

# HIPAA Compliance

*Using the LMS to Deliver Training and Manage Change in a HIPAA-Regulated Environment*

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## Executive Summary

The *American Recovery and Reinvestment Act* (ARRA) includes provisions that make it even more of a challenge for organizations to comply with the *Healthcare Information Portability and Accountability Act* (HIPAA). Among these are provisions set out in the *Health Information Technology for Economic and Clinical Health Act* (HITECH) that for first time require “business associates” to comply with the same HIPAA privacy, security and breach notification obligations as HIPAA-regulated healthcare organizations.

Broader coverage of business associates coupled with high staff turnover (especially within the healthcare community) are requiring organizations to create more robust training solutions to serve multiple locations and types of learners and manage e-content as well as instructor-led training. Meanwhile, training content continues to evolve rapidly as issues such as e-medical records raise new challenges for maintaining HIPAA-mandated portability, privacy, and security.

In addition, stiff new penalties for non-compliance apply. With the Obama administration making enforcement a priority, it's crucial for organizations not only to deliver broader-than-ever training to a broader-than-ever base of people, but to establish best practices and documentation that make sure the HIPAA training program, process and participation are fully accountable — and auditable.

In this rapidly changing HIPAA environment, organizations with an enterprise learning management system (LMS) will have a significant advantage in both delivery of training *and* in regulatory compliance.

The key to choosing the right LMS, however, is making sure the system does more than automate the learning process and distribute content to learners at multiple locations. Organizations should also give due diligence to flexibility and the system's capacity to deliver and *manage* instructor-led and e-content training, including both “off the shelf” content and custom content. Because learning content management systems (LCMSs) focus primarily on managing online learning content, they typically lack the versatility necessary to manage the full range of training, certification and continuing education formats within the HIPAA environment. Finally, the ideal enterprise-model LMS should be a proven performer in highly regulated environments, capable of providing the documentation needed to track ongoing training and help assure — and prove — regulatory compliance.

## Introduction

Implementation and enforcement of the *Healthcare Information Portability and Accountability Act* (HIPAA) began on April 14, 2003, adding a complex set of rules to the OSHA, JCAHO, CMS, EPA and FDA regulations many organizations were already required to meet. Since then, innovations such as Electronic Medical Records (EMR) systems and Electronic Health Records (EHR) have prompted ongoing evolution of regulatory guidance and compliance as well as the training programs necessary for meeting HIPAA requirements.

In February 2009, compliance and training grew even more complicated with enactment of the *American Recovery and Reinvestment Act*. This sweeping piece of legislation contained *Health Information Technology for Economic and Clinical Health Act* (HITECH) provisions that made substantial changes to HIPAA and — for the first time — “business associates” are legally obligated to comply with the same patient information privacy and security obligations as HIPAA-regulated healthcare companies.

This means that a broader-than-ever array of organizations must now comply with HIPAA requirements, including:

- Healthcare providers, payers, and data services
- Insurance companies
- Company HR departments and safety offices
- Pharmacies (including those located in grocery stores)
- Third-party business associates

HIPAA compliance has always involved rigorous training. Now, the HITECH provisions mean more organizations must address the need for HIPAA training. At the same time, HIPAA learning content itself must now reflect changes involving everything from e-medical records to tracking and accounting for the use and disclosure of all protected health information.

Courseware and curricula are, however, only half the picture. A sound HIPAA training strategy must also provide the records *and audit trail* to document the effectiveness of programs and processes for staff training, continuing education and certification. The Obama administration has made clear that it intends to move from an educational to an enforcement stance on HIPAA, and the HITECH provisions include severe civil and criminal penalties for noncompliance. In this environment, training is critical in making sure staff, contractors and partners understand exactly what to do in situations ranging from a breach of information to applying the latest HHS technical guidance.

In summary, the requirements for a training solution to successfully support HIPAA compliance include the capacity to:

- Make training accessible to a wide range of learners, organizations, and dispersed locations
- Support a variety of training formats (e-learning, instructor led)
- Deliver and *manage* a vast array of content (standards, compliance, institution-specific policies and procedures)
- Provide record-keeping and auditable documentation
- Seamlessly integrate new learning content as regulatory requirements continue to evolve

## The HIPAA Training Solution

In terms of reach, reliability and regulatory compliance, the best way to meet HIPAA requirements is with an enterprise-level training solution. Even better is having an **enterprise e-Learning initiative managed by a scalable Learning Management System (LMS)**. This combination consolidates all HIPAA training efforts on one platform.

By serving as the main training and the main record-keeping platform for all HIPAA training, the enterprise-level LMS:

- Ensures that all employees have access to appropriate training when they need it
- Delivers basic HIPAA Web-based courseware *plus* institution-specific content, instructor-led classes, on-the-job training, simulations and even document reviews
- Tracks all training events
- Makes it easier to keep content aligned with the latest regulatory revisions
- Reduces IT infrastructure, travel and training costs
- Minimizes potential liability for mistakes or noncompliance
- Facilitates successful federal and state audits by providing bulletproof audit trails

## What is an Enterprise-Level LMS?

An LMS (learning management system) is a database application specifically designed to deliver and manage Web-based and classroom learning and to provide the resources, logistics and tracking to support and document the learning. The LMS manages the data involved with all learning activities and automates many of the record-keeping, delivery and notification processes that otherwise bog down training administrators.

An enterprise-level LMS can offer many features. The core functionality of any LMS, however, should include its ability to:

- Maintain a course catalog
- Provide a central record-keeping system
- Manage training facility scheduling
- Manage individual training assignments
- Manage the class enrollment process
- Provide a common source of training status reports

- Provide access to and tracking of e-Learning

A large percentage of Global 2000 companies have at least one LMS, and some companies use several to manage different types of learning data. The trend, however, is toward consolidating multiple LMS systems onto one platform. In any business environment, moving to a single training platform offers significant advantages in terms of cost and administration. In environments where training is highly regulated, having this single-platform becomes a crucial part of the compliance strategy, giving organizations tighter control over both training activities and documentation.

## The LMS as a Foundation for HIPAA Compliance

**An organization can deliver all the right courseware and curricula *and still fail HIPAA audits.***

This is due to an often-overlooked phrase in the general administrative requirements for HIPAA — *45 CFR 164.530(b)(2)(ii)*: “A covered entity must document that the training ... has been provided.” This small mention of documentation can make the difference between successful HIPAA compliance and embarrassing — and catastrophically costly — audit failure.

“Documenting that training has been provided” requires more than recordkeeping. In light of precedents set in HHS audits, organizations may have to go the extra step to prove the *integrity* of those training records, such as verifying the authorization of the person who originated the records. Thus, training records must be complete *and* completely auditable. Fortunately, there are LMS applications whose internal management features have already been tested in highly regulated training environments and can document real world success in helping organizations successfully navigate audits.

With its ability to launch online courses, schedule different types of training and track who took what when, the LMS essentially provides “regulated training.” By applying this regulated approach to training within the HIPAA environment, the LMS gives organizations the advantage of being able to:

- Track non-course training requirements such as procedures, on-the-job training, certifications, etc
- Manage training revisions: documents, manuals, procedures (SOPs), coverage guidelines and code sets
- Provide comprehensive data audit trails to prove that data used in the LMS is accurate and unadulterated
- Manage credit-based and hours-based training requirements to fulfill local, state and professional licensing and certification requirements
- Unify all training requirements into one system, simplifying overall record-keeping and providing a comprehensive view of each individual’s training progress and needs

Until 2009, HIPAA did not expressly discuss the penalties for inadequate training record keeping. But now, provisions in the *HITECH Act* have given HIPAA regulations “teeth,” mapping out monetary, civil and criminal penalties. According to [SearchCompliance.com](http://SearchCompliance.com), expect to see a trend toward more criminal prosecutions and compliance enforcement activities. The LMS can function as a frontline defense in this new environment.

## The LCMS vs. LMS in HIPAA Training Management

As an alternative to the LMS, some organizations consider a learning content management system (LCMS).

An LCMS is designed to manage the delivery of online content, and may be “bundled” with a purchase of HIPAA training content. There are two major drawbacks to using the LCMS instead of the LMS:

1. **The LCMS is good for managing online content only.** For some single-purpose, online-only HIPAA training content, an LCMS can provide a “quick fix,” but its usefulness over the long-term must be questioned, especially in light of the blended content used by most HIPAA training programs.
2. **Most LCMS applications are not designed to operate in a highly regulated environment** and do not provide the documentation capabilities that can make all the difference in the outcome of an audit.

### Summary comparison of the LMS vs. the LCMS

	LMS	LCMS
Content Delivery	Manages all types and combinations of content deliver: online, instructor-led, self-paced and on-the-job ( <i>critical for HIPAA training that includes blended delivery</i> )	Manages online content only
Content Management	“Best of breed” LMS applications include most (if not all) of the content management functionality of LCMS applications	Excellent functionality for managing online content only
Compliance Support	Good LMS applications provide transaction audit trails, recordkeeping, and security features to help streamline — and document — HIPAA compliance	Most LCMS applications are not designed to operate in a regulated environment and do not provide the documentation HHS auditors may require to prove compliance
Enterprise-level Value	The LMS offers full enterprise management capabilities, creating a single platform not just for HIPAA compliance, but for enterprise-wide attainment of strategic training and business goals	Most LCMS applications can integrate with major LMS systems, combining features such as in-depth talent management and skills-based content management with the full enterprise management capabilities of an LMS

## Choosing the Right LMS

**Any LMS chosen to support HIPAA training and compliance will come under scrutiny by HHS auditors.**

There are many LMS applications available. Unfortunately, not every LMS delivers the record-keeping and reporting functionality needed to pass intense HIPAA auditing. Thus, choosing the right LMS is a critical factor in reducing the risk of audit problems — and the potential for monetary, civil and criminal penalties.

To reduce the chance of choosing a system that could fail to support compliance, due diligence should address HIPAA-specific requirements.

As a guide, here seven HIPAA-related questions to ask LMS vendors at the start of the selection process:

**1. Is the LMS currently managing auditable training data for an organization subject to HHS regulations? If so, are case studies available?**

Many HR, personal development and corporate training efforts are subject to HHS regulations, but not subject to audits. So, even though LMS applications may be in use at HHS-regulated organizations, *it doesn't necessarily mean the systems are used for auditable training records*. If a vendor is unable to provide case studies of the LMS managing auditable training data, there is no way to know beforehand whether the system is robust enough to stand up to the rigors of an audit.

**2. Does the LMS keep complete copies of records that have been modified or deleted?**

This functionality allows the organization to rebuild the state of the HIPAA training program at any time in the past. This will prove to be a critical capability during investigations when auditors may ask organizations to providing — and document — this type of training data.

**3. Does the LMS provide a user, date and time stamp for auditable transactions?**

HIPAA auditors are increasingly concerned about verification of training data. Time and date stamping helps prove “who did what when.” Combined with the ability to see the status of the training program at any given time, the time and date stamping can establish the chain of changes made to data and identify and verify the authorization of the persons originating those changes.

**4. Does the LMS guarantee the uniqueness of each administrative user?**

Over time, administrative users will come and go. Assuring the complete accuracy of historical data means giving each administrative user a unique identifier. This establishes who created, modified or deleted data, no matter how long ago the person worked for your organization.

**5. Does the vendor have experience developing functionality to specifically meet HHS requirements?**

The LMS is a mission-critical system. If it cannot respond to changes in regulations or agency guidance, it can put your business at risk. By asking about vendors' history in responding to regulatory changes, you gain trouble-shooting insights into their capacity for supporting your HIPAA compliance as requirements, training content and best practices continue to evolve.

## 6. Has an HHS-regulated customer ever stopped using this LMS and if so, why?

Some vendors claim to have implemented systems for various organizations, but those customers have subsequently stopped using their LMS. This is often due to changes in technology or standardization involving other applications. Sometimes, however, organizations stop using the LMS because it does not meet their needs in the regulated environment, or because the vendor doesn't support them well. This question forces the vendor to discuss losses and potential product shortcomings.

## 7. Have you ever had a failed implementation at an HHS-regulated customer and if so, why?

There is a big leap between purchasing the LMS and successfully implementing it to manage auditable records. This question forces the vendor to address any potential shortcomings of their product related to regulatory compliance issues. You may not find a vendor that has a 100% perfect implementation record. Some very good products have had failed implementations through no fault of the product or the vendor. The key is using the question to understand *why* implementations may have failed.

These questions are just examples of the due diligence necessary before purchasing an LMS. Clearly, the knowledge, experience and capability of the vendor are almost as important as the capability of the system.

Make sure the selected vendor understands *specifically* what the LMS must do to support HIPAA compliance in your unique organization. The key is to establish a level of confidence that the vendor offers an LMS with a proven track record in managing highly regulated training — particularly in the healthcare arena — and can provide the support necessary to keep the LMS aligned with changes as regulations and content evolve.

## Beyond HIPAA

### The LMS can drive improvements in employee performance, quality control and business processes.

Organizations often view HIPAA training as a cost center and invest in “spot solutions.” But if HIPAA is viewed as one training need within a larger enterprise learning strategy, the selection of an LMS can result in a tangible return on investment (ROI) in many other areas of the organization.

For instance, an enterprise-level LMS can:

- Improve overall regulatory compliance and risk management
- Reduce administrative staff time and training costs
- Align learning initiatives regulatory requirements *and* strategic business goals
- Customize learning to thousands of individual students
- Support *all* types of learning: new-hire training, e-learning for certification and continuing education, role-based training, on-the-job training, etc.
- Assess worker competencies and give administrators a clear view of who should be selected for a particular assignment.

## Conclusion

From training delivery to documentation, HIPAA significantly raises the bar on compliance not just for healthcare-related companies but also their business associates. With audits expected to intensify — accompanied by the potential for stiff monetary, civil and criminal penalties — organizations that address HIPAA training with an enterprise-level LMS will have a significant advantage not only in assuring compliance, but in reducing the administrative burden and cost of training as well.

Not every LMS is equipped to support organizations within the highly regulated HIPAA environment. By asking the right questions during the selection process, however, organizations can identify systems and vendors with proven capacity to support the wide range of curricula and learning opportunities necessary to train staff *plus* the documentation necessary to navigate HHS audits successfully. In addition, the enterprise-level LMS can serve as a unifying platform to support strategic training and staff development goals throughout the organization.

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