



SUN STORAGE TEK™ COMPLIANCE ARCHIVING SYSTEM AND VIGNETTE ENTERPRISE CONTENT MANAGEMENT SUITE

A solution for electronic health records
White Paper
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Abstract

Managing electronic health records (EHRs) presents numerous challenges to already overtaxed healthcare providers. This paper describes how Vignette Corporation's Enterprise Content Management suite and the Sun StorageTek™ Compliance Archiving system (a Network Attached Storage (NAS) appliance) combine to offer healthcare providers a secure, end-to-end solution to augment electronic medical record (EMR) applications and to help address EHR management.

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1. Executive summary

While longitudinal electronic health records (EHRs) are generating significant interest, the healthcare industry is faced with many challenges directly linked to the fact that the vast majority of healthcare-related information is still paper-based. In today's complex clinical processes, it's virtually impossible for each point of care to have a complete view of a patient's clinical history.

Healthcare providers today face major challenges, including patient safety, quality of care, preventive care management, and cost containment. To address these challenges, many vendors are developing electronic medical record (EMR) applications serving the complex and integrated functionality required to run a healthcare organization. Although EMR applications can provide many benefits, they currently are not management cure-alls for building an electronic health record. However, the combined technologies of the Sun StorageTek™ Compliance Archiving system and Vignette Enterprise Content Management Solutions for Healthcare deliver comprehensive solutions that can help fill the voids in today's EMR systems to assist healthcare providers in addressing their major challenges.

2. Introduction

Medical errors are the number one business issue facing the healthcare industry. Comprehensive management of electronic health records directly addresses this issue.

For the last two years, the number one business issue facing the healthcare industry has been reducing medical errors. This was followed closely by improving quality of care. Patient safety errors are clearly not issues that the healthcare industry wants to advertise. However, it is issues like these that are driving clinicians to take a deep breath and make a monumental shift in the way they manage patient care. Healthcare providers understand there is a distinct need to create an electronic health record environment that:

- Delivers an integrated set of clinical and practice management applications that streamline workflow efficiency
- Improves adherence to treatment standards
- Enhances patient education and participation
- Optimizes compliance with regulatory and managed care guidelines
- Reduces cost

But with that understanding dawns reality. The healthcare system is a huge network of discrete points of care, yet each point is connected through a common factor — the patient.

Let's start off with some definitions. The International Standards Organization (ISO) defines the electronic medical record (EMR) as the legal record created in hospitals and ambulatory environments that is the source of data for the electronic health record. The electronic health record (EHR) represents the ability to easily share medical information among stakeholders and to have a patient's information follow him or her through the various modalities of care engaged by that individual. Stakeholders are composed of patients/consumers, healthcare providers, employers, and/or payers/insurers, including the government.¹

An EMR system can also be described as an application that attempts to address all of the functionality required to run a healthcare practice — from scheduling appointments to tracking orders and results.

While EMR systems attempt to link discrete points of care, is it enough? Even with an EMR, 80 percent of a patient's clinical information consists of unstructured data that may not be well managed by EMR systems.² Unstructured data includes paper files, films, video, and other documents that are not electronic at their inception, and not easily managed in an EMR system. The primary reason for slow adoption of EMR systems is provider resistance to modifying a workflow that generally meets their day-to-day needs; however, adoption is also hindered because providers are often unwilling to make the capital investment in moving from paper to electronic systems.

Vignette's Enterprise Content Management Solutions for Healthcare — together with Sun's storage and identity management solutions — help healthcare organizations capture, store, manage and retrieve all types of information — structured and unstructured, optimize operational processes, and integrate the points of care across the various care venues. Sun and Vignette help providers acquire a comprehensive, digitized patient record and augment their investment in EMR technology.

¹ Garets, Dave and Mike Davis. "Electronic Medical Records vs. Electronic Health Records: Yes, There is a Difference" HIMSS Analytics, January 2006. http://www.himssanalytics.org/docs/WP_EMR_EHR.pdf

² Source: "IBM Offers Text Search, Analysis Framework To Open-Source World," CRN Web site, August 8, 2005, <http://www.crn.com/sections/breakingnews/dailyarchives.jhtml;jsessionid=2YQMWWUQGVYEWQSNDBNCKHSCJUMKJVN?articleid=167600378> and White, Colin. "Consolidating, Accessing and Analyzing Unstructured Data" BI Research, December 12, 2005. < <http://www.b-eye-network.com/view/2098>> ; and and "The rest of the iceberg, roughly 80 percent of all corporate data, is unstructured." From Pfeiffer, Eric. "The Battle to Tame Unstructured Data." CIO Insight. May 30, 2006. <<http://www.cioinsight.com/article2/0,1540,1969440,00.asp>>

While not the focus of this paper, Sun's identity management solutions allow organizations to assign data access to specific roles rather than individuals. Identity management is described in detail at sun.com/identity

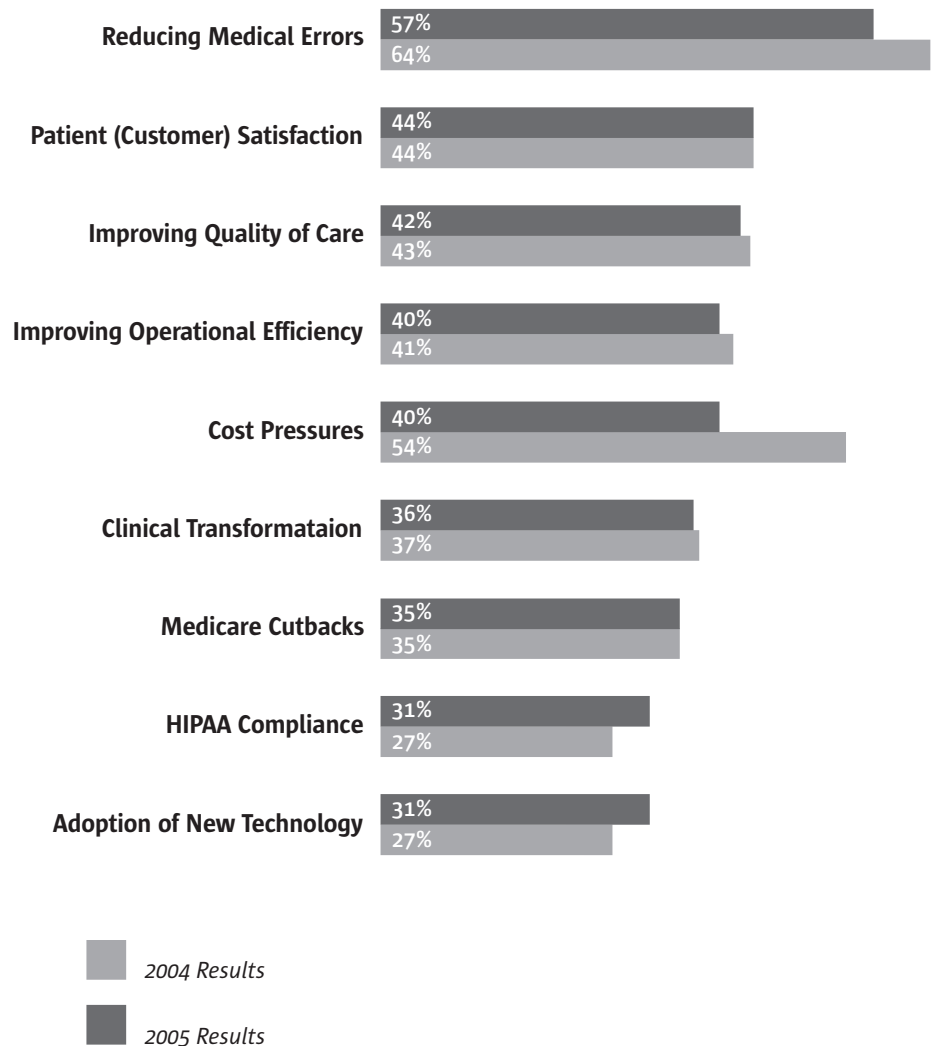


Figure 1. Healthcare issues in 2004 and 2005. The primary concerns are likely to remain largely the same for 2006 and into the foreseeable future. Source: HIMSS Foundation, "16th Annual HIMSS Leadership Survey," 2005, http://www.himss.org/2005survey/docs/Healthcare_CIO_key_trends.pdf.

Considering the four big challenges facing healthcare today — patient safety, quality of care, preventive care, and cost reduction — can providers really afford to carry the risk of a paper-based practice? With stricter U.S. regulations being imposed by the National Committee for Quality Assurance and other quality organizations, as well as HIPAA (the Health Insurance Portability and Accountability Act of 1996), skyrocketing malpractice insurance costs, smarter and Internet-savvy patients, and more electronically generated information, the answer is clearly no.

3. Vignette and Sun take EMR systems to new levels

The challenge of an EMR system is that it needs to deliver all patient clinical results at the point of care. This is currently not possible due to the volume of unstructured information coming from a variety of sources. Regardless, EMR systems are becoming more prevalent because they begin to address some of the key challenges facing the industry, and offer several key benefits. For example, they:

EMR systems are a great start toward a paperless practice, but need help to provide a secure, compliant, and — above all — complete patient record.

- Help facilitate quality and patient safety goals
- Automate order entry
- Tie orders to results
- Enable workflow of care team across a continuum of care
- Enable standardization of protocols across care venues and facilities
- Help reduce clinical inefficiencies
- Give caregivers access to some decision support capabilities

EMR systems are definitely a step in the right direction, but they are not a magic cure for the industry. EMR systems have a lengthy deployment cycle — sometimes up to three to five years. And there's more to it than just installing an application; it requires a complete transformation of clinical processes and practices. In essence, deploying an EMR system requires changing the behavior of all clinical and business staff in the healthcare network.

Most EMR systems natively support only discrete, coded data. That means that many unstructured clinical results — such as X-rays, ultrasounds, EKGs, echocardiograms, historical paper charts, and documents from outside facilities, among many others — are not well supported. As a result, even an EMR system can yield an incomplete electronic patient record.

However, clinicians can begin to address the four major challenges by augmenting their long-term EMR strategy today with Vignette's Enterprise Content Management (ECM) Solutions for Healthcare combined with Sun's range of storage and archive offerings. The combined technology of Sun and Vignette offers a facilitating solution and a clear migration path to help clinicians adjust to an EMR system.

With Vignette's Enterprise Content Management Solutions for Healthcare, healthcare providers can capture unstructured content ranging from printed charts to video. The StorageTek Compliance Archiving system then stores the data securely.

Vignette's solution augments a healthcare organization's EMR investment by capturing — in digital format — the unstructured information that comprises the patient record, and then presents that information through the EMR system's user interface. By integrating with an EMR system, Vignette enables access to a comprehensive patient record from the EMR screen. It offers the added benefit of providing a repository for all of the non-coded clinical and financial information that many EMR systems are unable to manage (such as X-rays, other clinical results, and paper documents). Vignette's ECM solutions for Healthcare go beyond traditional asset management to enable the capture, storage, processing, and

archiving of virtually all types of medical information, including scanned images, computer output to laser disk (COLD) reports, and electronic documents such as word processing files, spreadsheets, and e-mail. Outside reports, X-rays and other images, legal documentation, and clinical results not electronically interfaced (such as printed charts and advanced directives) can now be captured through Vignette. In addition, Vignette can manage and store information from other software systems, hardware, and clinical monitoring devices in the repository, and tie that information to a patient's record, as well.

When data integrity assurances, high data availability, and long-term protection of records are required, the Vignette repository takes advantage of the Sun StorageTek Compliance Archiving software. This software provides advanced retention and security features at the disk storage layer, as well as disaster recovery protection of patient records (through data mirroring to another StorageTek Network Attached Storage (NAS) appliance at a remote location)³ When the Sun StorageTek Compliance Archiving software is enabled on a StorageTek NAS appliance, the combination is referred to as the Sun StorageTek Compliance Archiving system.

4. Healthcare industry's major challenges

The four major challenges facing the healthcare industry today are patient safety, quality of care, preventive care management, and cost containment. We'll examine each of these areas and then take a closer look at how a combined Sun and Vignette solution can help address them.

4.1 Patient safety challenge

Medical error is by far the biggest issue facing healthcare; a haunting fact for anyone needing treatment. According to the Institute of Medicine, between 44,000 and 98,000 people die in the U.S. each year due to medical error⁴ — a fact that has placed an increased focus on patient safety. Safety issues generally fall into three primary areas: adverse drug reactions, surgical errors, and diagnostic errors.

By giving providers immediate access to a complete medical record, the healthcare industry could greatly reduce prescription and surgical errors.

Adverse drug reactions occur when a healthcare provider prescribes inappropriately. Examples include:

- Incorrect dosages
- Allergic reactions to medications
- Unexpected interaction with other medications

³ http://www.sun.com/storagetek/white-papers/nas_disaster_recovery.pdf

⁴ "The Institute of Medicine found that between 44,000 and 98,000 patients die each year as a result of preventable medical errors." Source: Press Release – "Senators Santorum and Frist Attack Victims of Medical Negligence to Garner Campaign Cash from Insurance Industry" Association of Trial Lawyers of America. June 1, 2006. < <http://atla.org/press-room/PressReleases/2006/June1.aspx> > http://www.sun.com/storagetek/white-papers/nas_disaster_recovery.pdf

In each scenario, the error is often the result of the clinician lacking appropriate medical history at the point of care. The clinicians may not know that the patient has a certain allergy or is on another prescription. The patient could simply neglect to tell the provider, or could be incapable of communicating due to a serious injury. Without an accurate clinical history, there's no way for the provider to know he or she is prescribing a medication that could actually make the patient ill or die. The Institute of Medicine estimates that up to 7000 people in the U.S. die each year as a result of medication errors.⁵

More than half of adverse hospital events relate to surgical errors. Test results get interchanged, for example, and the patient who was supposed to be operated on the left side is operated on the right side instead. Wrong-site and unnecessary surgeries can occur due to incomplete or incorrect information available at the point of care. The same is true for diagnostic errors. Clinicians end up treating a symptom rather than the root cause of the problem because of inadequate patient assessment, incorrect diagnosis, testing failures, or referral problems.

Safety issues are likely the biggest factor driving the move toward automation and, considering the root causes of safety problems — task overload, incomplete documentation, incorrect patient identification, communication breakdowns, and decisions based on incomplete information — automation makes perfect sense. Safety issues don't necessarily kill patients on the spot, but they can make them sick. If left undetected, serious illness or death can occur. In essence, safety issues can be viewed as a man-made disease, and the cure requires making a comprehensive clinical history available at the point of care.

4.2 Quality of care challenge

All healthcare organizations should be able to prove they are good at what they do. For that they need quality metrics and access to data that substantiates their claims.

Quality of care is linked to safety issues in that poor quality standards are likely to result in an increasing number of safety episodes. In general, quality relates to how well healthcare organizations are doing relative to standardized protocols and evidenced-based medicine guidelines. Clinical quality can and should be measured in the same manner that product vendors measure product quality. Having good clinical quality metrics is critical to the competitiveness of healthcare organizations. Patients will avoid a provider with poor quality metrics in the same way they leave a poor quality product on the shelf.

It behooves healthcare organizations to prove that they are high-quality care providers. This means establishing quality goals and associated metrics related to specific diseases and treatment settings. For diseases, it's important to measure how well a provider does in treating specific illness types based on proven, evidence-based guidelines. For example, how well does Hospital A treat heart failure, pneumonia, and stroke as compared to Hospital B? There are also established

⁵ "The National Academy of Sciences' Institute of Medicine estimates that 7,000 people die each year due to medication errors, with poor handwriting listed as one of the causes." Source: Farrell, Jodi Mailander. "Restoring lost art of pen and paper" The Miami Herald. July 16, 2006.<http://www.miami.com/mld/miamiherald/living/education/15036300.htm>

quality goals and metrics by treatment setting, or care unit, such as emergency department, intensive care, prenatal, or oncology.

Accurately measuring quality is nearly impossible when most clinical information is on printed charts. Such charts are not indexed by disease or by setting, but rather by patient name and number. As a result, there is no easy way to ascertain quality information by disease or treatment setting. Assessing provider quality today requires analysts to manually comb through literally thousands of paper charts.

4.3 Preventive care challenge

Healthcare payers and employers alike are driving preventive care — how to keep people healthy instead of simply treating them when they fall ill. This pressure results from the fact that around 80 percent of healthcare costs industry-wide are spent to treat the approximately 20 percent of the population with chronic conditions, such as heart disease, diabetes, or emphysema.⁶ Chronic diseases result in a higher incidence of care episodes and associated expenses for treatment. These costs pressure the industry to prevent or at least control chronic diseases. As a result, employers who pay a percentage of their employees' healthcare costs are asking insurance carriers to offer preventive care programs focused on disease management.

4.4 Costs challenge

Because of its heavy dependence on paper, the healthcare industry has many labor-intensive functions that drive up the total cost of patient care. These functions include:

- Chart pulls
- Registration and scheduling
- Clinical charting and encoding
- Claims submission, denials, and appeals
- Quality reviews of paper charts
- Transcription services

For example, in the U.S. the cost to pull a single chart can run as much as \$12.⁷

The entire revenue cycle across patients, providers, and payers is also lengthy, taking from 90 to 120 days. Anything that can be done to reduce or eliminate the amount of paper and manual processes in the total healthcare cycle will reduce costs.

After the initial expense, comprehensive EHRs can reduce operating costs in several ways — from reduced training time to simplifying on-the-job tasks.

⁷ "Benefits to an incremental approach: Easy view of the record, No chart pull (\$5 - \$12 per pull)" Source: Nelson, Rosemarie. "Productivity Trends in Medical Practice Information Technology: What's the right I/T investment for my practice?" HIMSS Physicians IT Symposium. February 13, 2005. <<http://www.himss.org/content/files/2005proceedings/PITS/pits06.pdf>>

Quality, safety, disease management, and cost containment are inter-related and can be addressed at least in part by moving to a complete electronic health record.

4.5 Addressing each challenge

Clinical organizations typically have four separate departments devoted to improving safety, quality, disease management, and costs. Often these independent teams do not communicate with each other, as there is a tendency to believe that their challenges are unique to their area. In fact, many of these challenges are inter-related and a comprehensive electronic health record is the cornerstone to improving all four. Improving disease management, patient safety, and clinical quality, for example, all require tracking patients across the continuum of care and making the complete clinical history available at all care settings.

Preventative care and patient safety also require that the clinical population be analyzed to detect trends. This calls for identifying high-risk patients based on clinical history, tracking the patients, and proactively managing them at the point of service. And while EMR systems provide a critical underpinning, Vignette and Sun can deliver to healthcare providers the missing pieces that will ultimately help them begin to fully address all four of their primary challenges.

5. A cure for major healthcare challenges

Although EMR systems provide the framework for providers to record their encounters with a patient, current implementations represent incomplete solutions. Vignette's Enterprise Content Management Solutions for Healthcare and the Sun StorageTek Compliance Archiving system offer healthcare providers a solution that will allow storage of patient documents, regardless of the point of origination. By seamlessly integrating with EMR systems, or even as a standalone solution until an EMR system is implemented, Sun and Vignette begin to help healthcare providers address the four major challenges impacting healthcare providers today.

5.1 Vignette's Enterprise Content Management Solutions for Healthcare

Vignette enables healthcare organizations to capture, store, manage, and share unstructured information (which constitutes approximately 80 percent of the patient's chart) and integrate it with the EMR data at all points of care. Regardless of the type of information or the source, Vignette's healthcare solution captures, creates, manages, stores and delivers patient information across the organization — from registration to the operating room; from billing to claims management. Vignette's robust integrated document management and workflow capabilities reduce costs and delays associated with record retrieval and storage and help mitigate HIPAA compliance risks. Providers can now have access to a more comprehensive electronic patient record.

Vignette delivers the complete electronic health record through a single interface — the EMR application (or patient/provider portal).

Vignette's ECM Solutions for Healthcare help enable comprehensive and consistent documents to be served up through any portal. This capability allows access to information across a distributed provider network, which is an extremely valuable tool. This is particularly true for teaching or research hospitals where rapid and accurate access to evidenced-based medicine resulting from clinical research is an essential part of the training and research process. Additionally, from a patient's perspective, providers are able to capitalize on the most current research results, thereby improving patient care, helping with disease prevention, and improving the quality of care. In other words, through integrated document and Web content management, Vignette facilitates the dynamic delivery of the right content to the right person in the right context. This "holistic" view of the patient helps each caregiver provide the most appropriate care possible.

Vignette integrates with EMR systems as well as patient and provider portals to provide consistent content. Portals serve as the mechanism not only to disseminate information, but also to facilitate collaboration among providers, as well as between providers and patients.

Furthermore, Vignette offers collaboration capabilities that help drive improvements throughout the healthcare process by facilitating collaboration among patients and all providers involved with that patient's care, thereby directly impacting the four major healthcare challenges. Through Web-based, shared workspaces that blend seamlessly with familiar tools within the EMR (or other applications), clinicians and patients can easily share information, whether at home or at any point within the care continuum. A more accurate and collaborative view of the clinical history reduces the risk of medical error and improves the quality of care.

Finally, Vignette also helps address security requirements and compliance with regulatory mandates such as HIPAA. The essence of healthcare is life; therefore, security is of utmost importance. Helping to ensure records are accurately maintained, accessible by only correctly credentialed people, and completely auditable is critical. Equally important is helping to ensure that medical documents are irrefutable and tamper-proof. The combined Sun and Vignette solution helps provide complete protection for patient records.

For detailed information about how a Sun and Vignette solution can help healthcare providers address HIPAA compliance, please see the paper "Addressing HIPAA Compliance — A Combined Sun StorageTek Compliance Archiving system and Vignette Enterprise Content Management Suite Solution," available from the Sun Web site, www.sun.com.

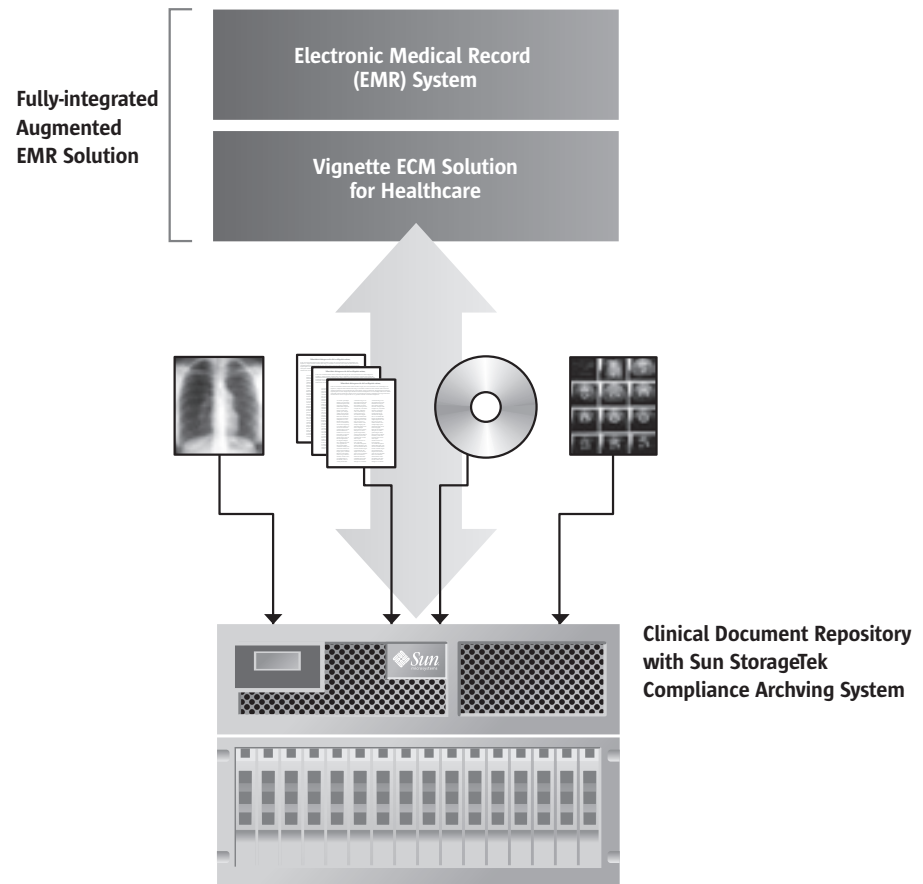


Figure 2. Vignette Enterprise Content Management Solution for Healthcare with the Sun StorageTek Compliance Archiving system.

5.2 Flexible storage with integrated data retention and protection features

EHRs consume huge amounts of storage and require extended retention periods. This is a perfect opportunity to employ an information life-cycle management (ILM) strategy to maximize resources. Sun's complete portfolio of storage systems and supporting software, integrated with Vignette's ECM Solutions for Healthcare, enable healthcare providers to control and manage comprehensive electronic health records throughout their life cycle - from the time the information enters the system to the time it is archived, or deleted, if appropriate. Additionally, performance and scalability options at the storage layer establish a foundation to help healthcare providers implement the optimal storage solution based on the criticality and access requirements of data.

Sun's line of network attached storage (NAS) appliances is particularly suited to the compliant management of EHRs.

Although Sun offers a wide range of data management and storage platforms, its StorageTek NAS family of appliances is ideally suited for hospitals and clinics using EHRs. Designed to support IT environments that may employ many different server vendors, the StorageTek NAS family simplifies file sharing among disparate platforms and departments. StorageTek NAS appliances provide advanced business continuity and disaster recovery functions, such as file system journaling, check pointing, remote mirroring, and monitoring. The NAS appliances are easy to operate and manage, and can be installed in less than 15 minutes using a highly intuitive wizard. Flexible configurations include a choice of Fibre Channel or Serial-ATA disks, single or dual NAS heads and RAID controller units, or providing file services to a storage area network (SAN). These flexible configurations match needs for availability, capacity, performance, and cost.⁸

The StorageTek Compliance Archiving software is pre-installed on all Sun NAS appliances. The ability to simply activate the software with a license key allows healthcare providers to easily add the compliance features if and when they are required.

Write-once, read-many (WORM) security and exhaustive audit trails are critical components of any compliant solution.

The Sun StorageTek Compliance Archiving system (the combination of a StorageTek NAS appliance and the Compliance Archiving software turned on) allows users to dynamically store data on magnetic disk in write once, read many (WORM) format, which is non-rewritable and non-erasable. When a client application, such as the Vignette ECM Solution for Healthcare, designates that a file must be retained and not modified, the Sun StorageTek Compliance Archiving system specifies that the file will be immutable for the duration of its designated retention period. From both inside or outside the application, no content or critical metadata attributes of these WORM files can be changed (even by administrators or other people with root accounts), and any attempt to do so is recorded as an auditable event in an immutable audit log.

Robust security features such as the audit logs, plus user authentication, a secure clock, and access controls, combine to help safeguard the integrity of vital patient records. The Sun StorageTek Compliance Archiving system also supports a mix of WORM-protected files and regular read-write files, offering greater flexibility for storing regular office documents that may not be required to be WORM-protected, as well as vital patient data on the same storage platform.

To provide consistent handling of document retention and disposition, administrators define policies centrally within the Vignette ECM Solutions for Healthcare, which then drive those policies down to the NAS appliance acting as the back-end archive. The Sun StorageTek Compliance Archiving software enforces the assigned retention periods and provides additional security. The Vignette ECM Solutions for Healthcare manage the recording and retrieval of information to and from the NAS appliance. When a document must be retained for regulatory or

⁸ <http://www.sun.com/emrkt/nas/nas-10-reasons.html>

The Sun and Vignette solution helps protect data at both the application and storage levels. Such security can be critical to verifying the trustworthiness of data during litigation.

healthcare compliance reasons, it is written to the NAS appliance as a read-only WORM file with an associated retention period during which the WORM protection is enforced, thereby significantly enhancing the retention management capabilities of the Vignette ECM Solutions for Healthcare.

With this WORM capability, the NAS appliances apply a double layer of retention protection by enforcing the retention of patient records at the storage level in addition to the application level. This helps prevent records from being deleted from the archive through IT error, intentional misdeed, or some system lapse. Once the retention period expires, the Vignette ECM Solutions for Healthcare are free to apply disposition actions on the documents and delete them from the NAS appliances. This additional security provided at the storage layer can also be instrumental in litigation support when the trustworthiness and integrity of information needs to be established.

The Sun and Vignette solution for healthcare touches virtually every aspect of medical practice. Switching to EHRs requires a culture change, but the switch is inevitable.

5.3 Driving value across the healthcare enterprise

The Vignette ECM Solutions for Healthcare have been optimized for the Sun environment to deliver end-to-end value to healthcare providers. The resulting Sun and Vignette solution helps healthcare providers reduce paper handling costs, floor space requirements for chart storage, and clinical errors related to manually maintaining patient charts. Operational improvements can be gained through the reduced exposure to security and privacy lapses, and increased quality and completeness of patient information at the point of care.

6. Conclusion

The challenges facing the healthcare industry demand that patient records, including clinical histories, become available across all points of care. Without this level of digital access, safety and quality issues will continue to rise along with healthcare costs. Preventive care will remain something employers and insurance companies talk about rather than implement.

EMR systems are not currently capable of providing the complete solution. And even if they could, the lengthy deployment cycle leaves a gap that creates safety and quality concerns. The StorageTek Compliance Archiving system and Vignette's Enterprise Content Management Solutions for Healthcare offer healthcare providers an affordable solution that can be quickly deployed to provide a comprehensive view of the complete patient record. Equally important, the combined solution offers healthcare providers a viable and protected migration path to an EMR. Vignette and Sun give healthcare providers a single, seamless framework that can capture, store, and manage critical patient information, which is essential to solving the serious safety, quality, preventive care, and cost issues facing the healthcare industry today.

For more information

For an overview of StorageTek Compliance Archiving software features, see the online data sheet at: http://www.sun.com/storagetek/management_software/data_protection/compliance_archiving/

For general information on the Sun StorageTek NAS appliances, visit <http://www.sun.com/nas>

As mentioned in this paper, Sun also supports end-to-end medical records through role-based identity management, in which access to records is based on an individual's function within the organization. For more information, see the "Sun Identity Management for Healthcare" data sheet, available online at: <http://www.sun.com/software/products/identity/verticals/index.xml>

For more information on the Vignette Enterprise Content Management suite, visit the Vignette Corporation Web site at www.vignette.com. An overview of Vignette Solutions for Healthcare can be found at <http://www.vignette.com/healthcare>.



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