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Introduction

Advances in digital imaging technologies and electronic patient record systems are presenting healthcare IT professionals with a number of new challenges in storing, managing, securing, and protecting information. A typical Computed Tomography (CT) study today consists of 256 slices—each slice is an individual image. At 0.5 MB per image, this generates 128 MB for a single study. A Computed Radiography (CR) image is 10 MB and a Direct Radiography (DR) image 18 MB. Add other medical imaging requirements, such as Magnetic Resonance Imaging (MRI), digital mammography, and x-ray images, and it is not unheard of for a large medical facility to produce more than 20 TB a year in patient data. And while radiology continues to be the powerhouse of medical imaging, significant advances in cardiac imaging and pathology are also generating very large files, further impacting healthcare providers’ storage requirements. With technology advances such as high definition scanning on the horizon, this is just the beginning of a digital information explosion for healthcare providers.

Innovations in imaging and other medical technology are not the only drivers of change in healthcare provider IT. Increased government regulations also have a tremendous impact on how healthcare provider organizations manage patient information. Government regulations now mandate that patient data be retained for long periods of time and during that period, it must be protected, secured, and still remain accessible to the right people—even if disaster strikes.

As a result, healthcare provider organizations face a delicate balancing act: meeting government-driven availability, compliance, and access requirements while dealing with data growth and fostering secure sharing and collaboration. This paper describes the aforementioned healthcare information technology challenges in detail and discusses how HP’s Medical Archive solution (MAS) helps address these issues.

Regulations Influence Data Management Rules

HIPAA Drives Information Retention and Access Requirements in the U.S.

In the United States, the most well known regulatory requirement applying to healthcare organizations is the Health Insurance Portability and Accountability Act (HIPAA). Its IT implications were first seen in 2003 with Title II, which incorporated the Privacy and Security Rules, both of which apply to ‘covered entities’ including insurance companies, clearing houses, and healthcare providers. The latter encompasses hospitals, dentists, and physicians in private practice.

The Privacy Rule centers on Protected Health Information (PHI), governing the privacy of patient information and establishing guidelines for the use and disclosure of PHI in many types of situations. The Security Rule specifically deals with electronic PHI (ePHI). It mandates security safeguards for administrative, physical, and technical elements of healthcare organizations. Administrative safeguards require a contingency plan for emergency situations, forcing organizations to back up their data and have tested and documented disaster recovery procedures. Physical safeguards require that controls be in place to protect against inappropriate physical access to facilities such as data centers where ePHI is kept, including when hardware or software is added or removed from the network, so as not to compromise access to any data. Additionally, this safeguard also mandates that technical measures such as check sums, digital signatures, and password systems be used to ensure data integrity.

HIPAA also requires that pediatric data be retained for seven years plus the state’s age of majority. Adult information must be saved for at least seven years. In February 2006, the Department of Health and Human Services added the Enforcement Rule to HIPAA, outlining civil penalties for any covered entity that fails to comply with the other aspects of the regulation. One violation of HIPAA, including the inappropriate release of a patient’s medical records, can incur a fine up to $25,000. If an entire medical system is breached, the number of violations could trigger multi-million dollar fines.
Beyond HIPAA

In the U.S., Medicare 42 Code of Federal Regulations (CFR) 482.24 mandates that hospitals must maintain medical records in their original or legally produced form for five years. That’s just the beginning; individual U.S. states have followed suit with their own regulations. As recently as September 2008, Massachusetts Governor Deval Patrick signed State Bill (S.B.) 2863, a law requiring hospitals and community health centers in the state to implement an electronic health record (EHR) system by Oct. 1, 2015. The law makes EHRs a condition of the facility’s state license. S. B. 2863 also requires hospitals and health centers to implement computerized physician order entry (CPOE) systems by Oct. 1, 2012. This follows on a similar initiative in New Mexico and has a high likelihood of being imitated by other states.

With the 2008 election of Barack Obama as the 44th President of the United States, the focus on EHRs will only increase. Obama’s proposed health plan figures that EHRs will play a key role in reducing the overall cost of healthcare, and he has pledged to make EHRs a reality for every American.

Healthcare regulation efforts are not limited to those in the United States—there are numerous international efforts underway, though most are still in the early stages. It is widely expected that these regulations will be modeled after HIPAA and drive for similar privacy and record retention requirements. A sample of the efforts underway includes:

- The European Institute for Health Records (EUROREC), an independent not-for-profit organization, is the European-authorized certification body that is working on Electronic Health Record (EHR) certification development, testing, and assessment by defining functional and other criteria.
- A 2005 government review in Australia found little consistency across jurisdictions regarding maintenance, retention, and disposal of medical records. Legislation is being enacted to provide consistent practices across jurisdictions.
- In Canada, the Personal Information Protection and Electronic Documents Act (PIPEDA) is related to data privacy. It governs how private-sector organizations—including healthcare—collect, use, and disclose personal information.

There is a common theme across these regulations: Most require or are expected to require that patient data be retained for extended periods of time. This information must be remain secure, retrievable, and authentic.

Healthcare Technology Creates Opportunities

Using Technology to Improve Patient Care

The number one drivers of any healthcare provider, regardless of size, are patient care and safety. Advances in information technology, especially the use of digital imaging systems and electronic medical records systems, can positively impact patient care. While there are several technologies that improve overall medical treatment, the two aforementioned solutions can:

- **Enable physician collaboration.** Numerous healthcare providers are leveraging a distributed physician network to assist with patient care, including reading images and performing diagnoses. Digital imaging makes it very easy for physicians located outside the primary care facility to access and analyze images. Further, if a patient is being seen by someone other than their normal provider, electronic medical records are much easier to securely share than paper-based printouts, which can easily be lost.

- ** Expedite diagnoses.** Having images available online can significantly speed patient diagnosis. Without a digital imaging solution, it can easily take an hour or more to just get an image read by a specialist.
Healthcare organizations have reported that implementing a digital imaging application can now get a diagnosis in that same amount of time.

- **Improve talent retention.** Many providers are also academic and research institutions. Within these organizations, clinicians can design projects leveraging new technology to help win research grants. In addition, research institutions can attract and retain top talent by having emerging technology in-house. Digital imaging and electronic medical record systems are examples of the latest and greatest technology available to clinicians and researchers.

**Implications for Healthcare IT Departments**

Nearly 65 million CT scans are performed nationwide every year. Digital mammography—where every image can reach 55 MB—is still in the early adoption stage, but with four images per study, the storage impact is already up to 220 MB per patient. If a patient has one mammography study each year after turning 40—as recommended in some countries—and that data is retained for the life of the patient, the amount of digital information generated starts to add up significantly. Advances in imaging technology and electronic medical records systems generate more data, creating numerous healthcare IT challenges:

- **Departmental imaging silos from cobbled-together storage solutions increase operational costs.** It is not just a matter of the amount of digital image data created; the challenge is also the variety of systems used across imaging departments. Even within a central imaging department, there are often systems from different vendors storing data in various formats. These building block storage approaches work—until they are slowed by increasing ingestion rates. They are also costly in the long-term. Manual integration, multiple vendor points of contact, and maintenance of individual components are costly propositions as it is difficult to scale each individual environment and upgrades can cause downtime.

- **Retention periods extend beyond the useful life of storage technology.** Many storage solutions carry three year warranties. With a typical minimum retention period of 7 years, data will outlive the hardware and media it resides upon. Just think about the number of technology changes (i.e., new applications, servers that run the applications, etc.) that are likely to take place over the course of a single decade in medical imaging departments alone, where access to this data can mean life or death.

- **Controlling Costs.** The retention requirements imposed on medical records can cripple IT budgets. IT must, therefore, balance information accessibility with storage costs. In healthcare, data accessibility requirements are difficult to gauge as information does not necessarily follow the pattern of ‘the older it is, the less clinical value it has, and therefore will not be accessed frequently.’ For example, when a patient arrives in an emergency room after suffering a heart attack, the attending physician may want to compare the most recent test results with those from when the patient last visited the hospital after fainting two years ago. The institution must have a solution that can access both old and new data relatively quickly even if the content is stored on slower media.

**The Solution: Building an Information Archive**

**The Definition**

It would be irresponsible to outline all the problems associated with managing today’s healthcare information without offering a solution. As organizations transition to digital imaging and electronic medical records, they must also find ways to store increasing volumes of data for longer periods of time easily and cost-efficiently. This can be achieved by building an information archive that can consolidate value-driven storage of data from numerous sources in a disparate environment.

Archiving is not the same as saving backup tapes for long periods of time. Nor is it the same as sending paper records offsite in boxes. An archive is a central location where data can be easily managed and stored within a
cost effective, long-term storage system. When information is in the archive, IT can manage retention periods, ensure access 24x7, and secure data so it is only accessible to those with the appropriate permissions.

Two Components

The archive is made up of two primary components: the software responsible for managing information and the storage hardware where the data is ultimately saved. In some solutions, these components are separate—archive software and storage systems are purchased individually and deployed together, which often requires manual integration and upgrades, further adding to long-term costs. Some offerings come fully integrated from the vendor with the servers, storage, and software configured and pre-tested as one entity.

Regardless of the implementation, the software and hardware carry out the same tasks. As information is moved into the archive, the software indexes data so it can be retrieved at a later time. During this process, the archive should also create a unique fingerprint of the image or file. The unique fingerprint allows the system to identify and remove corrupted data and also ensures that the data being retrieved is authentic (the same content that was stored). It is also responsible for determining where the data is ultimately stored, managing each piece of storage hardware as one logical entity. The software enables healthcare IT to manage all the information, ensures replication, privacy, and data integrity preservation while enforcing security controls—ensuring appropriate users can access the data when it is needed.

An archive should contain multiple storage tiers with varying cost and accessibility characteristics: A centrally-managed mix of disk-based systems using high performance disk drives; others leveraging dense, slower drives; tape systems; and potentially optical devices. This variety of choices gives customers the most options when saving information for long periods of time. An archive does not need to have all of these storage options; however, there should be tiers to allow healthcare providers to delineate the cost of saving and information and availability metrics.

HP MAS Facilitates Information Retention

HP can assist healthcare providers, from hospitals to imaging clinics, in building an archival storage solution to meet long-term information retention and access requirements with its Medical Archive solution (MAS). HP MAS is a purpose-built grid computing appliance designed to help customers centrally store and manage medical fixed content, including images and electronic patient documents. Unlike many other storage solutions, HP MAS is a healthcare-specific solution optimized to handle large medical objects and smaller documents from multiple data sources.

MAS is available as a modular integrated appliance consisting of HP storage, servers, and storage management software. HP pre-integrates the solution, making it relatively easy to implement and bring into production—which in turn means that operational savings can be quickly realized.

With its grid based, scalable architecture, MAS addresses the three biggest issues associated with information retention: controlling storage costs, improving information access, and facilitating compliance. More importantly, MAS does not require significant IT operational overhead, which is extremely important given that many healthcare providers do not have the technical resources to manage new systems.

Control Storage Costs

Customers can leverage Fibre Channel, SAS, and SATA disk, as well as tape, to underpin the HP MAS-managed storage. High end Fibre Channel capacity can be configured as part of a SAN and support up to 32 TB per node. To add capacity, customers simply introduce another node into the MAS grid. The two levels of efficient online storage, mid-level performance SAS storage (up to 4.5 TB per node) and high-capacity SATA-based storage nodes (up to 10 TB per node), allow customers to keep data on disk, but not at a significant cost.
As data ages or is no longer frequently accessed, the customer can have HP MAS move the data to an integrated tape library.

Customers do not have to worry about migrating between storage subsystems as HP MAS uses an automated, policy-based management solution to help align medical image data with the economically and clinically prudent tier of storage while helping to ensure that fast, ubiquitous access is always available to authorized users. The rules engine is configurable, providing a level of flexibility needed to assign a business value to the content and then ensure that the data is archived on the most appropriate storage media at the most appropriate time.

With HP MAS, healthcare providers do not need to store everything on the same type of storage system and they do not have to worry about moving data to more cost efficient media types during an image or records lifecycle.

**Improve Information Access**

HP MAS enables customers to archive patient data from multiple imaging applications, such as Picture Archive Communication Systems (PACS), by migrating images from disparate applications to a centralized, consolidated long-term storage appliance. Physicians within a hospital or across a group of hospitals can have easy access to complete patient information and share files when collaborating on a patient's treatment using HP MAS as the foundation.

Understanding that some medical information may be needed more frequently, HP MAS enables customers to store up to 1 TB of data in fast cache, based on file type and source, to ensure that important data has the fastest access possible. A built-in parallel fetch capability allows users to retrieve, aggregate, and cache individual images from a non-containerized study for faster access.

Of course, information access is a moot point if the system is not available. In healthcare, downtime is not an option and as such, HP MAS supports 24x7 operations through a high-availability, self-healing infrastructure that ensures continuous access at the primary data center. HP MAS uses real-time data replication, combined with business rules, to distribute data across the grid, allowing customers to control both the geographic location and number of replicas needed to achieve desired levels of redundancy. If someone is accessing content and there is an error, HP MAS knows to get the information from another source and immediately begins serving it again from where the error occurred. There is no need to start the access operation from the beginning. This can save clinicians valuable time and expedite a diagnosis.

**Enable Compliance**

When saving data for long periods of time, it is imperative that a healthcare provider mitigate risks to patient safety related to the archival system, such as data corruption and accidental deletion. HP MAS helps address these challenges in two ways: First, MAS has selective Write Once, Read Many (WORM) capability built-in, which ensures that data remains unaltered and adds additional security retention. This helps providers meet HIPAA and other regulations mandating data security and retention requirements. Secondly, MAS creates unique digital fingerprints for continuous data integrity and authentication checks. This helps to prove that an image or study is identical to what was originally stored. Digital fingerprints also help determine if an image or study has become corrupted and any access must be directed to another copy stored within the grid. HP MAS also encrypts data when replicating or migrating across the storage tiers. With MAS's comprehensive auditing and reporting capabilities, administrators can easily trace all data and actions taken against that information through a web interface. The audit trails, along with built-in WORM, encryption, and digital fingerprinting, facilitate security and privacy related regulations as access to MAS can be tracked and reported.

**Minimal Operational Burden**

HP MAS provides consolidated, web-based management, enabling customers to set up policies across all of the integrated grid components, including multiple storage devices. From this interface, customers can easily control all storage, management, and access for their vital medical fixed content.
HP has taken on the additional burden to make it easy for customers to use MAS with a variety of medical imaging applications. HP MAS has been validated to work with more than 35 medical imaging applications (mostly PACS). Once PACS sends an image to HP MAS, MAS applies policies to the data for retention, placement on the appropriate storage tier, protection, and access. There are no proprietary APIs required for communication between the PACS system and MAS. Medical imaging applications like PACS connect to MAS using open standards, such as NFS and CIFS, allowing customers to seamlessly add new data sources into the archive environment. This is especially important to healthcare organizations using multiple PACS across different imaging departments.

Given that customers are going to be archiving a growing volume of medical fixed content with HP MAS for multiple years, they will have to add storage capacity over time. The advantage of HP MAS is that customers can easily add capacity and make it accessible to existing and new imaging applications very simply without application downtime. MAS immediately recognizes added storage resources and does the configuration work, eliminating the need for IT to perform mundane and often time consuming configuration tasks. In addition, with its ability to easily migrate data from older MAS storage devices to newer devices and accept new storage on the fly, customers can easily upgrade or replace storage when necessary. This is extremely helpful when hardware assets come off of maintenance agreements.

Lastly, the entire HP MAS grid infrastructure can be monitored via simple network management protocol (SNMP) traps and these notifications can be viewed via the centralized management interface. MAS itself can be configured to alert IT based on pre-defined triggers, including warnings when the system is running out of storage capacity so that immediate action can be taken without disrupting information access.

Summary

Healthcare providers are trying to improve patient care, retain valued employees, and complete potentially lifesaving research. These challenges are becoming easier with the use of digital imaging and electronic patient record systems. However, these solutions present IT departments with issues of their own, such as adding incremental responsibilities to already overtaxed IT departments. And, if IT did not have enough to manage with more information being generated electronically, compliance adds incremental responsibilities by mandating data retention and security requirements.

Saving and securing data for extended periods of time can be extremely expensive if IT keeps it all on the same type of storage system. Also, costs can grow out of control if each modality and imaging application has its own storage solution. In this scenario, the data remains silo’ed and cumbersome to access. Paper records consume valuable floor space that could be used for other revenue-generating operations.

An information archive can help healthcare providers centralize management of data from multiple sources so IT can manage it more time- and cost-efficiently. Some of these information management tasks include setting retention periods, enforcing access controls, and moving data onto the most cost effective storage system as value changes over time. One such solution that is optimized for healthcare medical fixed content is HP MAS. With capabilities that allow the archive to scale, providers can store large volumes of data for decades. The system also supports multiple storage devices, allowing customers to balance the cost to archive patient content with accessibility, privacy, security, and compliance requirements. Inherent high availability and replication capabilities ensure that content archived within HP MAS is consistently available to clinicians when they need it. Most importantly, the security capabilities enable customers to protect information in accordance with governance regulations.

Healthcare providers’ IT budgets are often under duress as new technologies that directly impact patient care are constantly emerging—healthcare CIOs typically have <3% of the operating budget for IT and need to invest in new technology wisely. While HP MAS may not be the most glamorous solution as its purpose is served mostly behind the scenes, it can enhance other IT investments, including those in digital imaging and other applications while facilitating compliance and saving customers money in long term medical record storage costs. Any
healthcare technology purchase that can help providers improve patient care while cutting operating expenses should certainly by considered.