

HEALTHCARE

OVERVIEW

Healthcare is the largest single industry in the United States. It is a giant of an industry: 750,000 physicians, 5200 hospitals, annual expenditures of \$1.5 trillion, patient utilization census of 3.8 million daily inpatient visits and 20 million daily outpatient visits, a federal Medicare program treating 38 million seniors at an annual cost of \$300 billion. Additionally, Americans consume \$90 billion worth of medications and medical supplies per year. But, the most important statistic is that average life expectancy has increased from age 47 in 1900, to age 76 in 1998. Today, 70% of Americans will live to be 65, versus 20% in 1910.

**Y2K COULD PUT THE
HEALTHCARE INDUSTRY
IN INTENSIVE CARE.**

SENATOR DODD

Industry Technical Dependency

The increase in life expectancy is the result of many factors: scientific, economic, public education and a host of others. But an underlying cause is technological improvement in every aspect of healthcare. These medical technologies are susceptible to the Y2K problem in three ways.

1. Software

- Patient data systems start with admission of a patient to a hospital and the determination of insurance eligibility. All

subsequent medical treatment activities, including the results of all diagnostic tests, are automatically computer recorded. This insures communication between medical specialties, the carrying out of doctor's orders, and the creation of an audit trail to protect the patient and the caregivers.

- Health claim billing systems are the principal means of financing the huge cost of health care. Consequently, the 4 million daily Medicare health claims amounting to over \$1 billion are 85%-98% computer generated and processed in an Electronic Data Interchange (EDI) mode between provider and payor.

- Pharmaceutical research, manufacturing and distribution systems are the basis for providing the patient with effective medications. These systems electronically link the drug wholesaler to its pharmaceutical supplier and distribution outlets, principally retail pharmacies and hospitals. Finally, national direct mail order prescription services operate as both wholesaler and retailer.

2. Embedded microprocessors

- Biomedical devices are the

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core of medical technology, used by hundreds of millions of units. These devices occur in every kind of diagnostic test equipment (e.g. blood chemistry analyzers, MRI, X-ray etc.) and therapy (e.g. radiation) both inpatient and outpatient. Additionally there is a heavy usage (8 to 10 thousand per hospital) of bio-medical devices in in-patient hospital care. The health care industry currently relies on manufacturers' Y2K compliance data reports to determine whether the device will function appropriately when the date changes. Many device manufacturers have published these reports, indicating Y2K compliance status by model and serial number of each device they sell. But some medical device companies still have not informed FDA of the Y2K risks. Committee Vice Chairman, Senator Chris Dodd, formally published the names of these companies in the Congressional Record on September 23, 1998.

- Infrastructure operations use microprocessor controls in hospitals, clinics and medical office buildings controlling heating, ventilation, security and air-conditioning, as well as power and water
- Process control and analytical devices are critical for managing quality control in laboratories, manufacturing flow in

factories, and automated order activities in warehouses. Tolerances in most of its products are dependent on microprocessors to achieve them.

3. Electronic interconnections or interfaces

These are the most prolific and potentially the most likely cause of Y2K failures. For example, a doctor orders, through the hospital information system, that a patient be given an intravenous feeding. The microprocessor controlling the patient's infusion pump is connected to the same hospital information system. The infusion pump records the patient's ID, the quantity of the intravenous solution, and the date and time of the treatment. The patients could be in jeopardy if the hospital system and the biomedical devices are neither Y2K compatible nor compliant.

- Business partnerships are electronically linked throughout the industry. Consequently, a critical part of Y2K remediation is to determine if all the business partners of a healthcare entity are Y2K compliant.

MAJOR INITIATIVES

The Special Committee on the Year 2000 Technology Problem held two hearings dealing with healthcare issues. The first hearing was on July 23, 1998, "The Year 2000 Computer Problem: Will the Health Care Industry Be Ready?" The second hearing, dealing with Y2K problems of general

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business, was held on October 7, 1998. This hearing included a panel dedicated to the pharmaceutical industry with witnesses from a major pharmaceutical company, a large wholesale drug company, the national association representing wholesale druggists, and an independent pharmacy.

Industry Y2K Perspective :

The Gartner Group, a survey research company, issued reports stating the healthcare industry lags behind others in dealing with the Y2K problem in managerial attention, technical resources available, financial resources committed and remediation monitoring.

An additional problem is a highly decentralized system is used to process health claim payments, the underpinning of healthcare financing. It is comprised of a government-insurance industry mechanism that electronically processes nearly 4 million Medicare claims worth over \$1 billion daily at over 70 separate locations. Third party payors for private health claims utilize a similar type of electronic claims process.

HEARING SUMMARY

The following issues arose during the course of the hearings.

1. Biomedical Devices

These devices are the Trojan horses in the health care industry's compli-

ance. Users are often unaware or unknowledgeable about the impact of the microprocessors inside these sophisticated machines. For example, surgical suite machines such as a \$40,000 blood gas analyzer could close down operating rooms if they cannot function on January 1, 2000. Every major medical organization testified that they were experiencing significant problems with biomedical device manufacturers. In many cases, manufacturers were unable or unwilling to comment on their product's ability to function after the millennium change.

- After 2 letters of request, only 500 out of 2700 companies responded to an FDA survey.
- The Committee requested the FDA legal counsel to respond to this issue: Does the FDA have legal authority to require publication of biomedical devices? The FDA responded that it does not have blanket authority to require all device manufacturers to submit Y2K compliance reports. But, FDA indicated that in the interest of patient safety, manufacturers should inform the FDA of device problems and corrections.
- The Veterans Health Administration sent letters of request to 1600 firms for information on purchased medical devices. After three mailings, 233 firms failed to respond.
- The Health Industry Manufacturers Association (HIMA) initially said that it preferred for each manu-

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facturer to work with each customer rather than publicly publish Y2K compliance data. But subsequently, HIMA informed the Committee that they encouraged their members to work with FDA in providing public disclosure of Y2K compliance data.

- The Committee called upon all manufacturers of biomedical devices to publish relevant and accurate Y2K data for their machines in a central repository, the FDA Internet web site.
- The Committee requested that the Food and Drug Administration publish a list of biomedical manufacturing companies that have not replied to FDA requests for Y2K data by July 30, 1998.
- The Committee stated if the biomedical manufacturers were unwilling to respond voluntarily to providing data that can save patients' lives, the Congress will enact legislation promptly making mandatory the publication of such data. In response, device manufacturers began providing compliance data to FDA for publication on their Internet website.

2. Rural and Inner City Hospitals:

Rural and inner city hospitals have unique Y2K problems. First, because these types of hospitals tend to have limited financing, the expensive discovery, renovation, and testing process is beyond their means. Second, these institutions do not have access to the highly skilled personnel needed

to achieve Y2K compliance. Third, these hospitals are more likely to have older medical equipment, which may be disproportionately subject to Y2K problems.

- The Committee requested direction from the American Hospital Association (AHA) on handling the rural-inner city hospital Y2K problem. The AHA stated in correspondence, it did not have adequate data at present to know the ultimate cost. AHA stated that a coalition of smaller hospitals is being formed to share Y2K information.
- The Committee stated its concern with the American Medical Association (AMA), AHA and FDA about the need of a contingency plan for all hospitals. Rural and inner city hospitals in particular need a fall back if Y2K compliance is incomplete. The associations stated the Joint Commission on Accreditation of Health Care Organizations (JCAHO), the hospital licensing body, already requires disaster and contingency plans be in place. However, the Committee does not believe JCAHO requirements adequately anticipated the extent of Y2K problems. Also JCAHO only reviews hospitals on a triennial basis.

3. Medical Health Claims Payment - Medicare

The 38 million Medicare recipients, 5200 hospitals and 780,000 physicians depend on 4 million Medicare claims for \$1 billion in daily payment.

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Any significant failure or delay of Medicare payments would have a disastrous cash flow effect on their employees, suppliers and communities. The Healthcare Financing Administration (HCFA), the agency responsible for Medicare disbursements, gave an unsettling report on how they recently discovered 30 million more lines of code that needed remediation.

- The Committee asked the HCFA Administrator how the agency was going to handle a workload that had grown by two and one half times since a July 7 briefing to the Committee staff. The Administrator responded that the remediation would be the most extensive and expensive in the history of Medicare and HCFA was taking extraordinary steps to meet Y2K deadlines.
- The Committee asked the HCFA Administrator the current level of Y2K compliance of the external Medicare payment systems maintained by contractors - the core of Medicare payments. The most recent data supplied by the Office of Management and Budget (OMB) on November 13, 1998 demonstrates that HCFA has tested only 8 out of 108 external systems. However, the HCFA staff, in a late November meeting with the Committee, indicated substantial progress since the OMB report. Medicare renovation was to be completed by December 31, 1998 and full testing in the spring of 1999. None of these systems are Y2K compliant as of February 24, 1999.

- The Blue Cross/Blue Shield (BC/BS) representative assured the Committee that their organization, the largest Medicare contractor, would be ready on time for the December deadline. However, the OMB report referenced above, raises questions of completion dates. The GAO report of February 24, 1999 indicates Y2K problems continue at all BC/BS sites.
- The Committee raised the issue of contingency planning for Medicare payment processing in the event of contractor failure in meeting the Y2K deadlines. The HCFA administrator and BC/BS were requested to tell Congress about specific contingency plans when they are available. At present only general contractor directions for planning are available in lieu of specific plans.

4. The Domino Effect of Y2K Failure

Perhaps the most disturbing Y2K revelation to the Committee was the disclosure of the domino effect of Y2K failure. It can occur in both the use of biomedical devices and in Medicare payments.

- If one biomedical device malfunctions, it can potentially shut down an operating room. Or even worse, one device can pass erroneous data onto other devices creating adverse patient conditions. In other words, Y2K mistakes can reverberate throughout the health care system.

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- An exhibit displayed at the hearing showed the pathway for Medicare hospital claims, 98% of which are processed electronically. Each claim must pass through a series of steps beginning with patient eligibility at the hospital through final Medicare payments. A Y2K problem at any step in the process, could either delay payment or fail to remit payment.

ASSESSMENTS

Based on Committee hearings in July and October, subsequent meetings with healthcare industry personnel, and the October 17, 1998, Gartner Group Report, healthcare lags in its progress towards Y2K preparedness. Assessment is broken into the five portions of the industry: pharmaceuticals, large hospitals and hospital chains, health claim billing systems, rural and inner city hospitals, and doctors' offices.

Progress Of Healthcare Industry Segments

1. Pharmaceuticals

The Pharmaceutical segment of the industry appears best prepared to meet Y2K challenges. As an industry, pharmaceuticals benefited from an earlier start, their far-sightedness partially due to a long time-to-market horizon for their products. Furthermore, top management recognized Y2K as a business risk and provided the necessary management and resources to address it. This industry is

reported to be selectively stockpiling basic medical ingredients that could be in short supply. This assures that the industry will be capable of meeting strict FDA requirements for controlling batch source inputs to all medications. However, pharmaceutical companies face potential problems.

The first problem is the dependency on foreign suppliers and subsidiaries. The drug industry operates manufacturing plants worldwide that supply the U.S. market. Some suppliers exist in countries where basic infrastructures lack Y2K preparedness. A further complication is the high concentration of some drug production in foreign countries. Denmark, for example, produces 70% of the world's supply of insulin. Additionally 80% of the basic ingredients for pharmaceutical products produced in the U.S. come from abroad.

The just-in-time (JIT) inventory process presents another problem. JIT has replaced the large wholesale drug warehouses of the past with much more efficient Electronic Data Interchange (EDI) ordering and billing processes. JIT requires smaller warehouses and saves money. If adequate drug inventories are to be maintained locally, pharmaceutical products must be delivered promptly from a manufacturer to a wholesale drug company, then to retail pharmacists and hospitals. This can only occur if the telecommunications/transportation infrastructure functions.

Finally, pharmaceutical companies have a myriad of business partners, which must be Y2K compliant to be

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effective. Testing all of these electronic relationships is a challenging assignment for the industry.

2. Large Hospitals

While not as prompt as pharmaceuticals in responding to Y2K, large hospitals are dedicating considerable resources towards fixing the problem. They have all the usual Y2K problems of healthcare plus building management concerns. They have to provide water and power, heating, ventilating and air conditioning, plus maintain elevators and security systems. Hospitals must also address Y2K problems in biomedical devices and patient data systems. All of the above must function in harmony for the patient to be adequately protected. Hospital management is playing a catch up game.

As of October, a Gartner Group Report indicates that 64% of hospitals do not plan to test their Y2K software remediation - a disquieting fact which hearings in 1999 will attempt to verify. Second, many hospitals are relying solely on producers of medical devices to certify their Y2K compliance. Based on known inaccuracies of some producers' compliance certification, this could be a serious mistake. Third, Y2K contingency planning is in its infancy at hospitals.

3. Health Claim Billing Systems

Automated billing is the underpinning of the healthcare system. This \$1.5 trillion industry is almost totally dependent on third party payors (insurance companies, Medicare/Medicaid)

that finance colossal healthcare expenditures. Progress is moving very slowly.

Medicare (responsible for 40%-50% of all payments), has zero Y2K compliant payment programs, according to the most recent GAO report. Medicaid, the federal-state health care payment system, has widely varying stages of Y2K remediation progress that differs from state to state. A General Accounting Office report dated November 6, 1998 indicates that only 17 states have completed the renovation phase. No state has claimed victory in meeting Y2K goals.

The private sector has also experienced difficulties. In a recent publication of Securities Exchange Commission (SEC) 10Q financial reports, one of the largest private insurers recently set aside nearly \$200 million to renovate its Y2K health care billing systems. This indicates that significantly more Y2K remediation is required.

4. Rural and Inner City Hospitals

Rural and inner city hospitals depend on older equipment much more than large well-endowed hospitals do. On the plus side, low tech equipment may not have any Y2K exposure. On the negative, older versions of bill payment software are more likely to be non-compliant. The concern for rural and inner city hospitals stems from their lack of resources to prepare or test for Y2K problems. Additionally, it is unclear how aware rural and inner city hospitals are of Y2K problems.

5. Doctors' Offices

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Because the nation's nearly 800,000 doctors work out of thousands of separate offices, detailed data on the extent of the Y2K problem in this area is unavailable. (Gartner Group Reports are uncertain on the status of this healthcare area.) Offices have all the Y2K problems similar to hospitals on a smaller scale but **without** the comparable access to technical and financial resources. Since diagnostic testing depends upon biomedical devices, potential problems may exist. Patient data systems are not widely used in doctors' offices today, but electronic health claims billing systems are nearly universal for Medicare. If doctors have to return to paper billing because of Y2K failures, insurance companies and Medicare would be hard pressed to accommodate the resulting volume of health claims.

CONCERNS

There are substantial indications that in some healthcare settings, insufficient attention is being paid to Y2K issues. The October 17, 1998 Gartner Group Report paints a dismal picture of healthcare industry preparation for Y2K. Top management needs to engage this problem as a group, perhaps by formalizing compliance programs through governing bodies or industry groups.

Based on a 1996 National Institutes of Health Report, nearly 40 million Americans are chronically ill or physically impaired. Maintenance of adequate drug inventories can be a life

and death matter for patients dependent on drugs for survival, such as insulin for 10 million diabetics. Since some of these life saving drugs have a short shelf life, how will the healthcare system be structured to ensure availability of life dependent medications?

The Committee recognizes that medical malpractice insurance is the means by which both hospitals and medical doctors protect themselves against substantial loss. The insurance industry has already demonstrated an unwillingness to subject itself to Y2K liability. But hospitals and medical practitioners cannot function without liability insurance.

The Committee is also concerned that Y2K prepared hospitals may not follow proper documentation of remediation efforts. Compounding the problem, due diligence standards in this area have not been set.

The healthcare industry is faced with increased costs of Y2K remediation in 1999 and the possibility of extensive litigation after January 2000. How can costs affecting patient care services be controlled?

Excess supplies of non-compliant medical equipment will be available prior to, and after January 2000 due to replacements with compliant systems.

How will patient care be protected when this excess equipment is disposed of either domestically or internationally?

Healthcare managers are currently

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considering contingency planning programs. What is the optimal use of this approach in protecting patient care considering the multiple risks that can occur in any single facility?

Healthcare systems are trying to reduce Y2K exposure by excluding high-risk business partners from future deals. The cumulative impact of this practice in healthcare and other industries could negatively impact smaller firms irrespective of their competence or cost competitiveness. What can be done to insure that a "flight to quality" will include Y2K compliant smaller firms?

Rural and inner city hospitals could be endangered as a result of Y2K issues cited above. In many communities they are the center of health activities because of the low-income status of their patients. Furthermore, in rural communities these hospitals are frequently the largest employer. What public policy actions need to be taken promptly before the window of opportunity closes on solutions prior to the Year 2000?

How do the healthcare payment organizations (Health insurance companies and Medicare/Medicaid) plan to function if their own payment systems are not working or their customers (hospitals and doctors' offices) cannot produce EDI health claims?

The volume of electronic interfaces (paths) between biomedical devices and patient data and billing systems

within hospitals is staggering. How will all the paths be tested adequately for patient safety? What testing standards are being employed to ensure the results will protect patient safety and financial accuracy?

Contingency planning includes disaster recovery plans. Will contingency planners accomplish their work soon enough to be of practical assistance to the continuity of operations for patient safety and proper medical functions?

Several of the national associations that represent the health care industry were impressive in their assistance to the Committee and the country. They helped the Committee explain the extent and depth of Y2K compliance issues in their industry. It is obvious from the hearing however that no single organization or groupings of healthcare organization, are working together to assure the American public that the major issues are being addressed adequately. Can this industry unify quickly enough to insure that healthcare will become Y2K compliant before the Year 2000?

Testing of renovated biomedical devices, patient data systems and healthcare billing systems is in its early stages. The credibility of the test results is dependent on the quality of the testing criteria and processes. The Committee has not seen any data or discussion dealing with this ultimate measure of Y2K compliance.