The HIPAA Omnibus Final Rule

The *Omnibus Final Rule* was released by the Department of Health and Human Services on January 17, 2013. It was designed to strengthen the privacy and security protections offered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule enhances patient's privacy protections, provides individuals new rights to their health information and strengthens the government's ability to enforce the law.

Summary of Changes in the 2013 Final Rule

Notice of Privacy Practices (NPP)

The changes to the NPP apply to all Covered Entities.

Background

HIPAA requires all Covered Entities to provide patients with a *Notice of Privacy Practices (NPP)* that explain how the Covered Entities may use and disclose patient Protected Health Information (PHI) and some of the rights that patients must have related to the control of their information.

New Rule

The new rule changes the content that must be included in the NPP.

Under the new rule, the NPP must contain information about patient authorization forms. The revised NPP must:

- Describe the types of uses and disclosures that require a patient to sign an authorization form.
- Contain a statement that other uses and disclosures not contained in the NPP will be made only with authorization from the patient.
- Contain a statement that at any time a patient can revoke an authorization, if it is in writing. There are limited exceptions to the ability of a patient to revoke authorization. Two examples of these exceptions are:

  A. Where the Covered Entity has already used the authorization to use or disclose patient information. The revocation cannot be retroactive.

  B. If the authorization was for purposes of obtaining insurance coverage and there are other laws that grant them certain rights.

Fundraising

The Final Rule makes several changes to the rules governing the use of PHI for fundraising:

- Permits new types of PHI to be used for fundraising purposes.

  Note: The original Privacy Rule permitted Covered Entities to use or disclose only an individual's demographic information and dates of healthcare services for fundraising communications. The Final Rule expands the types of PHI which can be used to include department of service, treating physician, and outcomes. As a result, Covered Entities are now able to screen out individuals with sub-optimal outcomes from fundraising.

- Requires Covered Entities to inform individuals in their *Notice Of Privacy Practices* that they may be contacted for fundraising purposes and that the individual has a right to opt out of participation.

Restricted Disclosure to Health Plan

The Final Rule requires healthcare providers to include a statement in the NPP indicating the individuals were granted a new right that allows them to restrict certain disclosures of PHI to a health plan in instances where the individual pays out of pocket in full for a healthcare item or service. This applies only to healthcare providers. Other Covered Entities may retain the existing language indicating that a Covered Entity is NOT required to agree to a requested restriction.

Breach Notification

The Final Rule requires that Covered Entities include in their NPP a statement of the right of an affected individual to be notified following a breach of unsecured *Protected Health Information (PHI).*

Marketing and Sale of PHI

The Final Rule requires that Covered Entities include in their NPP a statement stating that patient information cannot be sold without the express written authorization of the patient and that authorization is required for certain marketing communications.

Psychotherapy Notes

The NPP must contain a statement indicating that authorization is required for:

1. Most uses and disclosures of psychotherapy notes (where appropriate)
2. Uses and disclosures of PHI for marketing purposes
3. Disclosures that constitute a sale of PHI
4. Other uses and disclosures not described in the NPP

A Covered Entity that does not record or maintain psychotherapy notes is not required to include the requisite statement in its NPP.

Breach Notification

The changes to the *Breach Notification Rule* apply to all Covered Entities.

Prior Rule

The prior rule did not require notification unless the impermissible use or disclosure posed a significant risk of financial, reputational, or harm to the individual.

New Rule

The new rule includes the following changes:

- HHS is the enforcement agent for the *HIPAA Breach Notification Rule* for Covered Entities and Business Associates.
- The Final Rule amends the definition of a breach.
- The impermissible use or disclosure of PHI is presumed to be a breach unless the Covered Entity or Business Associate demonstrates that there is a low probability that the PHI has been comprised.
- Breach notification is not required under the Final Rule if a Covered Entity or Business Associate demonstrates through the risk assessment process that there is a low probability that the PHI was compromised.

  Note: The Interim Final Rule required the Covered Entity or Business Associate to demonstrate that there was no significant risk of harm to the individual rather than that there was a low probability that the PHI was compromised.

- The risk assessment should consider the following factors:
  A. The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification
  B. The unauthorized person who used the PHI or to whom the PHI was disclosed
  C. Whether the PHI was acquired or viewed
  D. The extent to which the risk to the PHI has been mitigated
- Covered Entities and Business Associates can provide notification for each breach without performing the risk assessment. The risk assessment analysis is required only when the Covered Entity or Business Associate wants to demonstrate that no notification is required.
- The Final Rule requires breach notification for limited data sets that did not include dates of birth and zip codes and requires the Covered Entity or Business Associate to perform the four-factor analysis with respect to the PHI in question. Previously, these limited data sets were exempt from breach notification.
- The Covered Entity or Business Associate is not required to include a description of how the risk assessment will be conducted in the NPP.
- § 164.414 places the burden of proof on Covered Entities and Business Associates to demonstrate that all notifications were provided or that an impermissible use or disclosure did not constitute a breach. Covered Entities and Business Associates are also required to maintain documentation for all notifications.
- Uses or disclosures that violate the *Minimum Necessary* principle may qualify as breaches. Such incidents must be evaluated like any other security incident.
- The Covered Entity is ultimately responsible for notifying affected individuals of a breach under § 164.404. The Covered Entity can choose to delegate the task of notification to the Business Associate that suffered the breach or to another of its Business Associates, but it is responsible for ensuring that the notification occurs.
- The Final Rule modified § 164.408(c) as follows: Covered Entities are required to notify the Secretary of all breaches of unsecured PHI affecting fewer than 500 individuals not later than 60 days after the end of the calendar year in which the breaches were discovered, not in which the breaches occurred.

Business Associates and Subcontractors

The changes for Business Associates and subcontractors apply to all Covered Entities

Prior Rule

If a Business Associate or its subcontractor improperly used or disclosed patient information or violated the Business Associate Agreement, the government could not impose penalties on the Business Associate or subcontractor.

New Rule

- Providers are not required to enter into a Business Associate Agreement with all downstream contractors. However, they must sign a Business Associate Agreement with the entity with which they do business directly. The Business Associates are then required to get written *satisfactory assurances* from each of their immediate subcontractors. In the event of a breach, all downstream contractors are required to report up the chain to providers.
- Business Associates and their subcontractors are required to have or implement a HIPAA *Privacy and Security* program.
- Business Associates are not permitted to use or disclose PHI if it would be a HIPAA *P*rivacy Rule violation for the Covered Entity to do so. All disclosures must be in accordance with the Business Associate Agreement.
- Liability for the use and disclosure of PHI begins the instance a person or Business Associate *creates, maintains, or transmits* PHI on behalf of a Covered Entity, even if a Business Associate Agreement is not yet in place.
- Business Associates are liable under HITECH for uses and disclosures that violate the HIPAA Privacy Rule or that are in breach of a Business Associate Agreement. Business Associates are now directly liable under the HIPAA rules for:

  A. Impermissible uses and disclosures

  B. Failure to provide breach notification to the Covered Entity

  C. Failure to provide access to PHI to either the individual or the Covered Entity

  D. Failure to provide requested PHI to HHS

  E. Failure to provide an accounting of disclosures

  F. Failure to comply with the HIPAA *Security Rule*

- Business Associates and their subcontractors are now subject to criminal and civil sanctions for HIPAA violations to the same extent as Covered Entities.
- Business Associates are required to have Business Associate Agreements with subcontractors that access or use PHI on their behalf and to monitor these Business Associate Agreements.

Restricted Disclosure to a Health Plan

The changes for restricted disclosures to a health plan apply to all Covered Entities.

Prior Rule

The prior rule stated that Covered Entities were not required to agree to patient requests to not disclose PHI to their health plan. If the Covered Entity did agree to the request initially and then terminated the request, the Covered Entity was required to apply the restriction to patient information created or received before the termination.

New Rule

- The Final Rule modifies § 164.522 as per HITECH Act Section 13405(a) indicating that individuals now have the right to restrict certain disclosures of PHI to a health plan in instances where the individual pays out of pocket in full for the health care item or service.
- Covered Entities must have a process and procedure to identify the restricted PHI and mark or otherwise notate the restriction in the medical record of the patient requesting the restriction to prevent the transmission of the information to the health plan.

  Example: An individual wants to restrict disclosures to a health plan concerning a prescribed medication for which they intent to pay cash. To prevent the transmission of the information to the patient's health plan, the prescribing provider could provide the patient with a paper prescription. This would allow the individual an opportunity to request a restriction with the pharmacy and pay for the prescription before the pharmacy submits a bill to the health plan.
- Disclosures that are otherwise required by law are still permitted.
- The individual patient is required to notify a downstream Health Information Exchange of the restriction, not the Covered Entity.
- A restriction would also be initiated if a family member makes the payment on behalf of an individual.
- A restriction would not apply if the individual patient does not pay for the service in full and the Covered Entity is attempting to collect payment. No authorization is required in this situation.
- This restriction only applies to Covered Entities that are healthcare providers.

Patient Request to Obtain Copies of Health Records

The changes for patient requests for obtain copies of health records apply to all Covered Entities.

Prior Rule

The Covered Entity was required to act on a request for copies of health records within 30 days. Covered Entities were allowed 60 days if the information was offsite. If necessary, the Covered Entity could request one 30-day extension.

New Rule

Covered Entities must act on a request for copies of health records within 30 days, regardless of whether the information is onsite or offsite. The 30-day requirement applies to both electronic and paper records and begins on the date the Covered Entity receives the request.

Requests for Copies of Electronic Records

Prior Rule

Covered Entities had to allow patients to receive information in the format that the patient requested, if the information was readily producible in that format. If the information was not readily producible in the format requested, the Covered Entity could provide a readable hard copy.

New Rule

If a patient requests an electronic copy of their information and the Covered Entity maintains the information in electronic format, the Covered Entity must provide the information in electronic form. If the information is not readily producible in the format that the patient has requested, the Covered Entity must provide the information in an electronic format that the patient and the Covered Entity agree upon. If the patient does not agree to any of the electronic formats that the Covered Entity can readily produce, the Covered Entity must provide a hard copy.

Paper Records

If a patient requests information that the Covered Entity has in paper format, HIPAA still permits the Covered Entity to provide the patient with a paper copy. A Covered Entity is only required to provide electronic copies of records that the Covered Entity maintains electronically.

Electronic Records

Covered Entities that maintain electronic records must be able to provide an electronic copy of that information.

Electronic Media

Covered Entities may refuse to provide an electronic copy using electronic media provided by the patient (e.g., CD, USB drive) if it completes a written risk analysis and determines that there is an unacceptable level of risk in doing so. The Covered Entity can use their own electronic media to provide electronic copies to the patient.

Email

A Covered Entity may send a patient an electronic copy of their information in an unencrypted email if they have advised the patient of the risk and if the patient accepts that risk. The Covered Entity must implement reasonable safeguards which include reasonable procedures to ensure the recipient's email address is correct. The Covered Entity is not responsible for the email while in transit.

Requests to Provide Electronic Copies to Someone Else

If a patient requests the Covered Entity to send a copy of the patient information to someone else, the Covered Entity must do so either in paper or electronic format. The request must be in writing, signed by the patient, and must clearly identify who will receive the copy and where it will be sent.

Business Associates

If a Business Associate of a Covered Entity has patient information in a designated record set, the patient has a right to receive copies of the information. The Business Associate Agreement should state whether the Covered Entity or Business Associate will provide this information.

Fees for Copies

The changes related to fees charged to patients for copies of health records apply to all Covered Entities.

Prior Rule

The prior rule did not specifically address permissible fees for electronic records.

New Rule

The new rule states Covered Entities can charge a reasonable, cost-based fee for electronic copies.

Electronic Copies

A Covered Entity that provides an electronic copy may charge a reasonable, cost-based fee. The fee may include certain costs associated with labor and supplies for creating an electronic copy. Examples of allowed costs include:

- The cost of the electronic media (e.g. CD, USB drive) if the patient agrees to receive their record on electronic media supplied by the Covered Entity.
- The Covered Entity may charge for postage if the patient requests the record be sent via mail.

The Covered Entity may not include fees associated with maintaining systems, retrieving information, or infrastructure costs.

Labor

The Covered Entity may include the cost of labor for copying information whether in paper or electronic format, but not the cost of labor associated with retrieving the information.

Cost of New Technology

The Covered Entity may not charge for the cost of obtaining new technologies.

Maintaining Systems or Recouping Capital

Reasonable, cost-based fees do not include fees associated with maintaining systems or recouping capital for data access, infrastructure, or storage.

Retrieval Fee

The Covered Entity may not charge any retrieval fee for electronic or paper copies.

State Law Limits

State laws may limit the amount a Covered Entity may charge for providing patients with copies of their records. If so, the state limit is relevant in determining whether a Covered Entity's fee is *reasonable* under HIPAA.

Subsidized Marketing Communications

Applies to any Covered Entity that receives payment for making a marketing communication.

Prior Rule

Covered Entities were not required to obtain a patient's authorization for the following uses or disclosures (if permitted by HIPAA):

- When communicating a description of its own health-related product or service
- When using or disclosing patient information for treatment of a patient, case management, or care coordination
- When directing or recommending alternative treatment, therapies, healthcare providers, or settings of care to the patient

The authorization requirement depended in part on whether a marketing communication was for treatment purposes or for healthcare operations.

New Rule

A Covered Entity is required to have the patients sign an authorization form if the Covered Entity or its Business Associate receives financial renumeration from a third party, or another entity working on behalf of a third party, for creating a form of communication for a product or service being marketed.

Patients are not required to sign an authorization form if the third party provides the advertisements to the dental practice free of charge and does not provide financial renumeration to the Covered Entity money for sending the advertisements to the patient for a permissible purpose under HIPAA (treatment, case management, or healthcare benefits).

The authorization is required only if the dental practice receives financial renumeration for making a form of communication on behalf of a third party.

Payment

Covered Entities are required to obtain patient-signed authorization forms if the Covered Entity or Business Associate receives financial renumeration for making a communication for a product or service being marketed. Covered Entities are not required to obtain patients-signed authorization forms if they receive nonfinancial or in-kind remuneration.

Payment for Other Purposes

Covered Entities are not required to obtain patient-signed authorization forms if the financial renumeration received is for a permissible purpose and not related to the purpose of making a marketing communication on behalf of a third party.

Treatment-Related Communications

The Covered Entity must obtain a signed, written authorization from the patient prior to making the communication if the Covered Entity receives payment in exchange for:

- A marketing communication for treatment of the patient by a health care provider or to direct or recommend alternative treatments, therapies, health1care providers, or settings of care to the individual.
- A marketing communication for case management or care coordination, contacting of patients with information about treatment alternatives and related functions to the extent these activities do not fall within the definition of treatment.

Business Associates

If the Covered Entity is required to obtain a signed, written authorization from the patient before making a certain marketing communication on behalf of a third party, then any Business Associate sending the communication of the Covered Entity must also obtain a signed, written authorization from the patient. A Business Associate is also required to obtain signed, written authorization from the patient if it receives direct financial renumeration from third party in exchange for the marketing communication.

General Health Communications

Covered Entities are not required to obtain signed, written authorization from patients when making communications that promote health in general and do not promote a third-party product or service. Communications of this sort, such as promoting patients to schedule certain diagnostic tests, do not constitute marketing.

Government Programs Communications

A Covered Entity may use and disclose patient information to communicate with patients about eligibility for programs such as Medicare, Medicaid, or CHIP without obtaining a signed written authorization form.

Sale of Patient Information

Applies to any Covered Entity that intends to exchange patient information for any form of renumeration.

Prior Rule

A Covered Entity could not sell patient information, but HIPAA did not prohibit a Covered Entity from receiving financial renumeration for an otherwise permitted disclosure of patient information.

New Rule

Covered Entities and Business Associates are generally prohibited from selling PHI without first obtaining signed, written authorization from the patient unless an exception applies. A Covered Entity cannot exchange the patient information for remuneration from or on behalf of the recipient of the information without obtaining a signed, written authorization form from the patient acknowledging that the Covered Entity will receive renumeration for the disclosure.

Exceptions

The following exceptions apply to the new rule:

- Sale of the practice: A Covered Entity that discloses patient information during the process of selling the practice to another Covered Entity or for related due diligence.
- Disclosure of patient information that is required by law.
- Permitted reasonable, cost-based fee: A disclosure of patient information for a reasonable cost fee to cover the cost to prepare and transmit the information, if the disclosure is permitted by HIPAA.
- Health Information Exchange Fees: When a Covered Entity pays a fee to participate in a health information exchange and exchanges patient information as specified, the payment is for services provided by the health information exchange and not for the data itself.
- De-identified information: Once patient information is de-identified, the information is no longer protected by HIPAA. Exchanging de-identified information for remuneration is not considered to be the sale of patient information.

Decedents

This change applies to all Covered Entities and is specific to PHI for patients who have been deceased for more than 50 years.

Prior Rule

Health information about decedents is generally protected in the same manner and extent as that of living individuals.

New Rule

The decedent's information is no longer considered PHI if the patient has been deceased for more than 50 years.

Note: The 50-year period is not a record retention requirement. In general, state laws determine how long patient records must be kept.

Other HIPAA provisions pertaining to deceased patients remain the same, such as disclosures to coroners, medical examiners, and funeral directors.

Family Members

This change applies to all Covered Entities.

Prior Rule

The Covered Entity had to obtain a signed authorization from the deceased patient's *Personal Representative* before disclosing information about the deceased patient to family members or others who were involved in the patient's care, unless state law permitted a disclosure to a surviving family member, such a surviving spouse.

New Rule

Covered Entities can disclose the decedent's PHI to a family member or other person involved in the decedent's care or treatment, but only to the extent the PHI is relevant to the role the family member played in the family member's treatment.

- If the Covered Entity doubts the identity or explanation of the person seeking the information, it may deny the request.
- A Covered Entity may request reasonable assurance that the person requesting information about the deceased patient is a family member or was involved in their care or treatment.
- This provision does not generally apply to health care providers, health plans, public health authorities and other entities for which access to PHI is governed by other HIPAA provisions.

Enforcement

This change applies to all Covered Entities.

Prior Rule

The prior rule stated that the *Office of Civil Rights* had the discretion as to whether to investigate a complaint.

New Rule

The *Office of Civil Rights* will investigate when the preliminary review indicates a violation due to willful neglect. Covered Entities and Business Associates now face the possibility of a mandatory investigation of a complaint when a preliminary review of the facts by the OCR indicates a possible violation due to willful neglect. The *HIPAA Enforcement Rule* defines *willful neglect* as conscious, intentional failure, or reckless indifference to the obligation to comply with the administrative simplification provision violated. HHS retains discretion to decide whether to initiate an investigation or compliance review where the preliminary review indicates a degree of culpability less than willful neglect.

Penalties

These changes apply to all Covered Entities.

Prior Rule

Civil money penalties for Covered Entities that did not comply with HIPAA were limited to $100 or less per violation. There was an annual cap of $25,000 for all violations of the same HIPAA requirement.

New Rule

The new rule has tiered penalty amounts for increasing levels of culpability with maximum penalties for violations of the same HIPAA provision of $1.5 million per year. If the penalty was due to willful neglect and was not corrected within 30 days, there is minimum penalty of $50,000 per violation.

Tiered Structure

The tiered structure for imposition of civil money penalties under the HITECH Act and Final Rule distinguishes the level of culpability as follows:

Unknowing

The Covered Entity or Business Associate did not know and reasonably should not have known of the violation.

Reasonable Cause

The Covered Entity or Business Associate knew, or by exercising reasonable diligence would have known, that the act or omission was a violation, but the Covered Entity or Business Associate did not act with willful neglect.

Willful Neglect – Corrected

The violation was the result of conscious, intentional failure, or reckless indifference to fulfill the obligation to comply with HIPAA. However, the Covered Entity or Business Associate corrected the violation within 30 days of discovery.

Willful Neglect – Uncorrected

The violation was the result of conscious, intentional failure, or reckless indifference to fulfill the obligation to comply with HIPAA and the Covered Entity or Business Associate did not correct the violation within 30 days of discovery.

The corresponding tiers of civil money penalties relating to each level of culpability are as follows:

Violation Category	**Each Violation**	**Total CMP for Violations of an Identical Provision in a Calendar Year**
Unknowing	$100 – $50,000	$1,500,000
Reasonable Cause	$1,000 – $50,000	$1,500,000
Willful Neglect – Corrected	$10,000 – $50,000	$1,500,000
Willful Neglect – Not Corrected	At least $50,000	$1,500,000

Under the Final Rule, HHS does not have the authority to automatically impose the maximum civil money penalty for any given violation. Rather, in determining the amount of a civil money penalty, HHS must consider the following:

- The nature and extent of the violation, including the number of individuals affected and the time during which the violation occurred.
- The nature and extent of the harms resulting from the violation, including whether:
  A. The violation caused physical harm.
  B. The violation resulted in financial harm.
  C. There was harm to an individual's reputation.
  D. The violation hindered an individual's ability to obtain health care.
- The history of prior compliance, including previous violations.
- The financial condition of the Covered Entity or Business Associate, including whether:
  A. Financial difficulties affected the ability to comply.
  B. The imposition of the civil money penalties would jeopardize the ability of the Covered Entity to continue to provide or pay for health care.

Fundraising

These changes apply to all Covered Entities that wish to use patient information for a fundraising campaign for the practice.

Prior Rule

The Covered Entity could use or disclose only an individual's demographic information and dates of healthcare services for fundraising communications.

New Rule

The new rule expands the types of PHI which can be used to include:

- The department of service
- The treating health care provider
- Outcomes (to allow Covered Entities to screen out individuals with sub-optimal outcomes from fundraising)

This means that a Covered Entity seeking to raise funds for a specific program or facility can target its fundraising campaign to patients who have experienced positive outcomes in that program or facility.

Definition

Fundraising communication is a communication to a person by any means made for raising funds for the Covered Entity, whether it is made by:

- The Covered Entity
- A Business Associate on behalf of the Covered Entity
- A foundation related institutionally to the Covered Entity

Notice of Privacy

If a Covered Entity intends to use PHI for fundraising activities, its *Notice of Privacy Practices* must include a separate statement that the Covered Entity may contact individuals to raise funds for the practice and the individuals have the right to opt out of receiving such communications.

Opt Out

Covered Entities have flexibility to decide what methods individuals can use to opt out of receiving fundraising communications as long as the methods do not impose an undue burden on individuals. Covered Entities have similar flexibility to decide what methods individuals can use to opt back into receiving fundraising materials if the individual takes affirmative steps to opt back in.

Note: The act of making a donation is not considered in and of itself sufficient to be considered a request to opt into future communications.

Covered Entities have discretion regarding whether an opt out will apply for all future fundraising or only for a specified fundraising campaign. The Final Rule prohibits Covered Entities from sending further fundraising communications to those individuals who have already opted out. The Final Rule also prohibits conditioning treatment or payment on an individual's choice to receive fundraising communications.

Immunization Records

These changes apply to any Covered Entity seeking to use a simplified process for sending proof of immunization to a school when requested to do so by a patient or a patient's parent or guardian.

Prior Rule

Covered Entities needed a signed authorization form before it could send immunization records to a school.

New Rule

A Covered Entity must obtain authorization from a patient or from a patient's authorized representative before disclosing proof of immunization to a school where state or other law requires the school to have such information prior to admitting the student. The authorization can now be provided orally by the patient or the patient's authorized representative. Written authorizations are no longer required for this disclosure. The authorization is considered effective until revoked. The new rule requires Covered Entities to document the authorization but does not dictate the nature of the documentation or require the signature of the patient or the patient's authorized representative.

State Laws

Covered Entities should check state laws before changing their procedures for sending immunization information to schools. If the law of the state in which the Covered Entity operates are more stringent than HIPAA with regard to sending immunization information to schools, Covered Entities must follow the relevant state laws.

Request by School

A request by a school is generally not sufficient to permit the disclosure of PHI under HIPAA.

Training

Covered Entities who wish to use these less formal procedures in lieu of requiring a signed authorization form must train all staff on new procedures.

Genetic Information

This change regarding genetic information applies to all Covered Entities.

Prior Rule

Genetic information was considered PHI if it was maintained by the Covered Entity or Business Associate and it identified the patient.

New Rule

The new rule includes genetic information in the definition of PHI. The new rule defines genetic information to include:

- Information about a patient's genetic test.
- Information about the genetic test of a member of the patient's family.
- The manifestation of a disease or disorder of a member of the patient's family.
- Any request for genetic services by a patient or member of the patient's family.
- Any request for participation in clinical research that includes genetic services by a patient or a member of the patient's family.

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