

# **Health Insurance Portability and Accountability Act**

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**The Impact of HIPAA on Pharmacy and Emerging  
Compliant Pharmacy Information Technology**

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## **1. Overview**

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With the healthcare industry in the US rapidly expanding and modernizing, a technological push has resulted in many healthcare providers implementing process changing and cost efficient technological innovations. However, a recent focus on security and privacy of health records and information, called for by the United States HIPAA legislation, has conjured a new focus within the industry.

Pharmacy, with increasing demand for prescriptions and patient care, is a key player in both technological modernization of processes, and the requirement for security and privacy compliance of protected healthcare information. Taking a broad look at newly emerging technologies, with a focus on pharmacy automated systems and paperless physician order entry, pharmacies are fighting both the costs of increased demand and labor, and need for HIPAA compliant privacy and security safeguards, with an implementation of these new technologies.

## **2. Introduction to HIPAA**

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The Health Insurance Portability and Accountability Act, known as HIPAA, was a response to an increasing need to streamline the healthcare industry and respond to technological growth. Enacted in 1996, it emended the Internal Revenue Service Code of 1986, providing sweeping changes to all aspects of the healthcare industry, from patient care to administrative information systems. [WIKI] Also known as the Kennedy-Kassebaum Act, the overall goal of HIPAA is to not only provide health insurance portability between healthcare providers, but to offset costs and standardize health information. With healthcare technology increasing exponentially, electronic medical

records, process automation, and paperless health forms became both realizable and extremely cost efficient in the healthcare industry. HIPAA aims to not only regulate the privacy and security of patient information, but to standardize and govern rules for safe healthcare IT practices, and employee best practices. [PharmLet02]

## **2.1 Key Terminology**

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The HIPAA documentation employs key terminology in the description and guidelines of the regulation. *Protected Health Information*, often referred to as PHI, is any health information that HIPAA classifies as required to be private and secure. PHI refers to patient information that identifies the patient, describes the patient's health condition in the past, present, or future, and is transmitted between entities. It can be in many forms, from oral communication, to patient charts, prescription records, and billing records. [PharmLet02]

*Covered Entities* refers to any party that provides either direct patient care, or has access to PHI. Examples of covered entities can include individual doctors, healthcare institutions, pharmacies, and businesses such as health insurance companies who have access to patient information. Covered Entities must comply with all forms of the HIPAA regulations, including privacy and security guidelines [PharmLet02]

*Hybrid Entities*, while similar to Covered Entities, may not need to comply with all of the HIPAA regulations. These Entities, although in contact with Covered Entities, do not directly deal with PHI. An example of this would include the "front end" employees working at a retail pharmacy. As long as proper security measures are in place

in order to keep PHI within the Covered Entity locations, Hybrid entities would not need HIPAA training or compliance. [PharmLet02]

A *Business Associate* is not a member of the direct healthcare workforce, however provides services and functions in which PHI may be disclosed. This can include claims processing, administration, IT services, auditing, billing, and other forms of services which may involve the use of PHI. Business associates also refer to the relationship between pharmacies and other healthcare providers that occasionally work in conjunction to perform a healthcare service. Because of the association with PHI, Business associates have to follow the specified HIPAA regulations. Most are considered Covered Entities. [DHHS]

*Healthcare Clearinghouse* refers to a public or private entity, in which the main purpose is to provide standardization of PHI or translation of standardized data into a non standard input form. Healthcare Clearinghouses include health management information systems, billing services, and “value-added” networks and switches, and are considered Covered Entities. [DHHS]

## **2.2 Contents of HIPAA**

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HIPAA contains two Title sections. Title I of HIPAA addresses the protection of health insurance coverage for workers and family members when an interruption of employment occurs. Title II defines offenses in relation to the healthcare industry, and lists penalties, both civil and criminal, for health information tampering, fraud, and abuse. Title II’s key provisions are known as the Administrative Simplifications (AS). Within these provisions, the AS provides five subsections: the Privacy Rule, the Transactions

and Code Sets Rule, the Security Rule, the Unique Identifiers Rule, and the Enforcement Rule. [WIKI] The Administrative simplifications are instrumental in both regulation and compliance of both IT and employee practices. The Privacy and Security Rules are stressed as the key provisions governing IT and employee best practices in the handling of PHI.

## **2.3 Privacy Rule**

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The Privacy Rule in HIPAA's Administrative Simplifications, taking effect April of 2003, establishes proper procedures and regulations in use and disclosure of PHI. In general, the Privacy Rule attempts to provide protection of health information by not only presenting statures for the regulation of it, but rights of both patients and entities in use of PHI. [WIKI]

The Privacy Rule calls for the appointing of a Chief Privacy Officer, whose main responsibilities are to develop and implement policies to assist in the compliance with the regulations listed. The Chief Privacy Officer also deals with direct complains and issues with privacy from the customer to the employee. [PharmLet02] Covered entities must also identify all PHI used within the entity's functions, and those who have access to it. Policy dictates that records must have standard form, and must be disclosed to patients upon request. [Cutiletta07]

Specific regulations in the Privacy Rule govern proper disclosure of PHI. Throughout the Rule, a common prevalent concept is minimum necessary disclosure, in which the Rule states that providers should only divulge the absolute minimum amount

of patient information needed for the service or care in order to minimize unlawful disclosure of PHI. [PharmLet02] Special concerns also include rules governing the proper disclosure of PHI to business associates, hybrid entities, and for use in research, marketing, and philanthropy. [Cutiletta07]

Finally, the Privacy Rule states key regulations in employee training and compliance. Privacy Officers and administrators are required to create, distribute, and track a “Notice of Privacy Practices.” Written in plain language and outlining rights of both patients and entities, the Notice explains employee duty to maintain rights of the patients, describes permissible ways in which PHI may be used and disclosed by employees, and outlines patient abilities to deny disclosure of their information. [Shaw]

## **2.4 Security Rule**

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As the Privacy Rule defines rules and procedures for keeping PHI private, HIPAA’s Security Rule defines standards and implementation specifications to entities in order to keep PHI secure. The essence of the security rule is that covered entities must assess the potential risks and vulnerabilities in electronic maintenance and transmission of PHI, develop, implement, and maintain appropriate security measures, and document and update these measures. [Cutiletta07]

Established shortly after the Privacy Rule, the Security Rule is comprised of six principle sections. The General Rules section provides an overview of general requirements for covered entities. Organizational Requirements provides guidelines for business associate interaction, and group health plans. The Policies, Procedures, and

Documentation Requirements section asserts that any standards and implementations provided by the Security Rule must be documented, made available to all employees within a covered entity, and must be frequently updated and retained within the organization. [Cutiletta07]

The following three sections of the Security Rule establish three types of safeguards a covered entity must abide by for HIPAA compliance. Administrative Safeguards account for more than half of the Security Rule, and establish requirements for management, security, operations, and electronic PHI access. [Cutiletta07] Physical Safeguards provide guidelines to controlling physical access and protecting PHI from unauthorized use of facilities, workstations, and equipment. [WIKI] Finally, Technical Safeguards provide policy and procedure for technology that utilize PHI. From access control, audit controls, authenticity, and integrity, the Security Rule's Technical Safeguards outline policies such as unique user identification, emergency access, automatic logoff, and encryption, all in order to keep PHI secure. [CMS07]

What is key about the Security Rule, as with much of HIPAA, is the fundamental concepts of flexibility, scalability, and technological neutrality. There are no specific requirements in terms of types of technology and how to implement guidelines outlined within the Security Rule. It allows for covered entities to appropriately implement standards and compliance measures how the entity sees fit, in order to eliminate compatibility and technology issues. [CMS07] The Security Rule simply provides standards (what must be met), implementation specifications (how one might meet standards), and which standards are required or addressable if need be. [Cutiletta07]



### **3. Introduction to the Pharmacy Industry**

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The Pharmacy industry within the United States is rapidly expanding. With chain pharmacies such as Walgreens and CVS; pharmacies within large retail centers such as Walmart, Target, and Meijers; pharmacies within supermarkets and shopping malls; and outpatient pharmacies associated with hospitals and clinics, Americans are readily able to fill their prescriptions at the most convenient of locations. Institutionally, there are large pharmacies stocked with thousands, often times millions of dollars of medication in every hospital and health center. Prescription volume in the nation is continuing to grow by leaps and bounds. And in the center of all of this, HIPAA regulation stands.

#### **3.1 HIPAA and Pharmacy**

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Pharmacies are considered ‘covered entities’ which therefore require HIPAA compliance. Every retail pharmacy, clinical pharmacy, and online pharmacy, because of close association with PHI and insurance billing, must be HIPAA compliant. Although HIPAA stresses flexibility in policy and compliance, the pharmacy industry and pharmacy technology have been undergoing rapid changes to not only incorporate HIPAA, but introduce new, cost saving devices to meet the growing demand of consumers. [CDR04]

All practicing pharmacists with direct association with patients and records must comply with HIPAA. Within the pharmacy, generally both technicians who handle front end operations and filling of orders, and the pharmacists who directly enter, check, and

distribute the medication orders, are considered covered entities as patient information, such as the medications in which they are taking, are considered protected. Pharmacists are even considered to have “direct treatment relationships” with patients, in both a clinical and retail setting, requiring compliance with the appropriately outlined HIPAA policies. [PharmLet02]

This means, in general, that anything that applies to covered entities would be required by pharmacies to comply to and make policy for. Privacy Officers are required; however chain pharmacies and healthcare centers would only require one Chief Privacy Officer to oversee entire operations. Technological and other safeguards as outlined by the Security Rule apply directly to operations, pharmacy technology, and the handling of PHI. All pharmacy employees, as well as any business associates to pharmacies who come into contact with PHI, must have appropriate HIPAA training and compliance before entering the workforce. [PharmLet02]

## **3.2 Institutional Compliance**

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Institutional pharmacies, defined as pharmacies within a hospital, nursing home, hospice, or health clinic setting, provides specialized healthcare services and employ a larger variety of medication types as compared to that in a retail setting. Because of this, employee and IT HIPAA compliance within an institutional pharmacy may require special guidelines to meet operational and organizational needs. Because speed of service and departmental coordination are stressed in such a setting, specialized training practices and IT regulations are often employed.

As required by HIPAA, healthcare institutions, like other covered entities, are required to release a HIPAA Policy Manual to all departments, covered entities, and made available to all employees within the organization. Weiss Memorial Hospital, a leading healthcare provider in Chicago, Illinois, provides such a document for its organization. [Weiss]

Prepared by its parent company Vanguard and its Chief Security Officers, Weiss Memorial's HIPAA Policy Manual is sectioned into four distinct parts, covering all relevant and required HIPAA guidelines: individual rights of patients, restrictions on use and disclosure of PHI, administrative requirements, and business associate requirements and agreements. Within these four sections, topics from employee training, privacy issues, complaints, proper use of PHI, to acceptable secure IT practices and patient requests, are documented with appropriate and standardized forms relating to the individual sections. The Weiss Memorial pharmacy director is required to ensure that the pharmacy department complies with the HIPAA Policy Manual, and that the documentation is made available to all pharmacy employees. [Weiss]

Looking closer at employee compliance of HIPAA policy in an institutional setting, employees of Resurrection Healthcare, a system of hospitals and nursing centers in the Chicago and suburban areas, require mandatory HIPAA training to all newly hired employees, as well as annual recursive HIPAA compliance tests to all concurrent employees. In initial training, a PowerPoint presentation is given to new hires, outlining contents of the act of the Act, penalties involved in unlawful disclosure and practices, and Resurrection's own compliance enforcement and implementations of the Act. In particular, safe IT practices are often the focus, as PHI vulnerability is considered to be a

top issue in hospital IT. A test is then administered before new employees are allowed to work, with questions, again mostly IT related, and considered basic yet of most relevance to PHI security and privacy. [Res]

Resurrection Healthcare stresses simple, yet key employee compliant best practices relating to IT. Employees create secure logins and passwords to access patient information, and are required to update login and change passwords on a frequent basis. Simple practices like are instigated, such as facing workstation monitors away from patients, the public, and those who do not have permission to view PHI, as well as requiring logoff of unused workstations and instigating an automatic logoff after a certain period of inactivity. Transferring of PHI can only be done both physically and electronically using secure means. In general, employees are required to take justified and appropriate precautions in all practices relating to PHI security and privacy. [Res]

IT and technology itself obviously must also comply to HIPAA rules and procedures, especially so in an institutional setting. PHI is frequently transmitted through large intranets between departments and different healthcare providers within each healthcare system like Resurrection. As HIPAA states, encryption of protected data and transmissions of PHI is required, as well as secure login of PHI accessible workstations. Institutional pharmacies use a wide of technology and software systems, from hospital wide patient ordering systems, to lab report printout systems, and labeling software. Pharmacies work closely with IT vendors for frequent software updates, HIPAA compliance issues, and new technology implementations.

### **3.3 Retail Compliance**

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Retail pharmacies, although similarly regulated as institutional counterparts are, operate in slightly different manner. Because retail pharmacies, such as Walgreens or CVS, do not have to be as responsive to critical patients, nor coordinated with in-house doctors and nurses, different business functions have to be taken into account. Retail pharmacies deal with a wide variety of patients, networks of insurance companies, and must coordinate with countless healthcare providers in order to distribute prescribed medications to customers. Because of this, HIPAA rules and regulations must be adopted to not only the difference in setting, but the difference in operation.

Walgreens provides both employees and customers HIPAA compliance guides and patient privacy manuals on their website. Identifying the concept of PHI, Walgreens lists safe use practices, punishment and violations, in-house policy, and patient rights within their online HIPAA guides. Much like the institutional example, Walgreens also requires employees to take HIPAA compliance tests and demonstrate HIPAA safe practices in the workplace. Because of greater potential exposure to the general public and other retail employees who may be considered hybrid entities, retail pharmacies such as Walgreens may require even greater precaution with the privacy and security issues within pharmacy IT practices. [Walg]

### **3.4 Implications of HIPAA Implementation**

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The effect of HIPAA on pharmacy has been significant since its creation and initiation. The goal of compliance has affected not only business practices, but management, patient care, and IT. The Privacy and Security rules have had major influence on practices of pharmacists and support staff, as protecting PHI has become both a required and a key business process. Costs of implementation, however, have been vast in all areas of healthcare.

While before HIPAA, protecting patient privacy was an important part of medical professionalism, the lengthy and complex legislation of the act has had major tolls on healthcare with opposition by many physicians and professionals. Huge costs were incurred in all areas of the healthcare industry, including pharmacy, for employee training, IT and best practice compliance, and required change in business practices in order to protect PHI. Pharmacists and other medical professionals, caught up in the dictation and complexity of the act, have become overly cautious in withholding patient information, some of which might have been beneficial and legal for optimal patient care. Although pharmacy technology has gone through vast updates and transformations in order to secure PHI, pharmacies have been increasingly modernizing, adopting HIPAA compliant technologies and seeing large monetary and patient care benefits. [WIKI]

## **4. Emerging Pharmacy Technology**

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The Pharmacy industry is rapidly growing and modernizing. To provide the best service, patient care, and to meet ever growing volume of prescriptions, pharmacies have been employing new efficient technologies. Helping to eliminate costly processes, reducing tiers of labor required for pharmacy services, and providing the fastest and most secure patient care, newly emerging pharmacy technology, some already being adopted into many hospital and retail pharmacies, are aiding in compliance with the privacy and security standards of HIPAA.

Pharmacy processes revolve around getting patients the medications and treatments they need. In the past 20 years, pharmacy ordering systems have gone from a purely paper filing system, to specialized order entry software. In addition, integrated lab result systems, drug counting and labeling systems, and supply management systems have streamlined the business processes of pharmacy patient care. New cutting edge technologies being developed and implemented, such as paperless prescriptions and pharmacy automation machines, have provided great benefits and widespread adoption throughout the pharmacy industry.

### **4.1 Pharmacy Automation**

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Both retail and institutional pharmacies are increasingly adopting the usage of pharmacy automation systems. Labor and costs associated with the prime business function of pharmacies, prescription filling, has remained constant, while demand for

medication and prescriptions has increased exponentially. As technology developed, healthcare system providers developed automated systems for replacing the hands-on process of filling and delivering patient medication.

Originally, prescription medication was filled and delivered to patients and floor stock manually. Coordinated with technicians, pharmacists would enter incoming orders, technicians will fill the orders with the appropriate medications, pharmacists would check the filled orders, and delivery out to patients would be done by technicians or other healthcare support staff. Pharmacy automation, in both forms of medication counting machines, and automatic delivery machines, are beginning to replace the manual processes. [CDR04]

When a pharmacist enters the prescription order, automated machines such as Cardinal Healthcare's Pyxis system or McKesson's AcuDoseRx and RobotRx take over in the distribution of the medication. These machines are stocked with a supply of common pharmacy formulary medication, and upon receipt of the order through the system, can count out, label, and dispense the appropriate dose. Institutionally, many of these automated systems can even deliver this medication through a series of transport systems throughout the hospital. Patients receive their medication faster, with less chance of error or accident, in order to provide the best possible pharmacy healthcare. [McKesson]

Pharmacy automation is not only viable, but already being adopted widespread in many pharmacies, both retail and institutional, across the nation. Handling hundreds of prescriptions daily, large pharmacies in almost every light can benefit from the cost saving and labor-saving functionality of automation. Companies such as McKesson and



Cardinal also enter into long lasting relationships with their buyers, providing repair and updates to their systems. It is predicted within a decade, that almost every pharmacy will utilize some sort of drug automation system. [CDR04]

## **4.2 Physician Order Entry and Paperless Forms**

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Hospitals are vastly modernizing, moving away from tradition paper records, forms, and physician orders, to completely electronic paper-less systems. Pharmacies have already seen benefit from paperless adoption, especially in the forms of electronic doctor order entry, and paperless documentation and forms. Preventing costly errors, aiding in security, and streamlining many hospital practices, full scale paperless systems are efficient and extremely desirable in an institutional setting.

Pharmacies are seeing widespread benefit in hospitals which have implemented electronic physician order entry. Instead of a physician writing a patient order for medication on prescription paper, then having to deliver it to the pharmacy by way of nurse or technician, physician order entry allows doctors to enter a prescription directly into a PDA or workstation, so that pharmacists can instantly and securely receive and fill the order. Electronic physician order entry reduces labor costs associated with the process, as well as providing fast patient care and error-free means of transferring the patient prescription.

Companies such as SafeRating provide paperless, web hosted electronic forms for pharmacies and other healthcare processes. Secure and reliable, electronic paperless forms eliminate the use of paper to report on events such as medication errors, adverse drug reactions, pharmacist clinical interventions and system-wide incidents. Pharmacies

can capture cost and labor reducing advantages over paper form counterparts. Being completely electronic, security and privacy issues are also addressed by vendors such as SafeRating. [Saferating]

### **4.3 Other Pharmacy Technologies**

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Many vendors are providing new technologies to streamline and economize pharmacy processes. From backup systems, to security solutions, vendors are offering technologies specifically focused and tailored to pharmacy needs. Because security and privacy are becoming increasingly important in the industry with the adoption of HIPAA, almost every technology vendor offers HIPAA compliant features and guarantees.

In the retail sector, Walgreens is starting to adopt a system of E-Prescribing. Much like how electronic physician order entry works in an institutional setting, E-Prescribing allows doctors to fill out patient prescriptions using an electronic form for Walgreens to receive. E-Prescribing allows complete patient prescription information to be transmitted, reduces the errors associated with transcription and communications, and provides a secure, tamper-free means for the retail location to receive prescription orders. With Walgreens' already implemented satellite network connecting all their locations, E-prescribing provides a secure and cost beneficial advantage to the prescription receiving process. [Simko07]

VeriSign, Inc., who provides transaction and communication encryption and security to a wide variety of markets, has developed healthcare solutions specifically tailored for support of HIPAA compliance. Offering security solutions such as

compliance and risk assessments, encryption and authentication technologies, access control, and data exchange, VeriSign provides HIPAA security management services and guarantees compliance with specified sections of the HIPAA Security rule. [Verisign]

HIPAA compliance is also pushing for PHI data backup solutions. Vendor Lakeview Technologies, providing infrastructure and data storage software, is starting to implement their MIMIX dr1 technology in health care environments. The technology not only provides hourly automatic backup of PHI, it helps healthcare centers comply with strict HIPAA policy, and claims ease of use and management. The technology is being adapted to back up accounts payable, order entry, emergency room, radiology, laboratory interface, patient data, patient diagnosis, pharmacy and insurance information. [Lakeview]

Large IT consulting firm Infosys is offering a new “total package” pharmacy IT management solution. Their Pharmacy Benefit Management Services offers crucial services such as claims processing, network management, clinical support, and data reporting, all tailored to a pharmacy setting. Infosys emphasizes regulatory compliance and broad knowledge of HIPAA, and guarantees HIPAA compliant formats along with privacy and security regulation. With modular expandable capabilities, Infosys’s Pharmacy system ensures increased flexibility and greater cost savings. [Infosys]

#### **4.4 HIPAA IT Ramifications**

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With prescription rates on the rise, pharmacies have not only gotten busier, but patient care has become more in-depth. Pharmacies are employing technologies such as

automation and paperless prescriptions and forms in order to provide faster, more efficient and cost saving patient care. With HIPAA compliance now enforced, pharmacies need to be more secure, keeping PHI private and protected. Technologies such as automated PHI backup, secure encryption and authentication, and compliancy management systems, allow pharmacies to provide the security and privacy required in the HIPAA documentation.

A correlation between these two technological pulls does exist however. Automation and paperless adoption is actually promoted by a need to become HIPAA compliant. Working in conjunction, automation and paperless orders allow pharmacies and healthcare centers to, in a sense, become more private and secure with handling of PHI. Because paper orders and forms are hard to keep track, with greater possibility of PHI leaks, digitizing entire pharmacies and even hospitals will allow IT departments and administrators to keep track of this sensitive information. This also means less exposure of PHI on paper form as prescription orders travel from doctors to pharmacies. Automation also reduces exposure, as patient medication orders are filled automatically and travel directly to the patient floors. In conjunction, these technologies eliminate layers of labor required for the prescription filling process, which in turn also eliminates excess exposure to PHI. With technologies implemented specifically for HIPAA compliance like encryption, security systems, and backups, pharmacists can focus less on HIPAA compliant practices and disputes, focusing more on patient care and fast service.

The most important idea to employees in the healthcare industry, such as doctors, pharmacists, nurses, and technicians, is providing the best possible, error free patient care to patients. Slow, erroneous care could cost patients their money, their health, even their

life. With technological advancement in a healthcare setting, especially in pharmacy, technologies not only provide faster care with fewer errors, but reduce costs and labor associated with core processes, and provide privacy and security to patients in accordance to HIPAA regulation.

## **5. The Future of HIPAA in Pharmacy**

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Compared to the many sectors of the healthcare industry, it's not surprising the pharmacy is on top of already implemented HIPAA compliant technologies. With cutting edge, process changing technologies such as automation and paperless order entry, pharmacies are not only capturing greater efficiency of scale of doing business, but are aiding in the HIPAA complacencies of their practices. The push itself to become HIPAA compliant has even promoted many pharmacies to consider these technologies for implementation.

There has been much resistance to HIPAA in the healthcare industry, specifically by doctors. With technologies that benefit both compliance and practice, pharmacies however have benefited from a forced fulfillment of this new regulation. HIPAA, however, isn't over in pharmacy. Many pharmacies and pharmacy employees are still working to employ better practices, new information technologies, and greater security of PHI. With the rest of the industry struggling to reach compliance, new emerging technologies, that may promote even greater HIPAA compliancy and cost saving synergies, are bound to make an appearance in the coming years.

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