

## The HIPAA Final Omnibus Rule: 9 things you need to know



By Shawn M. Lindsay, JD, CIPP/US

**O**N JANUARY 25, 2013, the U.S. Department of Health and Human Services Office for Civil Rights published the HIPAA Final Omnibus Rule (Final Rule), which affects nearly every aspect of patient privacy and data security. The Final Rule became effective March 26, 2013, and enforcement for most provisions began September 23, 2013. The following summarizes nine major changes of the 500+ page Final Rule that, as dentists, you need to know.

### 1. The definition of “Business Associate” has expanded.

Business Associates are now defined to include a broader array of contractors and vendors that store and touch protected health information (PHI), including, for example, document storage companies and other contractors that “maintain” PHI, even if they do not actually view the information in their possession. As such, Business Associates are now held to the same strict standards as Covered Entities (i.e., dentists/providers), and they are now directly responsible for compliance with HIPAA, not just responsible for signing a business associate agreement.

### 2. Business Associate Agreements must be reevaluated.

Business associate agreements in force prior to January 25, 2013 (and that did not come up for renewal before March 26, 2013) may be grandfathered until September 23, 2014. All other business associate agreements must specify compliance with the HIPAA Security Rule and specify to whom the business associate provides electronic access to PHI.

### 3. Breach notification rules have changed.

What is a data breach? It happens any time unencrypted or unsecured PHI is shared, used, or disclosed in violation of the HIPAA Privacy Rule (e.g., losing a laptop with patient records on it). A breach is assumed to require notifications unless proved to be a “low probability” of risk. A breach assessment must be completely documented, and dentists and business associates have the burden of proof that notifications to affected individuals were made as required.

### 4. Use of Protected Health Information for marketing has been limited.

Dentists may not send marketing materials to patients on behalf of third parties if the communication is paid for by a third party whose products or services are being promoted. Further, PHI may not be sold, licensed, or accessed in exchange for giving anything of value—with a handful of exceptions.

### 5. Use of Protected Health Information for fundraising has been limited.

Dentists may use an individual’s demographic information and dates of care for fundraising efforts *so long as* fundraising material includes information about how that individual can opt out of further fundraising communications (opt out options must be easy and simple).

### 6. Use of Protected Health Information for research has been simplified.

A single patient consent for release of PHI in connection with research study participation can now cover future studies done using the same data.

### 7. Patients may now access Protected Health Information in different ways.

Upon request, dentists must provide a patient a copy of a requested medical record, *in the format requested*, within 30 days. Further, PHI may be disclosed to friends and family who are involved in the care and payment for care of a deceased person.

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**8. Patients may restrict disclosure of some Protected Health Information.**

If a patient pays for a particular service out of pocket, he or she may require that the dentist not disclose any information about the service to the patient's health plan.

**9. Because of all these above changes, dentists should publish new and compliant notices of privacy practices.**

Notices of Privacy Practices must reflect the changes to policies noted above. The revised notices should be prominently displayed on websites and made available to patients in both electronic and paper versions.

On top of all of the above changes, the Office for Civil Rights will be stepping up its enforcement of willful neglect, which is defined to be "conscious, intentional failure, or reckless indifference" to the obligation to comply with the Final Rule. If willful neglect is found, the penalty is a whopping \$10,000 per violation . . . if it is corrected within 30 days. If it's not corrected with the 30 days, it's \$50,000 per violation.

Now that you're aware of the changes, here are a few things to note: (1) the Final Rule is here to stay, and it's serious, so understand it and comply with it; (2) "Encrypting" electronic PHI is the most effective measure to secure PHI and avoid violations, so do it; and (3) purchasing cyber risk insurance can help you *when* (not *if*) you experience a data breach. ●

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