food and Drug Administration, however, cannot

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7FDA developed its mailing list from manufacturers that have registered their products with FDA and from the mailing lists of two scientific and research instrument manufacturing associations. Accordingly, this list included manufacturers that do not employ computers or embedded systems in their products (e.g., products such as rubber gloves, tongue depressors, and eyeglasses).
and does not make any independent assurances or guarantees as to the accuracy or completeness of this data.8

Further, except for diagnostic X-ray equipment, FDA does not test new medical devices entering the market. It also does not test devices for Year 2000 compliance. According to an FDA official, the agency does review the test results submitted by manufacturers requesting pre-market approval of their medical devices to see whether the manufacturers have demonstrated that their products are safe and effective for their intended uses. However, FDA does not plan to request test results from manufacturers that have renovated medical devices and/or scientific and research instruments that are not Year 2000 compliant. Accordingly, no assurances exist that manufacturers’ compliance certifications are accurate.

While FDA is making compliance information from biomedical equipment manufacturers available to the public, some users have expressed concern that information on the FDA web site is not detailed enough to be useful. Specifically, FDA’s list of compliant equipment contains no information on the equipment’s make or model. In contrast, VHA’s list of compliant equipment generally contains such information.

Further, the Year 2000 compliance information publicly available through FDA does not include responses from many of the manufacturers that have responded to VHA. For example, we selected, on a random basis, a sample of 53 manufacturers in VHA’s database that reported their products to be Year 2000 compliant; 48 of them were not listed in the FDA database. We likewise selected a sample of 13 manufacturers in VHA’s database that reported that their products were not Year 2000 compliant; 12 of these were not listed in the FDA database. These manufacturers’ products include cardiology equipment, defibrillator monitors, and ultrasound equipment.

An FDA official acknowledged that the biomedical equipment manufacturers were more responsive to VHA’s requests for compliance information. He stated his belief that the primary reason for this was VHA’s position as a large-volume customer that could take future action toward the manufacturer if information was not forthcoming. He also noted that FDA requested information on manufacturers’ complete product lines, while VHA requested information from manufacturers only on its list of suppliers.

VHA Plans to Make Compliance Information Available to the Public

Unlike FDA, VHA has not made information from biomedical equipment manufacturers available via the Internet. This is because (1) when VHA requested the information from manufacturers, it did not disclose its intention to release it outside of the federal government and (2) VHA had concerns regarding the possibly proprietary nature of some of the information provided.

VHA is currently in the process of resolving these concerns. Specifically, on the advice of VA’s Acting General Counsel, VHA informed manufacturers in a June 1998 letter that it plans to release information that the manufacturers provided and that VHA has determined not to be confidential commercial information. This is an important step, as compliance information from biomedical equipment manufacturers is of interest to all health care providers and users.

VA has not yet decided how and when a clearinghouse of compliance information provided to VHA from manufacturers will be made available to the public. FDA and VA have, however, discussed using FDA’s web site as such a clearinghouse.

Further Actions Needed to Minimize Risks of Year 2000 Failures

Given that some noncompliant biomedical equipment items could pose a risk to patient safety and that the Year 2000 compliance status of many equipment items in its inventory is unknown, VHA may not be able to handle Year 2000 failures affecting its biomedical equipment. Because of this, in our report being released today we recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to provide a Year 2000 contingency guidebook for biomedical equipment to all VHA medical facilities, and ensure that they complete Year 2000 business continuity and contingency planning for all biomedical equipment in their inventories.

It is also crucial that all health care providers and users of biomedical equipment have access to compliance information from the manufacturers in order that they may take prompt action on noncompliant and conditional-compliant equipment in their inventories. Accordingly, we recommend that the Secretaries of Veterans Affairs and Health and Human Services work together in developing a single data clearinghouse that provides compliance information to all users of biomedical equipment. Model-specific information should be included, along with the names of equipment manufacturers that have not responded, manufacturers that are no longer in business, and those that have not provided test results.
certifying Year 2000 compliance. VA and HHS have generally agreed to implement this recommendation.

HHS, however, stated its belief that it is neither necessary nor cost-effective to list all compliant products. It asserted that information at the individual model level is only needed for noncompliant products. We disagree. Model-specific information will provide users with detailed data on the reported compliance status of their products, especially for those manufacturers that VA has determined to have merged or been bought out by other manufacturers. In this way, rather than taking it on faith that all of a manufacturer’s equipment has been deemed compliant, users will have greater assurance by seeing the specific model number listed.

Last, because health care providers rely on manufacturers to validate, test, and certify that their equipment is compliant, there are no assurances that manufacturers have adequately addressed the Year 2000 problem for noncompliant equipment, especially since FDA does not require manufacturers to submit test results certifying compliance. To address this concern, we recommend that the Secretaries of Veterans Affairs and Health and Human Services, in conjunction with VA’s Under Secretary for Health and the Commissioner of the Food and Drug Administration, (1) determine what actions should be taken regarding biomedical equipment manufacturers that have not responded to their requests for compliance information, (2) determine what actions are needed to address equipment produced by manufacturers no longer in business, (3) take prudent steps to review test results for critical care/life support equipment once determined to be noncompliant but now judged by the manufacturers to be compliant, and (4) determine what legislative, regulatory, or other changes are necessary to obtain assurances that the manufacturers’ equipment is compliant, including performing independent verification and validation of the manufacturers’ certifications.

VA stated that it has no legislative or regulatory authority to implement the recommendation and deferred to HHS. HHS agreed to implement two components of the recommendation: specifically, to determine the actions that should be taken with respect to those manufacturers who fail to respond to requests for compliance information, and to include in the clearinghouse database the identity of defunct manufacturers, along with the known types, makes, and models of devices that they manufactured. It did not agree to reviewing test results supporting manufacturers’ certifications. It stated that the submission of appropriate certifications of compliance is sufficient to ensure that the certifying manufacturers are in
compliance. We disagree that this is sufficient. Through independent reviews of the manufacturers’ test results, users of the medical devices are provided with a greater level of confidence that the devices are Year 2000 compliant.

In summary, VHA and FDA do not yet know the full extent of the Year 2000 problem with biomedical equipment because they have not received compliance information from many of the manufacturers. Further, they have not reviewed test results supporting manufacturers’ certifications to provide the American public with a high level of confidence that biomedical equipment will work as intended. While some aspects of equipment noncompliance may not affect patient safety, some may; we do not know for sure. Therefore, VHA and FDA need to work together—along with others in the health care industry—to make this information available to the public quickly so that appropriate action can be taken to remedy any potential risks to patient safety.

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


Year 2000 Computing Crisis: National Credit Union Administration’s Efforts to Ensure Credit Union Systems Are Year 2000 Compliant (GAO/T-AIMD-98-20, October 22, 1997).

Social Security Administration: Significant Progress Made in Year 2000 Effort, But Key Risks Remain (GAO/AIMD-98-6, October 22, 1997).


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