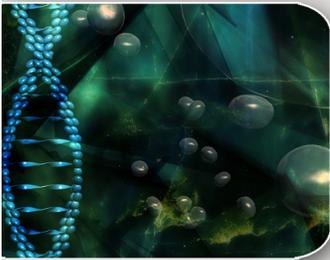




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Changes to Patients' Rights Under the Final Rule

Breaking Down the HIPAA Changes: Part 5 of our 5-Part Series

The final HIPAA omnibus rule published in the *Federal Register* on January 25, 2013, (the Final Rule) expands certain individual rights, including the right to access protected health information (PHI) maintained electronically and the right to restrict disclosures to health plans when paying out of pocket. This e-alert discusses these changes in more detail and provides some guidance to Covered Entities on how to implement these changes by September 23 – the required compliance date.

I. Right to Access Protected Health Information

Individuals currently have the right to review or obtain copies of their PHI,

to the extent such information is maintained in the designated record set(s) of a Covered Entity. The Health Information Technology for Economic and Clinical Health Act (HITECH Act) expanded this right of access to give patients the right to an electronic copy of PHI that is maintained in an electronic health record (EHR), and the Final Rule took that right one step further – to apply to all designated record sets maintained electronically.

Under the Final Rule, if an individual requests an electronic copy of PHI that is maintained electronically in one or more designated record sets, the Covered Entity must provide the individual with access to the electronic information in the electronic form or format requested by the individual, if it is readily producible in the requested

form or format. If the PHI is not maintained in the requested form or format, the entity must provide the individual with the PHI in a readable electronic form and format agreed to by both parties, e.g., providing a disc with a PDF file, sending a secure email with a Word file or providing access through a secure web-based portal. A hard copy may be provided if the requesting individual rejects all of the offered electronic formats.

HHS further clarified: (i) a Covered Entity is not required to provide individuals with direct access to their systems; (ii) if the designated record set contains electronic links to images or data, the images or other data must be included in the electronic copy provided; (iii) if a medical record is in mixed media (e.g., some paper and some electronic), a Covered Entity is not required to scan the paper documents to provide a single electronic copy – a combination of electronic and hard copies may be provided; (iv) a Covered Entity is not required to use an individual's flash drive or other device to transfer the electronic PHI if the Covered Entity has security concerns regarding the external portable media; and (v) a Covered Entity may send individuals unencrypted emails if it has notified the individual that there may be some level of risk that the information could be read by a third party, and the individual still prefers the unencrypted email.

Under the Final Rule, if requested by an individual, a Covered Entity must transmit the electronic copy of PHI directly to another person designated by the individual. However, the designation must be in writing, signed by the individual, and clearly identify the designated person as well as where to send the copy of the PHI. Note: This written request for PHI to be sent to a designated person is distinct from the authorization form, which contains many additional required statements and elements.

Covered Entities must act on an individual's request for access to his or her own PHI, whether paper or electronic, within 30 days following receipt of the request; however, they may have a one-time extension of up to 30 days upon provision of written notice to the individual (within the original 30-day time frame), and the notice must include

the reason for the delay and the expected date of completion. Significantly, under the Final Rule, the fact that PHI is maintained off-site will no longer warrant an additional 30-day extension. HHS expects Covered Entities who maintain PHI off-site to comply within 30 days of the request – or within 60 days if they provide written notice to the individual, as described above. These are the outer limits for responding to requests for access to PHI; HHS encourages Covered Entities to provide individuals with access to their information sooner and to take advantage of technologies that provide individuals with immediate access to their PHI.

The Final Rule also modified what may be included in the reasonable, cost-based fees that may be charged to individuals when providing them copies of their PHI. Under the Final Rule, labor costs for copying PHI, whether in paper or electronic form, may be included in a reasonable cost-based fee. These labor costs may include technical staff time spent to create and copy the electronic file, such as compiling, extracting, scanning and burning PHI to media. Reasonable, cost-based fees may also include: (i) the cost of supplies for creating electronic media (e.g., discs, flash drives, etc.); and (ii) the cost of postage if the individual requests that the portable media be sent by mail or courier. However, under the Final Rule, Covered Entities may not include: (i) costs of new technology, maintaining systems for electronic PHI, data access and storage infrastructure; or (ii) a retrieval fee (whether standard or actual costs) for



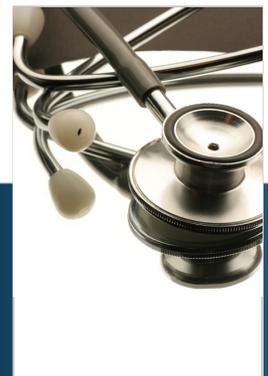
electronic copies. Note: If costs permitted under HIPAA exceed the state law limits, the Covered Entity may not charge more than the state law allows.

II. Restrictions on Health Plan Disclosures

Under the Final Rule, Covered Entities are required to comply with an individual's request to restrict disclosures of PHI to a health plan if (i) the disclosure is for the purpose of carrying out payment or health care operations, and is not otherwise required by law, and (ii) the PHI pertains solely to a health care item or service for which the individual, or a person acting on behalf of the individual (other than the health plan), has paid the Covered Entity in full.

A number of concerns were raised in the rule-making process about implementing these required restrictions. In response, HHS clarified:

- Providers are not required to create separate medical records or otherwise segregate PHI subject to a restricted health care item or service. However, they will need to flag or use some other method to identify portions of the record that contain PHI subject to a required restriction to ensure it is not inadvertently sent or made accessible to the health plan for payment or healthcare operations purposes (e.g., audits by the health plan);
- Providers are not required to abide by a required restriction if a patient's payment is dishonored. However, providers should make reasonable attempts to resolve payment issues with the patient prior to disclosing PHI to the health plan. Alternatively, a provider may require payment in full at the time the restriction is requested.
- To the extent a patient requests a restriction with respect to one of several items or services provided in a single patient encounter, the provider should counsel the patient on the ability or inability of the provider to unbundle the items or services and the impact of doing so (e.g., the health plan still may be able to determine the services performed based on the context). If the provider cannot unbundle the items or services, the provider should inform the patient and give the patient the option to restrict and pay out of pocket for the entire bundle of items or services.
- The obligation to notify downstream health care providers of restrictions on the disclosure of PHI falls on the patient – not the provider. HHS believes it would be unworkable at this point, given the lack of automated technologies to support such a requirement, to require health care providers to notify downstream providers of the fact that an individual has requested a restriction on the disclosure of PHI to a health plan.
- If the patient does not request a restriction and pay out of pocket for follow-up treatment, the provider may include previously restricted PHI when billing the health plan for the follow-up treatment – if necessary to have such a service deemed medically necessary.
- Contractual requirements for a provider to submit claims to a health maintenance organization (HMO) do not exempt the provider from his or her obligations with respect to the required restrictions. Note: Provider contracts may need to be updated to be consistent with these new requirements.



III. Guidance on How to Comply With the Expanded Patient Rights

In response to these changes in the Final Rule, Covered Entities should consider the following actions:

1. **Evaluate Electronic Systems** A Covered Entity should evaluate its current electronic system to determine (i) if it maintains PHI electronically in one or more designated record sets and, if so, can it provide copies of the PHI in a readable electronic format; and (ii) if information subject to a required restriction can be flagged or segregated in the system to ensure the information is not disclosed to health plans. Some Covered Entities may need to invest in upgraded systems in order to meet these requirements.
2. **Revise Notice of Privacy Practices (NPP)** As discussed in the first e-alert in this series, a Covered Entity may need to revise its NPP to incorporate these new individual rights – as well as other changes under the Final Rule. For example, a health care provider’s NPP must now include a specific statement that individuals have a right to restrict certain disclosures of PHI to a health plan where the individual pays out of pocket in full for the health care item or service.
3. **Review and Revise Policies and Procedures** A Covered Entity should review and modify its policies and procedures to incorporate these expanded individual rights. For example, a Covered Entity must implement reasonable policies and procedures to verify the identity of any person who requests PHI and a Covered Entity must determine the process by which its workforce members are going to “flag” data that is subject to a required restriction.
4. **Train Workforce Members** A Covered Entity should identify workforce members whose job functions will be affected by the Final Rule and train those workforce members in implementing these expanded individual rights. ■

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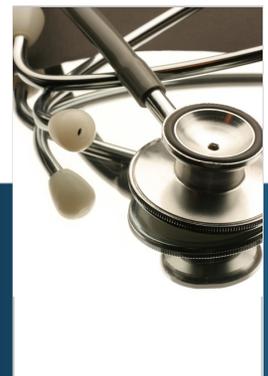
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