Electronic Medical Information Preservation and Legal Holds

Why the Healthcare Industry Needs to Take Action

By Brad Harris and Ken Rashbaum
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ABOUT ZAPPROVED INC.
Zapproved is a Software-as-a-Service (SaaS) provider based in Portland, Ore., with a platform that adds accountability to business communications. Zapproved’s first products focus on targeted compliance workflows that reduce liability risk in legal and regulatory compliance. The company is expanding its product line to create a suite of applications that address additional compliance issues and workplace collaboration.

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The amount of digitally-stored medical information continues to grow at an accelerating rate, being driven by government stimulus and overall efficiency initiatives in the healthcare profession. Simultaneously, the threats of litigation and government investigation, which require increasing volumes of electronic medical information, are creating an untenable risk for healthcare practitioners and insurance providers due to potential missteps when responding to a duty to that preserve information.

The HITECH Act (Health Information for Clinical and Economic Health), a component of the American Reinvestment and Recovery Act of 2009, appropriated roughly $27B to assist in and facilitate the transition to digital healthcare records. In June 2010, the Centers for Medicare and Medicaid Services issued the Final Rule for Medicare and Medicaid Programs: Electronic Health Record Incentive Program, setting forth requirements for accessing the Incentive Payment funds beginning in January 2011. The availability of these funds, as well as quality of care advantages through enhanced coordination of medical disciplines, will drive tremendous growth in the use of electronic media (including email and text messaging) to capture patient information and enhance communications between caregivers.

Further complicating this increase in electronically-generated information is the accelerating growth in the number of data types and repositories for retaining information. Traditionally, the “patient’s chart” existed as a paper record managed by the Medical Records Department of most healthcare providers. Yet even before the onslaught of the “digitization age” for health
records, patient information included radiology films, sonography videos (now in digital media), off-site laboratory reports, and notes from departments scattered throughout the facility yet beyond the formal chart.

Today, physicians routinely communicate via email and text messaging. Clinical departments may be communicating over their own remote “modules,” or applications that do not link to the organization’s network or the Medical Records Department (which was set up for paper, not digital records). Imaging specialties such as radiology and Nuclear Medicine often record their images and findings on their own systems, as do the clinical and pathology laboratories. All of these changes lead to an ever-increasing list of data types, sources and locations that must be considered when responding to a duty to preserve and protect a patient’s health record.

What does this burgeoning growth of electronically-stored information mean from a legal perspective? A bonanza of health information demands in litigation discovery and an ever-increasing risk if healthcare providers do not take appropriate steps to ensure such information is being preserved in the event of a duty arising out of litigation or government investigations.

Healthcare provider organizations should be aware that the need for documented “reasonable and good faith” efforts in response to a preservation obligation has never been greater. This need is growing due to three factors:

1. The accelerating growth of potentially-responsive electronically-stored information (“ESI”) that continues to increase both the time and risks associated with traditional approaches to e-discovery.

2. Adversaries and government oversight entities are becoming more e-discovery savvy, acutely aware of the leverage that e-discovery omissions and missteps can provide, especially those made during pre-discovery stages when litigation is first reasonably anticipated.

3. Courts are becoming far less tolerant of loss of data through failures to implement reasonable preservation protocols designed to suspend routine or inadvertent destruction of data, as signaled by numerous judicial decisions throughout 2010.

Growth of Total Data Associated with All North American Healthcare Providers

The Duty to Preserve Relevant Electronic Information: Emerging Nationwide Standards

The legal profession has seen a dramatic rise in the number of court opinions in response to spoliation claims (loss of digital information). Organizations are finding themselves under increasing scrutiny to ensure that documented reasonable and good faith efforts have been undertaken in response to a duty to preserve information for discovery. Courts have held that failing to do so including, in many instances, the mere lack of issuing a written legal hold notification, can constitute gross negligence and result in severe sanctions. In extreme cases, such sanctions can include judgment against the party that was obligated to preserve the information. While most the decisions in this area have come from federal courts, the state courts, without many published decisions of their own, have looked to the federal decisions for guidance.

The 2010 case that sounded the preservation trumpet most loudly was issued in mid-January 2010 by Judge Shira Scheindlin, of the United States District Court for the Southern District of New York, the same judge who issued the five landmark Zubulake opinions between 2004 and 2007. Judge Scheindlin’s Pension Committee opinion specifically dealt with motions for spoliation sanctions brought by the defendant in that case. Other opinions in 2010 echoed the courts growing expectation that counsel must take proactive steps to ensure reasonable protection of data once a duty to preserve has attached.

These and other cases demonstrate the critical need for assessing and proactively responding to a preservation obligation. Healthcare providers that fail to implement and document their reasonable and good faith efforts to protect needed information do so at their peril.

Pension Committee v. Banc of America Sec.

The Pension Committee case involved a complex securities litigation surrounding the collapse of two British Virgin Island-based hedge funds in April 2003. The case was filed on behalf of 96 plaintiffs (The Pension Committee of the University of Montreal, et. al.) in February 2004 in Florida, and transferred to the Southern District of New York in October 2005. 1

In October 2007, after several months of discovery, the defendants claimed that substantial gaps were found in the document productions and ultimately moved for sanctions against 13 plaintiffs. The opinion goes to great lengths to articulate a framework for the court’s review and analysis, including how it determined the level of culpability (negligent, grossly negligent or willful), the interplay between the duty to preserve and spoliation of evidence, which party should bear the burden of proof for both relevance and prejudice, and finally the appropriate remedy for harm caused by the spoliation.

According to the court, defendants showed that the 13 plaintiffs targeted by the motion “clearly failed to preserve and produce relevant documents.” 2 Missing documents included 311 cross-referenced emails that were not produced by some plaintiffs, although produced by other plaintiffs. The Court also concluded that relevant documents were missing, including materials presumed to have existed as part of the plaintiffs' fiduciary duty of due diligence prior to making significant investments. Plaintiffs argued that it was absurd for them to

2Id., p.34
be held responsible for an allegedly missing class of unknown documents. The court disagreed, holding that “[t]he paucity of records produced by some plaintiffs and the admitted failure to preserve some records or search at all for others by all plaintiffs leads inexorably to the conclusion that relevant records have been lost or destroyed.”  

The Court’s finding of gross negligence was based upon a litany of preservation failures, including failing to issue a written litigation hold prior to 2007, continuing to delete ESI after the trigger event, failing to request documents from key players, delegating search efforts without any supervision from management, destroying backup tapes relating to key players where other ESI was not readily available and/or submitting misleading or inaccurate declarations.  

Significant monetary sanctions were imposed. The court awarded costs to defendants, including their attorneys’ fees associated with bringing the motion, deposing the declarants and reviewing declarations, which will be allocated among the thirteen plaintiffs. These costs reached hundreds of thousands of dollars.  

Rimkus v. Cammarata  

The opinion in Rimkus v. Cammarata, issued by Judge Lee Rosenthal of the U.S. District Court for the Southern District of Texas, draws a direct parallel to Judge Scheindlin’s words in the Pension Committee opinion in articulating the court’s frustration regarding the distractions caused by spoliation of evidence:  

Spoliation of evidence – particularly of electronically stored information – has been held responsible for an allegedly missing class of unknown documents. The court disagreed, holding that “[t]he paucity of records produced by some plaintiffs and the admitted failure to preserve some records or search at all for others by all plaintiffs leads inexorably to the conclusion that relevant records have been lost or destroyed.”  

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assumed a level of importance in litigation that raises grave concerns. Spoliation allegations and sanctions motions distract from the merits of a case, add costs to discovery, and delay resolution. The frequency of spoliation allegations may lead to decisions about preservation based more on fear of potential future sanctions than on reasonable need for information.\(^7\)

In this case, a group of employees left the company and filed a suit against their former employer, Rimkus Consulting, to release them from their non-compete agreements. In a countersuit, Rimkus Consulting fired back that the former employees violated their non-competes and additionally made off with “trade secrets and proprietary information.” Unlike in Pension Committee, this case involved allegations of intentional destruction of electronically stored evidence.

The Rimkus opinion provides insight into how a court goes about deciding what type and level of sanctions are appropriate. Here, the court ordered that the defendants pay attorneys’ fees and costs associated with the spoliation.

**Merck Eprova v. Gnosis**

Merck Eprova v. Gnosis, from the District Court for the Southern District of New York analyzed the contents of a “good faith effort” when responding to a preservation duty, including the need to issue a proper and timely legal hold. On April 20, 2010, U.S. District Judge Richard J. Sullivan determined the defendants’ failure to preserve evidence as gross negligence.\(^8\)

This civil case was originally filed in June 2007 as a result of an alleged mislabeling of a nutritional ingredient. In this case the defendant, an Italian biomedical company called Gnosis, did a “haphazard”\(^9\) job of meeting its discovery obligations. Following a failed settlement agreement, the litigants entered into a year-long discovery battle.

After months of urging by the plaintiff, details emerged about the defendant’s preservation efforts. In a hearing on January 22, 2010 only days after the issuance of Pension Committee, the Gnosis CEO admitted that the company had not issued “an explicit litigation hold, much less a written one.” Further, employees continued to delete (or “at least fail[ed] to prevent automatic deletion of”) relevant emails, and responsive documents were not produced because the company allowed custodians to decide which were considered relevant.\(^10\)

Judge Sullivan relied heavily on Pension Committee when he concluded that a written legal hold represents a reasonable and good faith response to a preservation obligation.\(^11\) Gnosis’ CEO claimed he had instructed employees to “pay attention” to saving relevant documents. Yet the court responded: “there is no doubt that Defendants failed to issue a written legal hold”\(^12\) and ruled this failure a “clear case of gross negligence.”\(^13\)

**Medcorp v. Pinpoint**

Medcorp v. Pinpoint, issued in June 2010, concerned preservation missteps on the part of the plaintiff. When analyzing a failure to preserve, Magistrate Judge Kristen L. Mix in Colorado used Pension Committee as the template on which she based her decisions on sanctions.\(^14\)

\(^7\) Id., p.1
\(^8\) Merck Eprova AG v. Gnosis S.p.A. et al., 07 Civ. 5898 (SDNY Apr. 20, 2010)
\(^9\) Id., p.7
\(^10\) Id., p.6
\(^11\) Id., p.9
\(^12\) Id., p.11
\(^13\) Id., p.12
The opinion explores the appropriate sanctions pursuant to the Special Master’s findings that the plaintiff had destroyed 43 hard drives that contained relevant information to the case, had prejudiced the defendants’ case and interfered with the judicial process. Judge Mix upheld an order for an adverse inference instruction that the jury “may infer that the destroyed hard drives contained evidence which is unfavorable to Medcorp.”¹⁵ She went on to award reasonable costs in the amount of $89,395.88.

¹⁵ Id., p.4
The Preservation Process

Healthcare providers are especially vulnerable to claims of poor data preservation practices due to the burgeoning volume of ESI, a historical reliance on paper records, electronic record-keeping practices created in the era of paper records, and blurred organizational authority over the spectrum of electronic records. Provider organizations should be taking steps to ensure their data preservation practices and policies are adequate to respond to the enhanced risks of loss of electronic information. First and foremost is having a well-understood, consistently applied, and rigorously defended preservation process.

An effective data preservation process should address the following key elements:

1. **Triggering Event**

   Knowing when a duty to preserve as arisen is the crucial first step. What triggers a “reasonable anticipation of litigation” or investigation? What factors go into determining if the threat of a lawsuit has risen to the level requiring steps to preserve potentially responsive information? Who gets notified, and how does the organization ensure a timely response? A Litigation Hold Team, comprising counsel, records personnel, risk management and, perhaps, IT, should consider a number of factors in deciding whether to issue a hold, and to whom.

2. **Scoping**

   The next step is determining a reasonable scope of preservation. How are anticipated issues in a case identified and mapped to information that must be preserved (i.e., information in medical malpractice cases may differ from that required for employment or professional discipline litigation)? This may require an assessment of the types of data potentially subject to disclosure demands. Such data may comprise laboratory results, radiology images and caregiver notes, but may also include clinical logs, audit trails and emails between caregivers. How are custodians (those caregivers most likely to have relevant electronic information) identified? Where is such relevant data likely to be found beyond servers and desktops (i.e., laptops, home computers and portable devices such as iPads and Smartphones)? Data mapping to identify potential sources and repositories of information routinely required for discovery (or as a starting point, a record of sources identified in the past for similar cases) can be most helpful in this regard.

3. **Notification**

   Once the scope of preservation is understood, those in control of relevant information must be notified of the requirement to suspend routine data destruction. How are custodians or data stewards (those likely to be in possession of relevant information) and IT notified? Are instructions written, clear and well-articulated? Are steps taken to ensure instructions are received and understood, and have recipients agreed to comply with the instructions?

4. **Follow-up**

   A legal hold notice is not a “once and done” event. Courts require that the hold process is documented from inception through follow-up. Is there a tool or process for obtaining acknowledgements from custodians? Are such responses tracked to ensure compliance, and delinquent responses acted upon? Are updates and revisions to hold instructions routinely issued as conditions warrant? Are periodic notices sent to hold recipients to remind them of an ongoing obligation to preserve data over the life of the legal hold?
5. Release

Once actions to preserve information are no longer required by a given custodian, is a release notification being sent to allow normal retention and destruction practices to be resumed?

These five steps are critical elements to defining and implementing an effective and comprehensive data preservation policy.

The Benefits of Improved Preservation Practices

By taking proactive steps to improve a healthcare organization’s response to a preservation duty, the risks and costs associated with discovery can be significantly reduced. By implementing a transparent and well understood process, those responsible for implementing legal hold instructions are much more likely in turn to take appropriate steps to avoid inadvertent spoliation. And defending those actions as having been “reasonable and in good faith” is much easier when the organization follows a documented and well-defined process.

The benefits of sound data preservation practices can go beyond e-discovery readiness as well. By investing time in understanding where digital health information exists within an organization and its potential relevance to litigation or investigatory actions, healthcare providers can better prioritize where best to invest in information management initiatives.

Finally, having a defensible data preservation process in place can create strategic advantages for counsel. Knowing that reasonable and good faith efforts can be defended affords much greater leverage when negotiating a fair and reasonable scope of discovery or even settlement offers. It can also reduce counsel fees that would otherwise be incurred in lengthy searches for relevant information.

Automating the Legal Hold Notification Process

The process for notifying custodians of a need to preserve information can be made simpler and more effective through the consistency and reuse available with a legal hold tracking tool. A tool such as Zapproved’s Legal Hold Pro improves efficiency by automating routine tasks, facilitates greater consistency across an organization through reuse, improves defensibility by maintaining a comprehensive audit trail, and consolidates information about legal holds into a common and accessible knowledge source.

Automating the legal hold notification process can offer numerous benefits to an organization. Automating routine and repetitive tasks – drafting the hold notification, identifying custodians and data sources, sending emails and tracking responses – becomes far less onerous and time-consuming. Hold notifications can be drafted using standard templates and sent using a consistent format. Periodic reminders and updates can be sent with the click of a button. Questionnaires can be included to solicit feedback from custodians.

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in the form of web-based surveys. And an audit trail is automatically created that records all of the actions – when a custodian was initially notified, when and how they responded, when reminders were sent – that significantly improves an organization’s ability to defend its actions in response to a preservation obligation as being “reasonable and in good faith.”

By using a standard approach to legal hold notifications, it also eases the burden on recipients. Hold notifications and reminders are more consistent. Responding to a hold notification to acknowledge receipt and understanding (via an “I Accept” button included in the email), or alerting a legal team if someone has questions or concerns (“Contact Me”) is vastly simplified. By consolidating legal holds into a common database, custodians can also easily query the system to see a list of their active holds.

By keeping track of legal hold actions in one place, the organization can easily run status reports on their hold activity. A quick search can identify if an employee is subject to an active hold, such as when the employee is transferring between departments or leaving the organization, and thereby take appropriate steps to preserve information they have control over. A common database of legal holds can also assist in information management initiatives by helping to prioritize areas within the organization that are most at risk to the onslaught of electronic discovery.

In Closing

The powerful convergence of logarithmically growing electronic health data and increased judicial and regulatory demands is compelling today’s healthcare industry to take action. The risk for health providers and their insurers is increasing at an accelerating rate in this sector that is among the most vulnerable to government investigations, oversight proceedings and litigation.

As change arrives in many forms, the healthcare industry is undergoing a transformation that will enhance patient care, but also create potential risks and exposures. One step that can significantly reduce some of those risks and reduce costs associated with investigation, oversight and litigation is the use of new tools to manage the increasing volumes of electronic health information. Taking control of preservation is one affirmative and proactive step that will be beneficial regardless of the direction the healthcare industry is headed.