

Health Care Solutions for HIPAA and FDA E-Records Compliance

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Executive Summary

Companies in the health care industry including HMOs, physicians offices, food and beverage companies, pharmaceutical and medical equipment manufacturers face increasing regulatory pressures on all aspects of their day-to-day business operations. Regulations surrounding the management and availability of critical health care data including clinical trial data and patient and insurance claims information has lead to sweeping changes both in the United States and abroad.

Two of the most far-reaching of these regulations with great implications for the way in which health care companies handle their data are the Health Insurance Portability and Accountability Act (HIPAA) and the Food and Drug Administration (FDA) 21 CFR Part 11, E-Records, E-Signatures mandate. HIPAA and FDA E-Records regulations affect thousands of companies across the United States. Virtually all U.S. health care, pharmaceutical and food-services firms will need to implement data management strategies that ensure the integrity, resiliency and availability of business critical information in order to meet regulatory mandates in the coming months and years.

Under HIPAA, all health care organizations and other entities that process health related data are affected. FDA E-Records regulations require that all companies mandated by the US Food and Drug Administration must comply with provisions surrounding the collection and transmission of health care data. Although the industries affected by these two regulations may be somewhat different, there is considerable overlap in the scope of FDA and HIPAA legislation. This means that health care companies may be required to comply with both mandates. CEOs, CIOs and IT Directors alike cite compliance with HIPAA and FDA mandates among the top business issues facing the health care industry in the next two years. IT departments within all types of health care related companies are being called upon to deliver cost-effective data management solutions for meeting the demands of these regulations.

This paper examines the impact of HIPAA and E-Records legislation on health care companies. It also provides an overview of the technical aspects of HIPAA and E-Records compliance and offers selection criteria for choosing a cost-effective solution. The last section outlines DataMirror's unique end-to-end health care solution for data integration, resiliency and regulatory compliance.

What is HIPAA and how does it affect the health care industry?

The US Department of Health and Human Services' sweeping Health Insurance Portability & Accountability Act of 1996 is an act "to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes."

HIPAA regulations affect all health care organizations including *health care providers, physicians' offices, public health authorities, life insurers, health care clearinghouses, billing agencies, information systems vendors, service organizations, universities and other entities that process health data.*

HIPAA includes provisions for health care organizations to implement electronic transactions as well as new safeguards to protect the security and confidentiality of sensitive patient information. One positive by-product of this legislation is that it encourages health care companies to eliminate paper records altogether with the potential for cost savings and enhanced operational efficiency.

HIPAA has focused the entire health care industry on the security and integrity of relational databases containing patient information. One of the key requirements for HIPAA compliance includes contingency planning. Within a formal contingency plan, health care organizations must include the following critical elements:

- An applications and criticality analysis
- Data backup plan
- Disaster recovery plan
- Emergency mode operation plan
- Testing and revision procedures

Presently, HIPAA-regulated firms must have a solution in operation by October 16, 2002. Health care firms that do not comply face the risk of serious criminal and civil penalties. These penalties can include fines up to \$25,000 for multiple violations and fines up to \$250,000 and or imprisonment up to ten years for the knowing misuse of individually identifiable health information.

While it is clear that in the coming months the health care industry must take action to ensure contingency plans are in place to meet HIPAA requirements, interpreting the regulations and selecting solutions that best apply has posed numerous challenges for health care firms. Organizations must take into consideration a number of factors when selecting a solution that best meets their needs and computing environment.

HIPAA can also be viewed as a valuable opportunity for organizations to capitalize on the benefits that compliance brings. Health care firms with resilient and accessible data 24/7 can not only ensure business operations around the clock, they also gain the opportunity to implement e-Business initiatives that systems high availability makes possible. By leveraging existing systems with a HIPAA- compliance solution, health care firms can lower operational costs, increase revenue, improve customer service and remain competitive in today's marketplace.

What is Article 21 CFR Part 11 (E-Records)?

The FDA's Code of Federal Regulations Article 21 Part 11: Electronic Records; Electronic Signatures, established requirements to ensure that electronic records and electronic signatures are trustworthy, reliable and generally equivalent substitutes for paper records and traditional handwritten signatures. This policy affects all companies that fall under FDA regulations and has had the greatest impact on the

pharmaceutical and health care industry, the food services industry and medical equipment manufacturers.

Specifically, organizations affected by E-Records include any firm that manufactures good that are consumed or used by Americans and that can affect their health. Moreover, these regulations apply to any foreign or domestic firms that carry out business with the United States. E-Records also applies to HIPAA-regulated companies. Some of the many organizations that are affected by this mandate include food, drug and medical device manufacturers, vaccine and blood product producers, animal feed and drug manufacturers, cosmetic manufacturers and the manufacturers of radiation-emitting products such as cell phones, lasers and microwaves.

One of the most critical compliance standard that needs to be met in order to satisfy Article 21 Part 11 is the ability to provide historical information by capturing audit trail information generated by software applications. The compliance standards outlined by Part 11 mandates that solutions must have the following:

- Operator-independent, computer-generated, user and date/time stamped audit trails of operator entries and actions that create, modify or delete electronic records
- Any changes made to E-Records shall not obscure or overwrite previously recorded information
- E-Records must be made readily available for FDA review and copying

Article 21 CFR Part 11 applies to all electronic records used to meet GxP requirements including systems for batch records, SOPs, test methods, specs and policies such as:

- Chromatography data systems
- LIMS systems
- Automated document management systems
- Inventory records
- Calibration records
- Validation protocols and reports
- Training records
- Customer compliant files
- Adverse event reporting systems

Why does E-Records Pose Such a Challenge?

Typically, software applications designed for health care, food services and pharmaceutical organizations do not include audit trail functionality. The most crucial aspect of these software applications is the database component where all critical information is stored. When applications call the database to update or delete rows, old information is overwritten and lost. Under the FDA mandate, regulated organizations must incorporate a solution that enables them to preserve all information, including updates/deletes or adds and inserts, from that database. This is posing many challenges for IT

departments who are searching for cost-effective ways to leverage existing databases and applications, while incorporating a solution for capturing audit trails.

A Delete Example

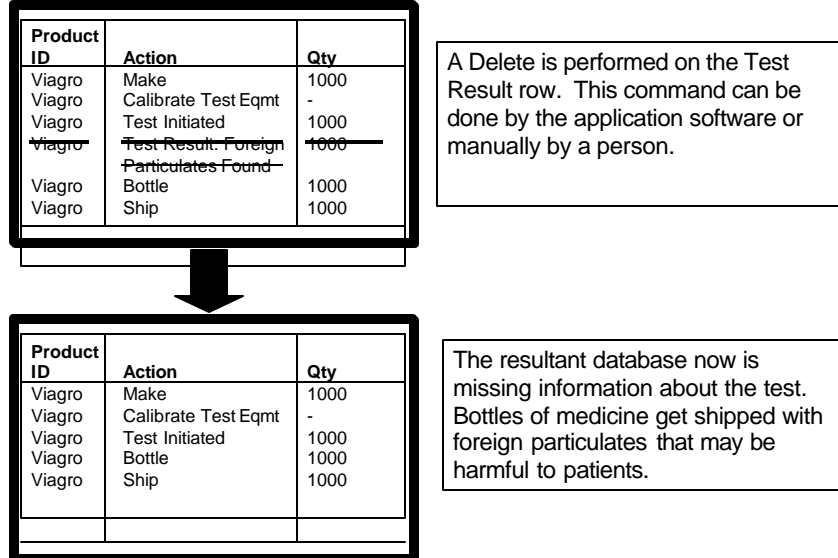


Figure 1: An example of a delete to a pharmaceutical trial database. E-Records mandates require that all changes to electronic records be tracked to ensure no critical data is lost or obscured.

E-Records Timelines for Compliance

Article 21 CFR Part 11, E-Records went into effect in 1997; however, before a company is cited for non-compliance, all potential regulatory action must go through FDA Compliance Centers for review. Currently, E-Records compliance is evaluated on a case by case basis. Firms are expected to have a “reasonable” time frame for promptly modifying any systems not in compliance. This less stringent timeline was enacted for companies with legacy systems where compliance was a serious challenge. However, to avoid legal action by the FDA, companies are required to have a corrective action plan with a timetable and be actively pursuing compliance with Part 11, in order for the FDA to be “reasonable” and look at all relevant factors. Beyond compliance with Part 11 requirements, electronic records and electronic signatures may also be used to meet record and signature requirements for other Parts of CFR 21 (such as Parts 210 and 211). Firms that do not implement solutions for compliance within a reasonable time frame can face legal action to ensure their infractions are remedied. To enforce compliance the FDA can seize the products in question, issue a court injunction against the business, refuse to supply certification for exporting goods or under the worst case scenario, firms could be forced to cease operations.

What does this mean for health care and FDA-regulated industries?

HIPAA and E-Records regulations bring about serious issues and challenges for the industries that must comply. The health care industry is now facing major changes to the way in which they manage their patient data. In response to these challenges, a number of solutions exist on the market ranging from consulting services and custom coding applications to a handful of out-of-the-box software products. What many health care organizations are discovering is that there are few single-vendor solutions that apply to every organization. However, in terms of data management and resiliency, there are cost-effective, proven software products available that can help ensure organizations have accessible and resilient data 24 hours a day, seven days a week and that electronic records meet FDA standards.

Creating a highly resilient and accessible data environment

For health care organizations, data resiliency, or the ability to ensure that critical data and applications are thoroughly backed up and continuously available, is an imperative for HIPAA compliance. Beyond compliance with HIPAA mandates governing contingency planning, there are many other reasons why having a disaster recovery solution in place is a corporate imperative.

The need for highly availability business environments has never been greater. The Internet has created a new breed of customer that demands 24/7 service from web sites and customer-facing systems. If a health care organization's server isn't on-line, or its critical patient and health care data is unavailable for any period of time, its ability to conduct business is seriously impaired. Database crashes can also seriously affect a company's ability to do business effectively with employees, partners, suppliers and customers. A long outage can cause the business to grind to a halt.

In order to deliver superior service and achieve 21st Century competitiveness, organizations must have a proven high availability (HA) solution in place in the event of planned or unplanned downtime. High availability software products are an effective solution for creating resilient and accessible health care data for HIPAA compliance. Using a proven high availability methodology, health care organizations can mirror critical data and objects from primary systems to one or more recovery systems in real-time, ensuring high speed operational switching and uninterrupted access to your data during planned or unplanned downtime.

DataMirror Solutions for HIPAA, FDA E-Records and Beyond

DataMirror has recently launched a number of initiatives targeting the health care industry. To help health care companies meet the challenges imposed by HIPAA regulations, DataMirror resiliency software offers a comprehensive solution for critical data backup and disaster recovery. The company's award winning software solutions and proven methodology can assist health care providers in implementing the necessary contingency plans to satisfy HIPAA requirements. DataMirror software mirrors critical data and objects in real-time from production systems to one or more recovery systems to provide highly available business operations.

DataMirror has also developed a number of innovative software solutions to help health care companies meet the challenges they face surrounding 21-CFR Part 11, E-Records regulations. By employing

DataMirror's real-time capture, transform and flow (CTF) data integration technology, the software ensures all critical health-related historical database information is preserved for FDA review.

Resiliency Solutions for HIPAA Compliant Disaster Recovery

iCluster / High Availability Suite

DataMirror iCluster software is for IBM iSeries and AS/400 customers who require uninterrupted 24/7 business operations and HIPAA-compliant disaster recovery. iCluster includes an intuitive graphical user interface to define nodes in a cluster, determine what data and other critical objects are mirrored to specific nodes and monitor the entire cluster from a single station. iCluster can detect primary system failure and invoke operational switching to maximize system uptime. Data and object transaction streams are matched and merged in real-time before being applied to the recovery system database, enabling real-time auto-registration. iCluster also handles the data and object mirroring requirements of clustered high availability environments. Users are able to define cluster groups, initiate cluster operations and set cluster security levels. iCluster supports IBM's ClusterProven™ standard for applications resiliency. iCluster also features breakthrough XtremeCache technology. DataMirror High Availability Suite is a single integrated product for highly available IBM iSeries business operations in non-clustered environments. It includes all the features and functionality of iCluster outlined above.

High Data Availability for Oracle (Beta)

DataMirror's High Availability Solution for Oracle mirrors Oracle database transactions from the primary system to the recovery system in real-time. The software can detect primary system failure and invoke operational switching to enable highly available business operations in Oracle environments. DataMirror's intelligent data-level mirroring provides a cost-effective solution to help health care organizations running Oracle achieve superior uptime and availability for their precious data assets. Using DataMirror's high availability solution for Oracle ensures that health care data residing in Oracle databases is accessible and available 24/7. It is an ideal solution for HIPAA-compliant disaster avoidance and recovery. Beyond HIPAA, the solution also allows for highly efficient distributed processing and workload balancing to enhance operational efficiency.

Professional Services

HIPAA is a major undertaking for health care organizations on a number of fronts, including information technology. By leveraging DataMirror's considerable high availability expertise, the technology challenges faced by the health care industry will be easier to manage and more cost-effective. In addition to offering proven quick-start solutions to thoroughly back up patient databases, DataMirror high availability experts can also help customers to develop or review disaster recovery policies for their organization and implement technical solutions and high availability methodologies to protect all health information.

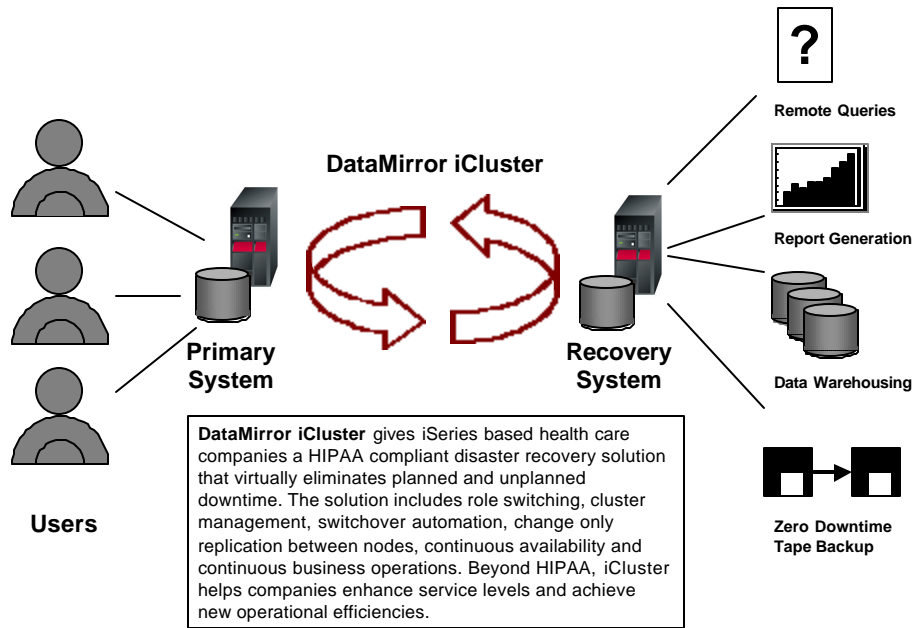


Figure 2: DataMirror iCluster software mirrors data from a primary system to a recovery system in real-time for 24/7 business operations.

Solutions for FDA E-Records Compliance

LiveAudit

LiveAudit for DataMirror Transformation Server enables firms to capture specified transactions from their software systems for the creation of FDA compliant electronic records. LiveAudit employs DataMirror's real-time capture, transform and flow (CTF) technology so that all historical database information is preserved, satisfying the FDA's overwrite provision. The recorded audit file and audit fields contain detailed time/date/action/time offset/user information and are captured in real-time as transactions occur on the source application. Customers are also able to run reporting tools against the audit file to generate the reports required by the FDA.

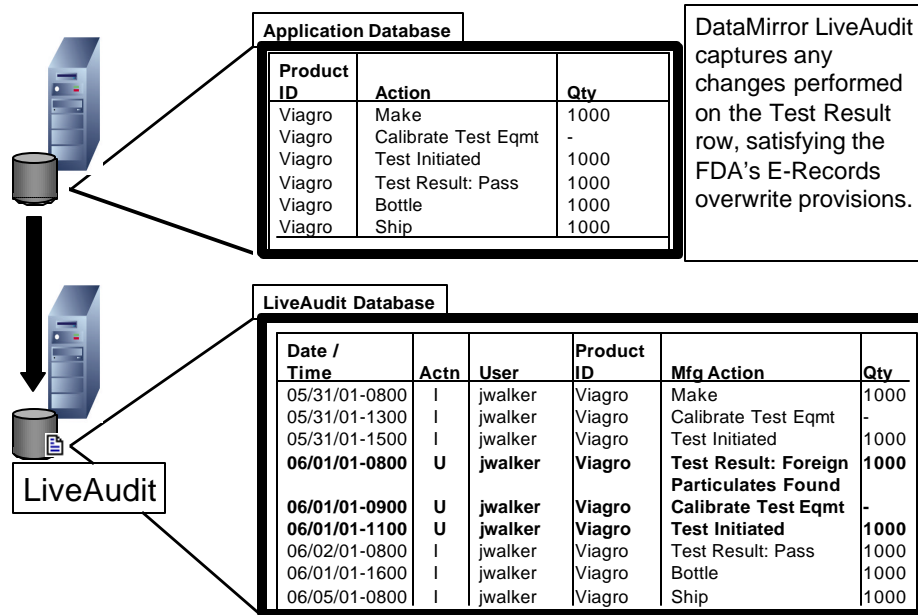


Figure 2: DataMirror LiveAudit ensures compliance with FDA E-Records mandates governing the capture and preservation of all types of health care data collected by software systems

Transformation Server

DataMirror Transformation Server lets users capture, transform and flow their data in real-time between DB2 UDB, Microsoft SQL Server, Oracle and Sybase across UNIX, Linux, Microsoft Window NT/2000, OS/400 and OS/390. Because Transformation Server is easy to implement and requires no programming changes to applications and databases, health care organizations can quickly implement a thorough e-records solution while realizing a rapid return on their software investment. Beyond FDA E-Records compliance, Transformation Server's out-of-the-box support for leading databases make it ideal for enabling EAI, e-Business, business intelligence, customer relationship management and a host of other distributed data applications.

iDeliver

DataMirror iDeliver software extends the capabilities of Transformation Server by allowing companies to securely filter and publish corporate data and E-Records audit information via the Internet so that compliance officers and legal counsel can easily access and monitor the information. iDeliver is an ideal data delivery solution that allows authorized users with web access to download the data on-demand into the most widely used desktop and server applications. There is no need to adopt a data standard or implement compatible software. iDeliver utilizes DataMirror Transformation Server software to capture data from a wide variety of data sources. Once the data is captured and selectively and securely published, iDeliver software enables health care organizations to transform and integrate relevant information onto the desktop or into server applications and databases.

Conclusion – The DataMirror Total Solution

All health care organizations including pharmaceutical, food services and medical equipment manufactures are under pressure to comply with FDA and HIPAA regulations. The challenges faced by IT departments responsible for ensuring that key systems comply with governmental regulations can be considerable. Moreover, the pressures of the current economic climate means that IT decision makers are continuously being asked to do more with less. This means that companies seek solutions that work seamlessly with existing software systems and allow them to extend their investments in these existing systems. By choosing solutions that allow companies to leverage existing technologies firms can achieve cost-effective compliance to meet the strict regulatory challenges imposed by HIPAA and Article 21 CFR Part 11.

DataMirror is one of only a handful of independent software vendors to introduce a comprehensive and cost-effective health care solution for ensuring both HIPAA compliant disaster recovery and FDA E-Records compliance. DataMirror is committed to helping customers in the health care industry rapidly achieve cost-effective governmental compliance through pre-packaged, out-of-the-box software solutions and a range of professional services specifically targeting the technical challenges faced by health care organizations. With DataMirror's end-to-end solution health care and FDA-regulated companies can create highly resilient environments for HIPAA compliance, capture audit trails for FDA E-Records compliance and incorporate a secure data delivery solution to ensure an FDA review does not impede operations. Beyond the immediate issues of regulatory compliance, DataMirror's proven solutions allow health care companies to maximize operational efficiency, enhance service levels and ensure their competitiveness in today's economy.

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About DataMirror Corporation

DataMirror (Nasdaq: DMCX; TSE: DMC) delivers solutions that let customers integrate their data across their enterprises. DataMirror's comprehensive family of products unlocks *The experience of now™* by providing advanced real-time capture, transform and flow (CTF) technology that gives customers the instant access, integration and availability they demand today across all computers in their business.

Over 1,500 companies use DataMirror to integrate their data. Real-time data drives all business. DataMirror is headquartered in Toronto, Canada, and has offices worldwide. DataMirror has been ranked in the Deloitte and Touche Fast 500 as one of the fastest growing technology companies in North America.



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