HIPAA Regulations and Podiatrists

It's important to abide by these rules.

BY LAWRENCE F. KOBAK, DPM, JD

Goals and Objectives

1) To have a working knowledge of how HIPAA applies to the podiatrist and the podiatry office.

2) To be able to detect how HIPAA would apply or not apply in common office and patient situations.

3) To be able to understand the concept of business associates and how it relates to patient privacy provisions.

4) To be able to determine how the HITECH Act impacts the practice of podiatry.

5) To understand the concept of protected health information and how it applies in the practice of podiatry.

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*Following this article, an answer sheet and full set of instructions are provided.—**Editor***

I. What Is HIPAA?

The Health Insurance Portability and Accountability Act (HIPAA) was passed by Congress and signed by President Clinton in 1996. It was meant to deal with patient privacy, security, and prevention of healthcare fraud. This law has been revised in 2000, 2003 and 2009. It is important not to lose focus that HIPAA was and is meant to protect the patient/consumer, not the healthcare providers. One note of caution is necessary; state law concerning privacy plays a role. In states where certain types of privacy protection go beyond HIPAA and HITECH, they must be observed by the podiatric practitioner.

PHI is an acronym for protected health information.

The four areas of protection for the healthcare consumer that are part of HIPAA are:

1) Privacy of health data
2) Security of health information
3) Medical records breach notifications and
4) The right to obtain copies of your healthcare information, such as your medical records.

II. What Is PHI?

Protected Health Information (PHI) under the HIPAA law is individually identifiable information that concerns the healthcare status of a specific person, in the past, in the present, or in the future. An example of the past would be a person's medical history. The present would be that you are currently being treated for a type of infection. The future might involve a genetic indicator that shows you are more likely to get cancer in the future. A podiatrist might consider the future to be a person's foot type or person's occupation that makes it more likely that the patient will experience degenerative arthritis in later years.

Names, addresses, phone numbers, email addresses, social security and insurance numbers are included as PHI. So are account numbers, license numbers, fingerprints, full face photographs, and other unique identifying characteristics or information. PHI is not just the information in a medical chart. It could include the name in an appointment book or a phone number in a card file.

III. What Is a Covered Entity?

A Covered Entity under HIPAA includes any healthcare provider, healthcare clearinghouse or health plan that conveys PHI in digital format. Let us focus in on healthcare providers. You, as podiatrists, are a covered entity, as you convey PHI in digital format, at least some of the time. You are a healthcare provider. Since 2013, with the Final Omnibus Rule, business associates are also considered covered entities as to coming under HIPAA law. Business associates are those you, as a podiatrist, do business with. As part of that business they do, they come in contact with people's PHI. The healthcare provider/podiatrist must have their business associates sign an approved Business Associate Agreement.

This agreement will spell out allowable uses of a person's PHI. For instance, a billing company can use PHI to facilitate processing medical insurance forms or electronic billing, but they may do not use PHI to contact a patient and refer them to an insurance broker to buy a health insurance policy. In turn, if your business associate subcontracts work to others that will interact with PHI, they too must sign a Business Associate Agreement with the entity that is subcontracting them. Any covered entity's employee is not a separate covered entity. The Business Associate Agreement that their employer signs covers them too. This also includes nurses supplied by an agency and volunteers. Your own employees do not need to sign a Business Associate Agreement.

Your outside billing service is an example of a Business Associate.

An exception to this rule that certainly would apply to podiatrists is if another specialist is treating your patient. The two of you want to confer and, in so doing, want to share PHI for the benefit of the patient. No business associate agreement is needed between the two treating healthcare providers. Nursing homes and pharmacies, under HIPAA, are considered healthcare providers and are covered entities. Remember, they must provide digital/electronic transactions, such as health claims to insurance companies, Medicare, HMOs, and the like. If you use an outsourced transcriptionist for your medical records, have them sign a business associate agreement with you.

IV. What Does the HITECH Act Have to Do with HIPAA?

By 2009, with the increasing use of IT services involving billing, marketing, and scheduling, more people were being involved with healthcare than just the providers. Enforcement of business associate agreements by the government was problematic the way the HIPAA law was originally enacted. The healthcare provider, such as the podiatrist, could claim she/he did not know that the covered entity was violating the HIPAA regulations and sidestep discipline. The HITECH Act of 2009, under President Obama, put considerably more teeth in the enforcement of PHI.

If a breach of PHI is discovered there is no presumption that the breach is harmful to your patients. A self-investigation is required to see the extent and likelihood of any improper spread of PHI.

This Act increased the breadth of HIPAA requirements and increased the punishment for violating HIPAA privacy. It also set in place the Breach Notification Rule. Notification of everyone involved in a PHI breach, such as a computer hard drive that was hacked, was required. The HIPAA Omnibus Rule, in 2013, helped to coordinate and modernize HIPAA and HITECH to include genetic information within HIPAA, along with other updates.

Of note, this last "Rule" was written by the Office for Civil Rights, Department of HHS. In other words, it is not a law passed by Congress, but a rule promulgated by a Federal Agency. Note of warning: these rules are as enforceable as a duly passed Congressional Law signed by the President. It closed a loophole with business associates. The business associates are now directly responsible for any PHI breaches. An obvious example of this relationship for the podiatry office would be an outsourced billing company that would have access to your office PHI.

V. Electronic Transaction and Code Set Rules and Security Rules

The HIPAA law mandated a single format to cover transmission of types of PHI documents that include healthcare claims. At the time, there were literally hundreds of formats for transmission of these claims. This standard format has been updated to include the use of ICD10-CM for coding diagnoses, the diagnostic codes that podiatrists currently use. It is imperative to make sure that your billing service adheres to the current set of transmission standard format.

Security Rules

The security rules that were adopted in 2003 apply to electronic health information (EPHI). This standard applies to all storage media such as hard drives, portable drives, thumb drives, memory cards, and magnetic tapes. You, or your personnel, must document and keep current what security measures you, the podiatrist, and your office are taking to keep your electronic files safe and secure. It should include the physical protection of the storage of your EPHI, the technical safeguards of the EPHI, in an attempt to avoid hacking and theft. It must, according to statute:

- Ensure the confidentiality, integrity, and availability of all EPHI that the covered entity [you] creates, receives, maintains, or transmits;
- Protect against any reasonably anticipated threats or hazard to the security or integrity of EPHI;
- Protect against any reasonably anticipated uses or disclosures of EPHI that are not permitted under the privacy regulation and
- Ensure compliance with the security regulations by the covered entity's workforce (45 C.F.R. §164.306).

It is important to emphasize that these security standards require your practice to assess what needs to be done to reasonably keep your EPHI safe, secure, and accessible. Note the work "reasonably". Cost is a factor in figuring out what is reasonable; so is the probability of security breaches in your practice. Your covered entities must also abide by these rules. It is your responsibility to ensure that they take these regulations seriously.

The fines are enforced by the HHS Office of Civil Rights, a Federal Agency.

VI. Penalties and Enforcement

Currently, for podiatry practices that were unaware of a PHI breach and would still have been unaware of it, had they showed reasonable due diligence, the fine goes as low as $100 per violation. If your practice should have been aware of a PHI violation with due diligence, the fines begin at $1000 per violation. With what is called "willful neglect" with no effort to rectify problems within 30 days of discovering a problem, the fines begin at $50,000 per violation. Per violation means that if your system was hacked, and potentially 1,000 patients' PHI were compromised, you multiply $100 by 1000, for the lowest level violation. That adds up to $100,000 in a relatively small violation scenario. The fines can really get your attention very quickly. The fines are enforced by the HHS Office of Civil Rights, a Federal Agency.

If you knowingly disclose PHI that includes the identification of an individual, it is a criminal offense punishable by up to $50,000 fine and/or up to one year incarceration. If you violate a person's PHI under false pretenses, the maximum fine goes up to $100,000 and up to five years in prison. HIPAA violations are reported to state boards. As such, it can also impact on your license to practice podiatry and your hospital privileges.

According to HIPAA law, a podiatrist must make a copy of a patient's records available if 30 days or less have elapsed and there is no anticipated serious harm to the patient by giving a copy of the records to the patient.

VII. Reporting Obligations

Originally, a covered entity, such as a podiatrist, would have to give notice to a person of a breach of their PHI, if they thought the breach posed a significant threat to their reputation, financially, or in some other way. Perhaps the breach could jeopardize getting a life insurance policy or might disclose an HIV positive status. No more! That changed with the HITECH Act. Now, there is a presumption that each breach is harmful. The only exception this notice requirement of a breach is if, through a risk assessment, there is a low probability that the PHI was been shared with a non-allowable third party, such as a hacker or a thief. An example of this would be if you misplaced your external hard drive and found it the next day, undisturbed, in the back seat of your car. To your knowledge, nobody else used the car during that time. Let's examine this in greater detail. What about this risk exception?

The Omnibus Final Rule has four factors:

1) The type and amount of the PHI involved, and the likelihood of disclosure of the actual identity that the PHI belongs to. To assess this factor, the covered entity or business associate should consider how sensitive the PHI is. This may include fi-

nancial information or clinical information. Examples of each might include a debit card number or medication list.

2) The unapproved person who had access to the PHI or to whom the revelation was made. For this factor, one should consider if it was disclosed to another covered entity. This may result in a lower likelihood that the PHI was compromised.

3) Whether the PHI was really obtained or seen by somebody that was not allowed to see or view it. The extent to which the PHI might have been seen or viewed is also considered. An example of this might be if, upon examination, a lost IPAD with PHI was never accessed as it was found for the period in question that nobody entered in the password.

4) The degree to which the risk to the PHI has been abated. Risk mitigation approaches may include obtaining the recipient's satisfactory assertions that the information will not be further released or will be deleted.

If a patient wants a copy of their podiatric records, under HIPAA, you may charge the cost of the medium used to copy the digital files on, such as the cost of a thumb drive plus postage, if the patient wants it mailed to them.

HHS's Office of Civil Rights is responsible for enforcing violations of patient privacy and security regulations. CMS is responsible for enforcing digital breeches of PHI. The U.S Department of Justice is responsible for prosecuting criminal violations. However, any patient may report you to the HHS if they feel you are violating HIPAA regulations. An investigation will commence. This is still another reason to keep your patient's privacy utmost in fact and in deed. Any appearance of being careless with your patients' PHI can set off an investigation. Office personnel cannot gossip about the health of your patients. Walls have ears. Texts involving PHI can be mistakenly sent to the wrong party, and the same goes for emails.

As a podiatric physician, you must be particularly aware of not violating your patients' privacy. It is your responsibility to make certain that all your employees and business associates understand that. Reviews with your staff explaining HIPAA regulations are highly advisable. Perhaps have each employee view a video or take a course annually. Have them sign off upon completion or save their certificates of completion. Upon hiring a new employee, make sure that they are educated in ardent protection of a patient's privacy.

Reviews with your staff explaining HIPAA regulations are highly advisable. Perhaps have each employee view a video or take a course annually.

VIII. What You Must Do If a Breach Occurs with Your Patient's PHI?

The HITECH Act requires the podiatrist and all other covered entities, to notify your patient in writing as soon as you are able, but in no case later than 60 days after the breach is discovered. The notification must have a description of the breach, with the dates and discovery dates of the breach, which PHI was breached, actions that the patient should take to protect themselves from damage due to the breach and to mitigate any damage from the breach. Additionally, you must disclose to the patient what you are doing to mitigate any harm. You must also provide your contact information to the patient to contact you with any questions about the breach.

If the breach involves more than 500 patients, you must notify "prominent media entities" in your area. This would include radio and newspapers. You must also disclose all breaches to HHS via their website as soon as possible, but in no case more than 60 days.

IX. A Patient's Right to a Copy of Her Records

A patient has a right to inspect the original records and to obtain a copy of those records. They have a right to have onsite access to their PHI within 30 days of the request. HITECH allows the patient to demand a copy of their medical records in electronic format. The final regulation allows you, the podiatrist, to charge for labor costs for copying the health records in paper or digital format, including the cost of the electronic media—for example, the cost of a thumb drive. If the patient requests that the copy be mailed to them, the postage is also chargeable.

After the patient reviews the records, they have the right to request that you amend their PHI to make it accurate and complete. The requested change, if accepted, need not be expunged, only amended. The request must be formally accepted or denied by you, the covered entity. An example of this might be that your patient, upon review of their medical chart, sees an error in their prescriptions from other healthcare givers. They give you the correct information to amend their record. You agree to do so, in writing. Then, you amend your chart to reflect the correct information.

One interesting wrinkle that was added with the HITECH Act…if a

patient is paying you out of pocket, that patient may request that any requested PHI not be provided to a patient's third-party payor. This would come into play in cases when you as a podiatrist are treating a patient in an out-of-network situation and the patient pays you directly.

There are cases where access to part of the PHI can be denied by the medical provider, if the provider deems that something about it can be harmful to the patient. Usually, but not always, this occurs in the mental health arena. From a practical point of view, the "patient harm" exception would be rarely considered in a podiatric practice.

X. Conclusion

While the HIPAA Act, along with its HITECH companion legislation, has had a very big impact on the practice of podiatry, it's important to emphasize that it has been used to increase your patients' privacy. We are all patients, and we can all appreciate that. **PM**

References

1. U.S Department of Health and Human Services Administration Simplification: https://aspe.hhs.gov/administrative-simplification

2. U.S Department of Health and Human Services Office for Civil Rights: https://www.hhs.gov/hipaa/index.html

3. HIPAA Journal http://www.hipaajournal.com/what-is-the-hitech-act/a-HIPAA Journal http://www/hipaajournal.com/hipaa-history

Dr. Kobak is Senior Counsel in Frier Levitt's Healthcare Department in New York. Larry has extensive experience representing physicians in connection with licensure issues, as well as successfully defending physicians before Medical Boards, OPMC, OPD investigations, as well as Medicare Fraud, Fraud & Abuse, Hospital Actions, RAC Audits, Medicare Audits, OIG Fraud, Healthcare Fraud, Medical Audits, and Health Plan Billing Audits. As a licensed podiatrist prior to becoming an attorney, he served as the international president of the Academy of Ambulatory Foot and Ankle Surgery.

CME EXAMINATION

1) PHI is an acronym for:
- **A) Proper health instruction**
- **B) Potential hazard information**
- **C) Protected health information**
- **D) Perpetual health insurance**

2) The following people are considered covered entities by HIPAA:
- **A) The answering service personnel**
- **B) The podiatric medical assistants**
- **C) Your medical transcriptionist**
- **D) All of the above**

3) Which of the following is an example of a Business Associate?
- **A) A podiatrist that you employ**
- **B) Your podiatric medical assistant**
- **C) Your practice manager**
- **D) Your outside billing service**

4) What is required if a breach of PHI is discovered?
- **A) There is a presumption that the breach is harmful to your patients.**
- **B) There is no presumption that the breach is harmful to your patients. A self-investigation is required to see the extent and likelihood of any improper spread of PHI.**
- **C) All patients must be notified about the breach even if there is no reason to think that the breach resulted in any of the PHI actually coming into possession of an unauthorized party.**
- **D) Take out a full-page announcement advertisement announcing the breach all over the entire state where you practice.**

5) HIPAA wrongdoers may be imprisoned if they:
- **A) Intentionally and willfully disclose PHI for money for the commercial benefit of another person or company.**
- **B) Unintentionally lose a hard drive from a computer that was left mistakenly in a taxi.**
- **C) Use state-of-the-art computer security.**
- **D) Have their computer hacked by an unknown source for the first time after assurance by their IT team that their software and hardware were up-to-date.**

6) According to HIPAA law, a podiatrist must make a copy of a patient's records available if:
- **A) 2 weeks or less have gone by since the request and there is no anticipated harm to the patient by giving a copy of the records to the patient.**
- **B) 30 days or less have elapsed and there is no anticipated serious harm to the patient by giving a copy of the records to the patient.**
- **C) The patient is not entitled to a copy of their records unless they first pay $100 for their records.**
- **D) They have first been offered a chance to inspect their records in the podiatrist's office.**

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CME EXAMINATION

7) All are examples of PHI except:
- **A) Medical records**
- **B) HCFA form submitted to medical insurance company**
- **C) A copy of your patient's winning, unsigned lottery ticket**
- **D) Your office appointment book**

8) It is considered PHI if:
- **A) There is any reference to anything medical**
- **B) There is reference to a patient's size 8 shoe size, without their name**
- **C) There is reference to the patient's first name, John, and no other identifying information**
- **D) There is reference to something that positively identifies the identity of the patient, even without their full name, such as Elvis, Madonna, or Liberace or a full frontal photograph of the patient's face.**

9) If a patient wants a copy of their podiatric records, under HIPAA, you may charge
- **A) $1 per page, regardless of whether it is a hard copy or digital**
- **B) The cost of the medium used to copy the digital files on, such as the cost of a thumb drive plus postage, if the patient wants it mailed to them.**
- **C) $1 per page plus the cost of the thumb drive**
- **D) All patients that request their podiatry records cannot be charged anything.**

10) Who is responsible for enforcing the HIPAA Act?
- **A) The FBI**
- **B) The Office of Civil Rights division of the HHS**
- **C) The AG's office**
- **D) The appropriate state government**

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HIPAA Regulations and Podiatrists
(Kobak)

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1.	**A**	**B**	**C**	**D**	**6.**	**A**	**B**	**C**	**D**
2.	**A**	**B**	**C**	**D**	**7.**	**A**	**B**	**C**	**D**
3.	**A**	**B**	**C**	**D**	**8.**	**A**	**B**	**C**	**D**
4.	**A**	**B**	**C**	**D**	**9.**	**A**	**B**	**C**	**D**
5.	**A**	**B**	**C**	**D**	**10.**	**A**	**B**	**C**	**D**

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