



HHS ISSUES LONG-AWAITED HIPAA OMNIBUS FINAL RULE – PART II

As noted in our prior E*Bulletin,¹ on Thursday, January 25, 2013, the Department of Health and Human Services ("HHS"), Office of Civil Rights ("OCR") published in the Federal Register the HIPAA omnibus final rule titled, "Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules" ("Rule" or "Final Rule").²

As also noted in our prior E*Bulletin, the Final Rule finalizes numerous modifications to the HIPAA Rules³ which have been contained in four separate rules published by HHS since 2009. Of the four rules, two of the rules are interim final rules while the other two rules are proposed rules. First, on August 24, 2009, HHS published an Interim Final Rule⁴ setting forth breach notification provisions, which became effective September 23, 2009. HHS then published an Interim Final Rule⁵ on October 30, 2009, which incorporated the HITECH Act's increased and tiered civil money penalty structure, which became effective on November 30, 2009. Next, on July 14, 2010, HHS published a proposed rule⁶ to implement certain privacy, security, and enforcement provisions of the HITECH Act ("2010 Proposed Rule"). Finally, on October 7, 2009, HHS published a proposed rule ("GINA Proposed Rule"),⁷ which HHS states was designed to strengthen the privacy protections for genetic information under the HIPAA Privacy Rule by implementing the protections for genetic information required by the Genetic Information Nondiscrimination Act of 2008 ("GINA") and would prohibit most health plans from using or disclosing genetic information for underwriting purposes.

In our previous E*Bulletin, we discussed certain provisions of the Final Rule, including, without limitation, the definition of "business associate" and its extension to subcontractors, the direct liability of business associates, business associate

¹ Our prior E*Bulletin may be accessed [here](#).

² The Final Rule was published in the Federal Register on Friday, January 25, 2013. 78 Fed. Reg. 5566 (Jan. 25, 2013).

³ The HIPAA Privacy and Security Rule, 45 C.F.R. Part 160 and Part 164, and the HIPAA Enforcement Rule, 45 C.F.R. Part 160, may collectively be referred to herein as the "HIPAA Rules." References to the "HIPAA Privacy Rule" in this E*Bulletin generally refer to the applicable provisions of 45 C.F.R. Part 164.

⁴ 74 Fed. Reg. 42740. The Interim Breach Notification Rule is entitled "Breach Notification for Unsecured Protected Health Information."

⁵ 74 Fed. Reg. 56123. The Interim Enforcement Rule is entitled "HIPAA Administrative Simplification: Enforcement."

⁶ 75 Fed. Reg. 40868. The 2010 Proposed Rule is entitled "Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act."

⁷ 74 Fed. Reg. 51698. The GINA Proposed Rule is entitled "HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information."



agreements, the breach notification rule and the new "objective" breach assessment approach, the concept of agency and its application to business associates, and the strengthening of certain enforcement provisions.

In this E*Bulletin, we focus on certain remaining provisions contained in the Final Rule, including, without limitation, changes to requirements for when individual authorizations are required, including with respect to marketing, research, and the sale of protected health information, provisions relating to fundraising, the notice of privacy practices, an individual's right to request restrictions on uses and disclosures of protected health information and to access their protected health information, and modifications to the Privacy Rule as a result of GINA.

I. Authorizations

Prior to the Final Rule, under §164.508 of the Privacy Rule, except as otherwise permitted or required under the Privacy Rule, a covered entity ("CE") has not been permitted to use or disclose protected health information ("PHI") without a valid authorization.⁸ With certain exceptions, authorizations have been required, for example, for the use or disclosure of PHI for marketing, and for the use or disclosure of psychotherapy notes. In addition, with respect to the use of PHI for research purposes, with certain exceptions, an authorization has not been permitted to be combined with any other document to create what is called a "compound authorization." In addition, HHS notes that it has required authorizations for future research to be study specific. As described below, the Final Rule makes significant changes to these provisions and also requires that an individual authorization be obtained in connection with any disclosure of PHI that is a "sale of PHI," as defined in the Final Rule.

A. Marketing

As noted above, the Privacy Rule has required, with certain exceptions, that a CE must obtain an authorization in order to use or disclose PHI for marketing purposes. Prior to the Final Rule, marketing has been defined as making "a communication about a product or service that encourages recipients of the communication to purchase or use the product or service." The definition of marketing has also been defined to include arrangements between a CE and any other entity whereby the CE discloses PHI to the other entity, in exchange for "direct or indirect remuneration," for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Prior to the Final Rule, three exceptions to the definition of marketing have been included, which, in pertinent part, have been for communications made (i) to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the CE making the communication; (ii) for treatment of the individual; or (iii) for case management or care coordination for the individual, or to direct or recommend alternative

⁸ Pursuant to §164.508(b), a "valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii) [relating to marketing involving direct or indirect remuneration to the CE], (c)(1) [entitled "Core elements."], and (c)(2) [entitled "Required statements."], of this section, as applicable."



treatments, therapies, health care providers, or settings of care to the individual.⁹ As HHS notes, these exceptions to the definition have allowed CEs to make such communications without an individual's authorization as either treatment or health care operations communications, as appropriate, under the Privacy Rule. In addition to the exceptions to the definition of marketing, the Privacy Rule has also contained exceptions to the requirement for individual authorizations. These exceptions have been for communications in the form of: (1) a face-to-face communication made by a CE to an individual and (2) a promotional gift of nominal value provided by the CE.

Accordingly, unless a communication were to meet an exception to the definition of "marketing," or unless the communication were to meet an exception to the authorization requirement, a CE has not been permitted to use or disclose PHI for marketing purposes without a valid authorization. Thus, HHS notes that the Privacy Rule has required a CE to have obtained prior written authorization from an individual to send communications to the individual about *non-health* related products or services, or to give or sell the individual's PHI to a third party for marketing. However, HHS also notes that concerns have remained about whether, prior to the Final Rule, a third party has been permitted to pay a CE to send *health-related* communications to an individual about the third party's products or services.

As noted above, the Final Rule makes several changes to the marketing provisions contained in the Privacy Rule. First, although the Final Rule retains the general definition of marketing to mean making "a communication about a product or service that encourages recipients of the communication to purchase or use the product or service," it makes significant changes to the exceptions to the definition of "marketing" and thus to when an individual authorization is required in connection with therewith.

First, the Final Rule excludes from the definition of marketing certain treatment and health care operations communications. For example, the definition of marketing generally does not include communications made for the treatment of an individual by a health care provider, including case management or care coordination of the individual, or directing or recommending alternative treatments, therapies, health care providers, or settings of care to the individual. It also generally does not include communications describing a health-related product or service provided by a CE making the communication, as well as communications for case management or care coordination, or contacting individuals with information about treatment alternatives, and related functions to the extent the activities do not fall within the definition of treatment. However, it is critical to note that the exceptions *do not apply* where the CE receives "financial remuneration in exchange for making the communication."¹⁰

⁹ The three exceptions state in full: "(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; (ii) For treatment of the individual; or (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual." 45 C.F.R. §164.501.

¹⁰ The Final Rule states: "Marketing does not include a communication made: . . . (ii) For the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication: (A) For treatment of an individual by a health care provider, including case management or care coordination for the individual, or to



Specifically, HHS notes that the Final Rule changes the exceptions to the definition of "marketing" and requires authorizations for all treatment and health care operations communications where the CE receives "financial remuneration" for making the communications from a third party whose product or service is being marketed. HHS refers to these communications where the CE obtains financial remuneration from a third party as "subsidized treatment communications." Further, under the Final Rule, "financial remuneration" means "direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual." Thus, HHS notes that the Final Rule treats "subsidized treatment communications" as marketing communications that require authorization.

It appears that one reason for requiring authorizations for all subsidized treatment communications may relate to HHS' previously proposed exclusion, which HHS notes was set out in its 2010 Proposed Rule and which would have permitted certain treatment communications where financial remuneration were received in exchange for making the communications, if certain conditions were met.¹¹ Specifically, HHS notes that it had previously proposed to exclude from the definition of "marketing" certain treatment communications about health-related products or services by a health care provider to an individual where financial remuneration were received in exchange for making the communications, but only if, among other things, the individual were provided "with notice and an opportunity to opt out of receiving such communications." Under the proposed exclusion, however, communications for health care operations purposes where financial remuneration were received in exchange for making the communications would not be permitted. Thus, under the 2010 Proposed Rule, HHS notes that the receipt of remuneration by a CE would have applied differently depending on whether a communication were for treatment or for health care operations purposes.

With respect to this proposed exclusion, HHS notes that commenters requested guidance regarding the distinction between communications for "treatment" and those for "health care operations purposes." In responding to these commenters, HHS notes that the distinction between what constitutes a treatment versus a health care operations communication "may be difficult to make with precision in all cases, placing covered entities at risk for violating the authorization requirement for marketing communications." Accordingly, HHS states that requiring authorizations for all

direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual; (B) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or (C) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment." 45 C.F.R. §164.501.

¹¹ In its 2010 Proposed Rule, HHS notes the following with respect to the proposed exclusion: "Third, proposed paragraph (2)(i) would exclude from marketing treatment communications about health related products or services by a health care provider to an individual, including communications for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual, provided, however, that if the communications are in writing and financial remuneration is received in exchange for making the communications, certain notice and opt out conditions are met." 75 Fed. Reg. 40868, 40885.



subsidized communications that market a health related product or service will ensure that all such communications are treated as marketing communications, "instead of requiring CEs to have two processes in place based on whether the communication provided to individuals is for a treatment or health care operations purposes."

In addition, HHS provides guidance regarding the term "financial remuneration" and specifically what constitutes "direct" and "indirect" payment. HHS states that "direct payment" means financial remuneration that flows from the third party whose product or service is being described directly to the CE. "Indirect payment," according to HHS, means financial remuneration that flows from an entity on behalf of the third party whose product or service is being described to a CE. Further, HHS notes that financial remuneration does not include non-financial benefits, such as in-kind benefits, provided to a CE in exchange for making a communication about a product or service. Rather, it includes only *payments* made in exchange for making such communications.

HHS also notes that the financial remuneration a CE receives from a third party must be for the purpose of making a communication and such communication must encourage individuals to purchase or use the third party's product or service.¹² If the financial remuneration provided to the CE is for any purpose other than for making the communication, then HHS states that the marketing provision does not apply. HHS provides the example of a third party providing financial remuneration to a CE to implement a program, such as a disease management program. In such case, the CE could provide individuals with communications about the program without obtaining individual authorizations as long as the communications are about the CE's program itself. This is the case, according to HHS, because the communications would only be encouraging individuals to participate in the CE's disease management program and would not be encouraging individuals to use or purchase the third party's product or service.

Further, in the event an authorization is required because the CE is receiving financial remuneration, the Final Rule requires that the authorization disclose the fact that the CE is receiving financial remuneration from a third party. HHS notes that the scope of the authorization does not need to be limited only to subsidized communications related to a single product or service or the products or services of one third party. Rather, the authorization may apply more broadly to subsidized communications generally, so long as the authorization adequately describes the intended purposes of the requested uses and disclosures (i.e., the scope of the authorization) and otherwise contains the elements and statements of a valid authorization. According to HHS, such elements include making clear that the individual may revoke the authorization at any time he or she wishes to stop receiving the marketing material.

In addition to the exceptions from the definition of "marketing" noted above, the Final Rule adds an exception to the definition of marketing for communications made to provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, but only if any financial remuneration received by the CE in exchange for making the communication is "reasonably related" to the CE's cost of making the communication. HHS notes that it would consider this exception to include communications about the generic equivalent of a drug being

¹² HHS notes that "where a business associate (including a subcontractor), as opposed to the covered entity itself, receives financial remuneration from a third party in exchange for making a communication about a product or service, such communication also requires prior authorization from the individual."



prescribed to an individual, communications encouraging individuals to take their prescribed medication as directed, and all aspects of a drug delivery system for individuals who have been prescribed a self-administered drug or biologic (e.g., an insulin pump).

In discussing what it means for the CE to be able to receive financial remuneration for the communication but only if such remuneration is "reasonably related" to the CE's cost of making a communication, HHS states that this would cover only the costs of labor, supplies, and postage to make the communication, including, for example, the CE's drafting, printing and mailing the refill reminders. However, HHS states that if the financial remuneration would generate a profit for the CE or include payment for other costs, such remuneration would not be permitted. For example, according to HHS, if a pharmacy receives financial remuneration from a drug manufacturer to provide refill reminders to individuals taking a particular drug that covers only the pharmacy's cost of drafting, printing, and mailing the refill reminders, the exception would apply and no authorization would be required. However, if the drug manufacturer also provides the pharmacy with a financial incentive beyond the cost of making the communication to encourage the pharmacy's continued willingness to send such communications on behalf of the drug manufacturer, the exception would not apply and the pharmacy must obtain an individual authorization. HHS also notes, however, that if a pharmacy provides refill reminders to individuals only when they visit the pharmacy (in face to face encounters), such communications would be permitted and thus, an authorization would not be required even if the pharmacy receives financial remuneration above and beyond what is reasonably related to the pharmacy's cost of making the communication.

HHS notes that in addition to the communications that fall within the exceptions to the definition of marketing, including the refill reminder exception, two other types of communications, which HHS clarified in its 2010 Proposed Rule, do not constitute marketing, and continue to be exempt from the marketing provisions.¹³ First, HHS states that communications that promote health in general and that do not promote a product or service from a particular provider, such as communications promoting a healthy diet or encouraging individuals to get certain routine diagnostic tests like annual mammograms, do not constitute marketing and do not require individual authorization. In addition, communications about government and government-sponsored programs do not fall within the definition of "marketing," as HHS notes there is no "commercial component" to communications about benefits through public programs. Therefore, a CE may use and disclose PHI to communicate with individuals about eligibility for programs, such as Medicare, Medicaid, or the State Children's Health Insurance Program without obtaining individual authorizations.

Finally, the Final Rule also retains the exceptions from the authorization requirement that currently exist for face-to-face communications and for promotional gifts of nominal value provided by the CE. In providing guidance with respect to these exceptions, HHS notes that a health care provider could, in a face-to-face conversation with the individual,

¹³ In the 2010 Proposed Rule, HHS stated: "We also clarify that communications made by covered entities to individuals promoting health in general, such as communications about the importance of maintaining a healthy diet or getting an annual physical are still not considered to be marketing. These types of communications do not constitute marketing because they are not promoting a specific product or service, and thus do not meet the definition of "marketing." Similarly, communications about government and government sponsored programs do not fall within the definition of "marketing" as there is no commercial component to communications about benefits available through public programs." 75 Fed. Reg. 40868, 40886-40887.



recommend, verbally or by handing the individual a pamphlet, that the individual take a specific alternative medication, even if the provider is otherwise paid by a third party to make such communications. However, HHS notes that communications made over the phone do not constitute face-to-face communications; therefore, the communications would require individual authorization where the CE receives remuneration in exchange for making the communications.

B. Research-Related Authorizations

1. Compound Authorizations

The Privacy Rule has prohibited CEs from conditioning treatment, payment, enrollment in a health plan, or eligibility for benefits on the provision of an authorization. HHS explains that this prohibition is intended to ensure that an authorization from an individual for a use or disclosure of PHI is voluntarily provided. However, HHS notes that there have been exceptions to this general rule for certain circumstances, including in the research context, where a CE *may* condition the provision of research-related treatment, such as in a clinical trial, on obtaining the individual's authorization for the use or disclosure of PHI for such research. HHS explains that allowing the use of PHI in the research context is part of the decision to receive care through a clinical trial, and health care providers conducting such trials are able to condition research-related treatment on the individual's willingness to authorize the use or disclosure of PHI for research associated with the trial.

Notwithstanding the foregoing, HHS notes that, with certain exceptions, the Privacy Rule has generally prohibited the use of "compound authorizations." HHS explains that a compound authorization is where an authorization for the use and disclosure of PHI is combined with any other legal permission. While compound authorizations are generally prohibited, HHS notes that an exception has been provided for combining an authorization for a research study with any other written permission for the same study, including another authorization or informed consent to participate in the research. Even though this exception has existed in the research context, HHS notes that what has *not* been allowed are compound authorizations that combine "conditioned authorizations" with "unconditioned authorizations." Specifically, HHS notes that the Privacy Rule has prohibited combining an authorization that conditions treatment, payment, enrollment in a health plan, or eligibility for benefits (a "conditioned authorization") with an authorization for another purpose for which treatment, payment, enrollment, or eligibility may not be conditioned (an "unconditioned authorization").

For example, HHS describes a research study where PHI is sought to be used or disclosed for two purposes. First, PHI would be used for purposes of the research treatment part of the study. In order to participate in the research treatment study, a research participant would have to provide a conditioned authorization; the authorization is a "conditioned authorization" because participation in the research treatment study is conditioned on the participant providing the authorization. In addition, PHI would be used for the collection of the study participants' specimens, which would be used as part of a central repository (e.g., tissue banking). In order to participate in the central repository, a research participant would have to provide an unconditioned authorization; the authorization is an "unconditioned authorization" because participation in the treatment part of the research study is not conditioned on the participant providing the unconditioned authorization for participation in the central repository.



HHS explains that prior to the Final Rule, CEs have had to have obtained two separate authorizations; one for the treatment part of the study, which would require the conditioned authorization, and another for the central repository or tissue banking part of the study, which would require the unconditioned authorization. Accordingly, a study participant would have to provide a conditioned authorization in order to receive the research treatment. However, HHS notes that whether the individual also provided the unconditioned authorization—that is, the authorization for the central repository or tissue banking—would be completely voluntary and would not affect whether the individual received the research-related treatment. HHS notes that the limitation on certain compound authorizations was intended to help ensure that individuals understand that they do not have to agree to participate in the activity described in the unconditioned authorization but may still receive treatment or other benefits or services by agreeing to the conditioned authorization.

The Final Rule now allows a CE to combine conditioned and unconditioned authorizations for research, but only if certain requirements are met. First, the authorization must clearly differentiate between the conditioned and unconditioned research components. In addition, the authorization must clearly allow the individual the option to opt *in* to the unconditioned research activities. Of note, HHS declines to allow a combined authorization that only allows the individual the option to opt *out* of the unconditioned research activities (e.g., "check here if you do NOT want your data provided to the biospecimen bank"), stating that "an opt out option does not provide individuals with a clear ability to authorize the optional research activity, and may be viewed as coercive by individuals."

Combined authorizations that meet these requirements may therefore be obtained for the use of PHI in a clinical trial and for any sub-studies, as well as for biospecimen banking that contemplates future use of the specimens (see below for a discussion of future use authorizations). In addition, HHS explains that the use of compound authorizations can be for any type of research activities, and not solely for clinical trials and biospecimen banking.¹⁴ In addition, HHS notes that CEs may combine such authorizations with informed consent documents for the research studies. HHS also notes that CEs, institutions, and Institutional Review Boards have flexibility to determine the best approach for clearly differentiating the conditioned and unconditioned research activities and giving research participants the option to opt in to the unconditioned research activities.

2. Authorizations for Future Research

As briefly noted above, clinical research may involve obtaining health information and biological specimens to create a research database or a central repository for future research. HHS notes that it has previously interpreted the Privacy Rule to require that authorizations for research must be study specific and that an authorization must include a description of each purpose of the requested use or disclosure. HHS explains that its interpretation was based on a concern that patients could lack necessary information in the authorization to make an informed decision about future research. Since issuing this interpretation, HHS notes that it became aware of concerns that its interpretation regarding authorizations for future research encumbers secondary research, and has been inconsistent with current practices under the "Common Rule,"

¹⁴ HHS notes, however, that a compound authorization cannot be used for the use or disclosure of psychotherapy notes. It explains that an authorization for psychotherapy notes can only be combined with another authorization for a use or disclosure of such notes.



which HHS notes generally allows a researcher to seek subjects' informed consent to future research so long as the future research uses are described in sufficient detail to allow an informed consent.¹⁵

In the Final Rule, HHS states that it is modifying its prior interpretation that research authorizations must be study specific. Although HHS notes that this modification does not make any changes to the authorization requirements at §164.508, HHS no longer interprets the "purpose" provision (§164.508(c)(1)(iv)) as requiring that an authorization for the use or disclosure of PHI for research purposes be study specific. Thus, HHS notes that in order to satisfy the requirement that an authorization include a description of each purpose of the requested use or disclosure, an authorization for uses and disclosures of PHI for future research purposes must adequately describe the purposes "such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research." HHS further notes that all required elements of a proper authorization must be included in an authorization for future research, although they may be described in a more general manner than is done for specific studies. In addition, HHS notes that CEs, researchers and Institutional Review Boards have flexibility to determine what adequately describes a future research purpose, depending on the circumstances.

C. The Sale of PHI

As noted above, §164.508 of the Privacy Rule has permitted and continues to permit a CE to use and disclose PHI for purposes not otherwise permitted by the Privacy Rule if it has obtained a valid written authorization from the individual who is the subject of the information. As also noted above, prior to the Final Rule, §164.508 has specified two circumstances under which, with certain exceptions, an authorization from the individual must be obtained: (1) uses and disclosures for marketing purposes, and (2) uses and disclosures of psychotherapy notes. HHS notes that the HITECH Act added a third circumstance where authorization is required, specifically the sale of PHI.

Accordingly, the Final Rule adopts the HITECH Act's prohibition on the sale of PHI and defines "sale of protected health information" to generally mean, with certain exceptions, "a disclosure of protected health information by a covered entity or business associate, if applicable, where the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information." HHS explains that a sale of PHI occurs when the CE primarily is being compensated to supply data it maintains in its role as a CE (or business associate ("BA")) and such disclosures require the individual's authorization (unless they meet an exception, discussed below). In addition, HHS notes that a "sale" is not limited to transfers of ownership, but includes remuneration for disclosures of PHI that result from access, license, or lease agreements.

In addition, HHS provides guidance as to what does and does not constitute a sale of PHI. First, HHS notes that a sale of PHI does *not* include remuneration a CE receives in the form of grants, contracts, or other arrangements to perform

¹⁵ According to HHS, "[t]he Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies . . . For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance." See, <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>



programs or activities, such as a research study, because any provision of PHI to the payer is a "byproduct" of the service being provided. For example, HHS notes that the payment by a research sponsor to a CE to conduct a research study is not considered a sale of PHI even if research results that may include PHI are disclosed to the sponsor in the course of the study. Further, HHS states that the receipt of a grant or funding from a government agency to conduct a program is also *not* a sale of PHI, even if, as a condition of receiving the funding, the CE is required to report PHI to the agency for program oversight or other purposes. Finally, HHS states that the exchange of PHI through a health information exchange ("HIE") that is paid for through fees assessed on HIE participants is not a sale of PHI because the remuneration is for the services provided by the HIE and not for the data itself.

HHS also provides guidance as to the term "remuneration." HHS explains that since the HITECH Act uses the term "remuneration," and not "payment," (as it does with respect to the marketing provisions) the term "remuneration" used in connection with the sale of PHI is *not* limited to financial payment in the same way it is so limited in the marketing provisions. Accordingly, the prohibition on the sale of PHI applies to the receipt of nonfinancial, as well as financial benefits. Thus, HHS states, a CE or BA may not disclose PHI in exchange for in-kind benefits, unless the disclosure falls within one of the exceptions (discussed below). Further, HHS notes that the provisions prohibit the receipt of remuneration not only from the third party that receives the PHI, but also from another party on behalf of the recipient of the PHI.

Finally, HHS notes that it adds the term "business associate" to the general prohibition on the sale of PHI, even though, "without the addition, a business associate still would not be permitted to sell protected health information as a business associate may generally only make uses and disclosures of protected health information in manners in which a covered entity would be permitted under the Privacy Rule."

As noted above, the prohibition on the sale of PHI contains certain exceptions. First, the Final Rule contains a broad exception to the definition of the "sale of PHI" for exchanges of remuneration for public health purposes. HHS notes that the HITECH Act required HHS to evaluate the impact on public health activities of restricting this exception to require that the price charged for the data must reflect only the costs of preparing and transmitting the data. If HHS were to find that this restriction would not impede public health activities, the HITECH Act stated that the restriction could then be included in the regulations. In light of this, HHS notes that although it previously did *not* propose to include such a restriction on remuneration, it requested public comment to assist it in evaluating the impact of doing so. Accordingly, HHS notes that, based on concerns from public comments that narrowing the exception could discourage voluntary public health reporting, HHS does not limit the exception to only those disclosures where all the CE receives as remuneration is a cost-based fee to cover the cost to prepare and transmit the data. Rather, the Final Rule contains a broad exception, which states that a sale of PHI does not include a disclosure of PHI "for public health purposes . . ."

The Final Rule also contains an exception for disclosures for research purposes in exchange for which the CE receives only a reasonable, cost based fee. Unlike the broad exception for public health purposes, disclosures for research purposes are excepted from the remuneration prohibition, but only to the extent that the only remuneration the CE or BA receives is "a reasonable cost-based fee to cover the cost to prepare and transmit the protected health information for such purposes." HHS clarifies that the remuneration may include both direct and indirect costs, including labor, materials, and supplies for generating, storing, retrieving, and transmitting the PHI; labor and supplies to ensure the PHI is disclosed in a permissible



manner; and related capital and overhead costs. However, HHS notes that fees charged to incur a profit from the disclosure of PHI "are not allowed." HHS also notes that it intends to work with the research community to provide guidance and help the research community reach a common understanding of appropriate cost-based limitations on remuneration.

The Final Rule also contains exceptions for treatment and payment disclosures, which HHS explains are necessary to make clear that these core health care functions may continue, as well as for disclosures for the transfer, merger, or consolidation of all or part of a CE with another CE, or an entity that following such activity will become a CE, and related due diligence. In addition, the Final Rule contains an exception for disclosures that are otherwise required by law to ensure a CE can continue to meet its legal obligations without imposing an authorization requirement, as well as an exception for disclosures to the individual to provide the individual with access to PHI or an accounting of disclosures, where the fees charged for doing so are in accordance with the Privacy Rule.

Also contained in the Final Rule is a general exception permitting a CE to receive remuneration in the form of a reasonable, cost-based fee to cover the cost to prepare and transmit PHI for any disclosure otherwise permitted by the Privacy Rule, as well as an exception for remuneration paid by a CE to a BA for activities performed on behalf of a CE. HHS provides certain clarifications regarding the ability of a BA (rather than a CE) to receive the permitted remuneration. First, HHS clarifies that BAs may continue to recoup fees from third party record requestors for preparing and transmitting records on behalf of a CE, to the extent such fees are reasonable, cost-based fees to cover the cost to prepare and transmit the PHI or otherwise expressly permitted by other law. In addition, HHS clarifies that this exception also covers remuneration by a BA to its subcontractor for activities performed by the subcontractor on behalf of the BA.

With respect to the types of costs that would be permitted as part of a "reasonable, cost-based fee," HHS notes that the Final Rule permits the same types of fees as discussed above with respect to the research exception, as well as costs that are in compliance with a fee schedule provided by State law or otherwise expressly permitted by other applicable law. Thus, HHS states that the fee may include the direct and indirect costs to prepare and transmit the data, including labor, materials, and supplies, but may not include a profit margin. HHS also states that it intends "to continue to work with interested stakeholders to develop more guidance on direct and indirect costs and on remuneration."

II. Fundraising

With respect to fundraising, HHS notes that the Privacy Rule has permitted a CE to use, or disclose to a BA or to an institutionally related foundation, the following PHI about an individual for the CE's fundraising from that individual without the individual's authorization: (1) demographic information relating to an individual, and (2) the dates of health care provided to an individual. HHS also notes that the Privacy Rule has required a CE that plans to use or disclose PHI for fundraising to inform individuals in its notice of privacy practices that it may contact them to raise funds for the CE. Finally, HHS notes that a CE has had to include in any fundraising materials it sends to an individual a description of how the individual may opt out of receiving future fundraising communications, and has had to make "reasonable efforts" to ensure that individuals who do opt out are not sent future fundraising communications.



The Final Rule makes certain changes to the Privacy Rule's fundraising provisions. First, HHS notes that the Privacy Rule has permitted CEs to use or disclose only dates of health care provided to an individual, demographic information relating to the individual for fundraising communications, and health insurance status.¹⁶ HHS clarifies that "demographic information relating to an individual" includes names, addresses, other contact information, age, gender, and dates of birth. In addition, the Final Rule now allows CEs to use and disclose department of service information, treating physician information, and outcome information for fundraising purposes. HHS notes that these three categories of information were most frequently identified by commenters as the most needed for CEs to further target fundraising communications to appropriate individuals. Although HHS does not clarify the terms, it notes that that department of service information includes information about the general department of treatment, such as cardiology, oncology, or pediatrics. Additionally, HHS clarifies that outcome information includes information regarding the death of the patient or any "sub-optimal result of treatment or services," which may be used by the CE to screen and eliminate from fundraising solicitations those individuals experiencing a sub-optimum outcome. HHS also reminds providers that a CE must apply the minimum necessary standard to ensure that only the minimum amount of PHI necessary to accomplish the intended purpose is used or disclosed.

In addition, the Final Rule strengthens the fundraising "opt out" requirement, which, as noted above, requires a CE to describe how an individual may opt out of receiving future fundraising communications. Prior to the Final Rule, CEs were required only include "a description of how the individual may opt out of receiving any further fundraising communications." The Final Rule requires that a CE provide, with each fundraising communication sent to an individual, "a clear and conspicuous opportunity" for the individual to elect not to receive further fundraising communications. HHS explains that, while CEs may decide what method individuals can use to opt out of receiving further fundraising communications, the Final Rule states that the method may not "cause the individual to incur an undue burden or more than a nominal cost."

For example, HHS notes that requiring individuals to write and send a letter to the CE asking not to receive further fundraising communications would constitute an undue burden. However, HHS believes that requiring individuals to opt out by mailing a pre-printed, pre-paid postcard would not constitute an undue burden. Further, HHS suggests that CEs consider using a toll-free phone number, an e-mail address, or similar opt out mechanisms that provide individuals with simple, quick, and inexpensive ways to opt out of receiving further fundraising communications. HHS also suggests that CEs may employ multiple opt out methods, allowing individuals to determine which opt out method is the simplest and most convenient for them, or a single method that is reasonably accessible to all individuals wishing to opt out.

Regarding the scope of the opt out, HHS notes that it is up to the CE to determine whether the opt out will apply to all future fundraising communications or to a specific fundraising campaign. Thus, CEs have the discretion to apply the opt out to all future fundraising communications or to apply the opt out to specific fundraising campaigns only. HHS notes,

¹⁶ HHS notes that in the preamble to its Final Rule titled, "Standards for Privacy of Individually Identifiable Health Information", it identified insurance status as falling within the category of demographic information. (65 Fed. Reg. 82462, 82718 (Dec. 28, 2000)). In the preamble to the Final Rule, HHS states that the Final Rule continues to allow CEs to use or disclose information about an individual's health insurance status for fundraising purposes, but lists this as a separate category in the regulatory text, since HHS states that it does not believe this information truly constitutes demographic information.



however, that whatever method is employed, the communication should clearly inform individuals of their options and any consequences of electing to opt out of further fundraising communications. With respect to any consequences of opting out, HHS notes that the Final Rule states that a CE may not condition treatment or payment on an individual's choice with respect to receiving fundraising communications.

In addition, HHS notes that the Final Rule changes the requirement that CEs make "reasonable efforts" to ensure that those individuals who have opted out of receiving fundraising communications are not sent such communications. Specifically, HHS notes that this requirement is strengthened to be more protective of an individual's right to elect not to receive further fundraising communications by removing the "reasonable efforts" standard. Thus, rather than allowing CEs to use "reasonable efforts" to ensure opted-out individuals do not receive fundraising communications, the Final Rule states that a CE "may not make fundraising communications to an individual . . . where the individual has elected not to receive such communications . . ."

In discussing this change, HHS notes that the Final Rule is intended to make clear the expectation that CEs abide by an individual's decision not to receive fundraising communications, as well as to make the fundraising opt out operate more like a revocation of authorization. In response to concerns about lag times between the creation of mailing lists and the receipt or update of opt out lists, and the difficulty in accurately identifying individuals on the fundraising lists due to name changes or variations and multiple addresses, HHS indicates that such issues are common in the management of the medical or billing records and effectuating revocations of authorization, requests for access, and other general communications between the entity and the individual. HHS notes that it "expect[s] the same care and attention to the handling of protected health information in fundraising communications as is necessary for the proper handling of this information in all other health care operations performed by the covered entity. Covered entities voluntarily choosing to send fundraising communications to individuals must have data management systems and processes in place to timely track and flag those individuals who have opted out of receiving fundraising communications to ensure that they are not sent additional fundraising communications."

Finally, the Final Rule requires that the notice of privacy practices inform individuals that a CE may contact them to raise funds for the CE and that an individual has a right to opt out of receiving such communications. HHS clarifies that the Final Rule does not require CEs to send pre-solicitation opt outs to individuals prior to the first fundraising communication. HHS also clarifies that because the Privacy Rule applies to communications made over the phone, fundraising communications over the phone must clearly inform individuals that they have a right to opt out of further solicitations. Further, HHS emphasizes that the notice and opt out requirements for fundraising communications apply only where the CE is using or disclosing PHI to target the fundraising communication. If the CE does not use PHI to send fundraising materials (e.g., if a public directory is used), then the notice and opt out requirements do not apply.

III. Notice of Privacy Practices

As HHS notes, the Privacy Rule has required that most CEs must have and distribute a notice of privacy practices ("NPP"), which describes the uses and disclosures of PHI a CE is permitted to make, the CE's legal duties and privacy practices with respect to PHI, and the individual's rights concerning PHI. CEs have also been required to include separate statements about permitted uses and disclosures that the CE intends to make, including uses and disclosures for certain



treatment, payment, or health care operations purposes, and have been required to include a statement that any uses and disclosures other than those permitted by the Privacy Rule will be made only with the written authorization of the individual, and that the individual has the right to revoke an authorization.

The Final Rule makes a number of changes to the NPP requirements, which, among other things, will require CEs to revise their NPPs. First, the Final Rule requires the NPP to describe the uses and disclosures that will require authorization. HHS notes that the Final Rule does not require the NPP to include a list of *all* situations requiring authorization. Instead, the NPP must contain a statement indicating that most uses and disclosures of psychotherapy notes (where appropriate), uses and disclosures of PHI for marketing purposes, and disclosures that constitute a sale of PHI require authorization, as well as a statement that other uses and disclosures not described in the NPP will be made only with the authorization from the individual.

In addition, the Final Rule requires the NPP to contain a statement regarding fundraising communications and an individual's right to opt out of receiving such communications, if a CE intends to contact an individual to raise funds for the CE. The Final Rule also requires the NPP to inform individuals of their 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 (discussed below). With respect to such restrictions, HHS notes that only health care providers are required to include such a statement in the NPP; other CEs may retain the existing language indicating that a CE is not required to agree to a requested restriction.

Further, the Final Rule requires CEs to include in their NPPs a statement of the right of affected individuals to be notified following a breach of their unsecured PHI. HHS notes that, contrary to the belief that such a statement would cause individuals unnecessary concern and would create unfounded fear that CEs cannot appropriately secure PHI, HHS believes that the statement "should provide helpful context" for individuals in the event they later receive a breach notification. HHS clarifies that the NPP need only contain a simple statement that an individual has a right to or will receive notifications of breaches of his or her unsecured PHI. HHS explains that it does intend for this requirement to add undue complexity or length to a CE's NPP. Therefore, HHS notes that CEs do not need to include information such as how the CE will conduct a risk assessment, do not need to include the regulatory definitions of "breach" or "unsecured PHI," and do not need to describe the types of information to be provided in the notice. HHS notes, however, that CEs may include additional or more detailed information regarding breaches in its NPP if it so chooses.

As a result of the "material changes" to the NPP requirements, HHS notes that new NPPs will need to be distributed since the modifications "are significant and are important to ensure that individuals are aware of the HITECH Act changes that affect privacy protections and individual rights regarding protected health information." HHS clarifies that, for health care providers, the Final Rule does not modify the current requirements regarding distributing revisions to the NPP. In response to commenters' concerns about printing costs for new NPPs, HHS also clarifies that providers are not required to print and hand out revised NPPs to all individuals seeking treatment. Rather, health care providers with direct treatment relationships with individuals must make the NPP available upon request on or after the effective date of the revision, must have the NPP available at the delivery site for individuals to request to take with them, and must post a notice in a clear and prominent location. HHS explains that providers are only required to give a copy of the NPP to, and obtain a good faith acknowledgment of receipt from, new patients.



With respect to health plans, HHS notes that the Final Rule now requires that a health plan that currently posts its NPP on its web site to: (1) prominently post the material change or its revised notice on its web site by the effective date of the material change to the notice (e.g., the compliance date of the Final Rule) and (2) provide the revised notice or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan, such as at the beginning of the plan year or during the open enrollment period. Health plans that do not have customer service websites are required to provide the revised NPP, or information about the material change and how to obtain the revised notice, to individuals covered by the plan within 60 days of the material revision to the notice. HHS notes that the requirements apply to all material changes including, where applicable, the Rule change adopted pursuant to GINA (discussed below).

IV. Right to Request Restrictions on Uses and Disclosures of PHI

The Privacy Rule has required CEs to permit individuals, among other things, to request that a CE restrict uses or disclosures of their PHI for treatment, payment, and health care operations purposes. Prior to the Final Rule, CEs have not been required to agree to such requests for restrictions. However, the Privacy Rule has required that, if a CE were to agree to restrict the use or disclosure of an individual's PHI, the CE must abide by that restriction, except in emergency circumstances when the information is required for the treatment of the individual. The Privacy Rule has also included provisions for the termination of such a restriction, and has required that CEs that have agreed to a restriction to document the restriction in writing.

The Final Rule makes certain changes to the right of individuals to request restrictions on uses and disclosures of their PHI for treatment, payment and health care operations purposes. Specifically, the Final Rule states that a CE *must* agree to a request by an individual to restrict the disclosure of PHI about the individual to a health plan if: (1) the disclosure is for the purposes of carrying out payment or health care operations and is not otherwise required by law, and (2) the PHI pertains solely to a health care item or service for which the individual, or person on behalf of the individual other than the health plan, has paid the CE in full.

HHS provides clarification with respect to this requirement. First, HHS clarifies that health care providers are not required to create separate medical records or otherwise segregate PHI subject to a restriction. They will, however, need to employ some method to flag or make a notation in the record with respect to the PHI that has been restricted to ensure that such information is not inadvertently sent to or made accessible to the health plan for payment or health care operations purposes.

In addition, HHS provides guidance with respect to the restriction on disclosures and a provider's obligation to meet its legal obligations, such as disclosing PHI to Medicare or Medicaid for required audits. HHS notes that, notwithstanding a restriction, the Final Rule allows disclosures to be made that are required by law. Under §164.103, "required by law" is defined as a mandate contained in law that compels a CE to make a use or disclosure of PHI and that is enforceable in a court of law. HHS clarifies that, for purposes of this definition, "required by law" includes Medicare conditions of participation with respect to health care providers participating in the program, and statutes and regulations that require the production of information if payment is sought under a government program providing public benefits. Therefore,



according to HHS, if a CE is required by law to submit PHI to a federal health plan, it may continue to do so as necessary to comply with that legal mandate.

HHS also provides guidance with respect to individuals who may request a restriction with respect to only one of several health care items or services provided in a single patient encounter, where the provider either cannot unbundle, or it is more costly for the provider to unbundle, the services for purposes of billing a health plan. HHS declines to adopt a general rule that an individual may only restrict either "all or none" of the health care items or services that are part of one treatment encounter. Rather, HHS states that it would expect a provider to accommodate an individual's request for a restriction for separable and unbundled health care items or services, even if they are part of the same treatment encounter (such as if a patient were receiving treatment for both asthma and diabetes). In such event, HHS states that it expects providers to counsel patients on the ability 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 that the restricted item or service was performed based on the context). If a provider is able to unbundle the items or services and accommodate the individual's wishes after counseling the individual on the impact of unbundling, HHS states that the provider should do so. If the provider cannot unbundle a group of items or services, HHS states that it would consider the group as one item or service, and the provider should inform the individual and give him or her the opportunity to restrict and pay out of pocket for the entire bundle of items or services.

With respect to notifying subsequent or downstream providers of the restriction, HHS notes that it would be unworkable to require health care providers to notify downstream providers of the fact that an individual has requested a restriction to a health plan. This is the obligation of the individual seeking the restriction. However, HHS "encourages" providers to counsel patients that the patients would need to request a restriction and pay out of pocket with respect to other providers for the restriction to apply to the disclosures by such providers. In addition, HHS notes that, while it does not require it, providers are permitted and encouraged to assist individuals "as feasible" in alerting downstream providers of the individual's desire to request a restriction and pay out of pocket for a particular health care item or service. HHS also notes that it is also the obligation of the individual, and not the provider, to notifying subsequent or downstream providers when an HIE is involved.

Finally, under the Final Rule, a CE must apply a restriction not only where an individual pays in full for the healthcare item or service, but also where a family member or other person pays for the item or service on behalf of the individual. In addition, HHS advises that in the event an individual's payment is dishonored, HHS expects that providers will "make a reasonable effort to contact the individual and obtain payment prior to billing a health plan." Although HHS does not prescribe the efforts a health care provider must undertake to obtain payment, HHS notes that it does not require that the individual's debt be placed in collection before a provider is permitted to bill a health plan for the health care services. HHS notes that a provider may choose to require payment in full at the time of the request for a restriction to avoid payment issues. Additionally, with respect to restrictions in connection with follow-up care, HHS states that if an individual (i) has a restriction in place with respect to a health care service, but (ii) does not pay out of pocket and requests a restriction with regard to follow-up treatment, and (iii) the provider needs to include information that was previously restricted in the bill to the health plan in order to have the service deemed medically necessary or appropriate, then the provider *is* permitted to disclose such information so long as doing so is consistent with the provider's minimum necessary policies and procedures.



V. Access of Individuals to PHI

According to HHS, the Privacy Rule currently establishes, with limited exceptions, an enforceable means by which individuals have a right to review or obtain copies of their PHI to the extent such information is maintained in the designated record set(s) of a CE. HHS notes that an individual's right of access exists regardless of the format of the PHI, and the standards and implementation specifications that address individuals' requests for access apply to PHI in electronic and paper format.

The Final Rule strengthens this right of access with respect to CEs that use or maintain an electronic health record ("EHR") on an individual and requires that if an individual requests an electronic copy of PHI that is maintained electronically in one or more designated record sets, the CE *must* provide the individual with access to the electronic information in the electronic form and format requested by the individual, if it is readily producible. If it is not readily producible, the CE must provide access to the information in a readable electronic form and format as agreed to by the CE and the individual. In such cases, HHS notes that, to the extent possible, HHS expects CEs to provide the individual with a machine readable copy of the individual's PHI. According to HHS, a "machine readable copy" means digital information stored in a standard format enabling the information to be processed and analyzed by computers (e.g., formats of MS Word or Excel, text, HTML, or text-based PDF).

HHS notes that CEs will vary in terms of the readable electronic form and format they have, and that CEs will improve their technological capabilities over time. Accordingly, HHS states that CEs have the flexibility to provide readily producible electronic copies of PHI that are currently available on their various systems, and that CEs do not have to purchase new software or systems in order to accommodate a request for a specific form of electronic copy that it cannot readily produce at the time of the request (so long as the CE can produce *some* form of electronic copy). However, HHS also notes that some "legacy" or other systems may not be capable of providing any form of electronic copy; therefore, certain CEs may need to make an investment in order to meet the basic requirement to provide some form of electronic copy. Further, HHS notes that if an individual requests a form of electronic copy that the CE is unable to produce, the CE must offer other electronic formats that are available on their systems. If the individual does not accept any of the electronic formats that are readily producible, the CE must provide a hard copy as an option to fulfill the access request. HHS also notes that CEs do not have to scan paper documents in order to provide individuals with electronic copies of those records.

In addition, in response to comments, HHS clarifies that a CE is allowed to send individuals unencrypted emails if the CE has advised the individual of the risk associated with unencrypted emails, and the individual still prefers to receive the unencrypted email. HHS notes that CEs have no "duty to warn" individuals of the risks, since HHS believes it would be unduly burdensome on CEs to "educate individuals about encryption technology and the information security." Rather, HHS expects the CE to notify the individual that there may be "some level of risk that the information in the email could be read by a third party." If the individual still prefers an unencrypted email, the individual has the right to receive PHI in such email, and CEs are not responsible for unauthorized access of PHI while in transmission to the individual. Further, HHS notes that CEs are not responsible for safeguarding information once it has been delivered to the individual.



The Final Rule also expressly provides that, if requested by an individual, a CE must transmit the copy of PHI directly to another person designated by the individual. However, the request must be made in writing, be signed by the individual, clearly identify the designated person, and clearly identify where to send the copy of the PHI. HHS states that CEs may rely on the information provided in writing by the individual when providing PHI to a third party recipient identified by the individual. However, the CE must also implement reasonable policies and procedures to verify the identity of any person who requests PHI, and must implement reasonable safeguards to protect the information that is used or disclosed. For example, HHS states that reasonable safeguards would not require a CE to confirm that the individual provided the correct e-mail address of the third party, but *would* require reasonable procedures to ensure that the CE correctly enters the e-mail address into its system.

HHS also notes that CEs have been able to charge reasonable, cost-based fees for copies of PHI (or summaries or explanations of such information). HHS provides guidance as to what constitutes "reasonable, cost-based fees." First, HHS states that the Final Rule separately identifies the labor for copying PHI, whether in paper or electronic form, as one component that may be included in a reasonable cost-based fee. Further, with respect to electronic copies, HHS notes that a reasonable cost-based fee includes costs attributable to the labor involved to review the access request and to produce the electronic copy, as well as "technical staff time" spent to create and copy the electronic file. HHS states that this could also include the time spent preparing an explanation or summary of the PHI, if appropriate. However, HHS clarifies that a CE may not charge a retrieval fee (whether a standard retrieval fee or one based on actual retrieval costs) in connection with either electronic access or hard copies. Further, HHS notes that the Final Rule also provides separately for the cost of supplies for creating the paper copy or electronic media (i.e., physical media such as a compact disc or USB flash drive), if the individual requests that the electronic copy be provided on portable media. In addition, if an individual requests that the CE transmit portable media containing an electronic copy through mail or courier, HHS states that the CE is permitted to charge for postage. However, since HHS does not require CEs to obtain new types of technology to comply with specific individual requests, HHS notes that any cost of obtaining such new technologies are not permitted to be included in supply costs. Similarly, fees associated with maintaining systems and recouping capital for data access, storage, and infrastructure are not considered reasonable, cost-based fees.

Finally, the Final Rule modifies the timeliness requirements in connection with the right to access and to obtain a copy of PHI. Specifically, while the Final Rule still provides a CE with 30 days after its receipt of a request for access to act on such request, the Final Rule removes the provision that has given a CE 60 days for timely action when PHI for access is not maintained or accessible to the CE on-site. The Final Rule, however, still permits a CE a one-time extension of 30 days to respond to the individual's request (with written notice to the individual of the reasons for delay and the expected date by which the CE will complete action on the request). As HHS notes, this means, for example, that a CE must provide an individual with access to off-site records, within 30 days of the individual's request when possible, with a 30-day extension available (for a total of 60 days, rather than for a total of up to 90 days). HHS notes, however, that, while a CE is permitted 30 days to provide access (with a 30-day extension when necessary), HHS "encourages" CEs to provide individuals with access to their information sooner, and "to take advantage of technologies that provide individuals with immediate access to their health information."



VI. Modifications as a Result of GINA

As HHS notes, GINA prohibits discrimination based on an individual's genetic information in both the health coverage and employment contexts. HHS also notes that, with respect to health coverage, GINA generally prohibits discrimination in premiums or contributions for group coverage based on genetic information; proscribes the use of genetic information as a basis for determining eligibility or setting premiums in the individual and Medicare supplemental ("Medigap") insurance markets; and limits the ability of group health plans, health insurance issuers, and Medigap issuers to collect genetic information or to request or require that individuals undergo genetic testing. HHS states that GINA also generally prohibits the use of genetic information in the employment context, restricts employers and certain other entities from requesting, requiring, or purchasing genetic information, and strictly limits such entities from disclosing genetic information. In addition to these nondiscrimination provisions, HHS notes that GINA contains new privacy protections for genetic information, which require HHS to revise the Privacy Rule to clarify that genetic information is health information and to prohibit group health plans, health insurance issuers (including HMOs), and issuers of Medicare supplemental policies from using or disclosing genetic information for underwriting purposes.

According to HHS, GINA describes four types of entities (i.e., group health plans, health insurance issuers, and health maintenance organizations, as defined in the Public Health Services Act, as well as issuers of Medicare supplemental policies), that correspond to the types of CEs listed in the Privacy Rule. However, HHS notes that, in addition to these four types of entities, the Privacy Rule also includes a number of other entities within the definition of "health plan" including, without limitation, long-term care policies (excluding nursing home fixed-indemnity policies), employee welfare benefit plans, State high risk pools, and certain public benefit programs, such as Medicare Part A and B, Medicaid, the military and veterans' health care programs, the Indian Health Service program, and others. In the GINA Proposed Rule, HHS proposed to apply the prohibition on using and disclosing PHI that is genetic information for underwriting to all health plans that are subject to the Privacy Rule, rather than solely to the plans GINA explicitly requires be subject to the prohibition.

According to HHS, the Final Rule adopts the approach of the GINA Proposed Rule to apply the prohibition on using or disclosing PHI that is genetic information for underwriting purposes to all health plans that are CEs under the Privacy Rule, including those to which GINA does not expressly apply, except with regard to issuers of long term care policies. HHS states that it believes that individuals have a strong privacy interest in not having their genetic information used in an adverse manner for underwriting purposes and believe that this privacy interest outweighs any adverse impact on most health plans covered by the Privacy Rule.

HHS notes that, notwithstanding the exception for long term care plans, HHS believes that an individual also has a strong privacy interest in the way his or her genetic information is used for the underwriting of long-term care insurance. "At the current time, however," HHS states that it "does not have sufficient information to determine the proper balance between the individual's privacy interests and the industry's concerns about the cost effects of excluding genetic information. For that reason, we are looking into ways to obtain further information on this issue." Based on the information HHS may obtain, HHS notes that it will reassess how best to move forward in this area in the future.



HHS also explains that while it generally adopts the definition of "underwriting purposes" contained in GINA, it moves the definition to within the underwriting prohibition (§164.502(a)(5)(i)) in order to make clear that the definition applies only for purposes of the prohibition on a health plan's use or disclosure of genetic information for underwriting purposes. In addition, HHS notes that it adds certain clarifications to this prohibition. For example, HHS notes that it includes a parenthetical to explain that the rules for, or determination of eligibility for, or determination of, benefits under the plan include changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program. HHS also note that it includes a parenthetical to make clear that the computation of premium or contribution amounts under the plan, coverage, or policy includes discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program.

Further, HHS clarifies that "underwriting purposes" does not include determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy. Accordingly, HHS notes that, to the extent that an individual is seeking a particular benefit under the plan and the health plan needs genetic information to determine the medical appropriateness of providing the benefit to the individual, the plan may use or disclose the minimum necessary genetic information to determine the medical appropriateness of providing the benefit. HHS provides the example of a health plan that covers yearly mammograms for individuals under age 40 only in cases where the individual can demonstrate she is at increased risk for breast cancer. In such case, HHS notes that the plan can ask an individual under age 40 to provide the results of a genetic test or family health history and use such information to determine medical appropriateness prior to paying a claim for the mammogram.

While noting that the Final Rule prohibits health plans from using or disclosing genetic information for underwriting purposes (except with regard to health plans that are issuers of long term care policies) regardless of when or where the genetic information originated, HHS clarifies that the prohibition should *not* be construed to limit the ability of a health plan to adjust premiums or contribution amounts for a group health plan based on the manifestation of a disease or disorder of an individual enrolled in the plan (even though a health plan cannot use the manifestation of a disease or disorder in one individual as genetic information about other group members and to further increase the premium for the plan). HHS also explains that, with respect to the individual health insurance market, a health plan is not prohibited from establishing rules for eligibility for an individual to enroll in coverage or from adjusting premium or contribution amounts for an individual based on the manifestation of a disease or disorder in that individual or in a family member of such individual where such family member is covered under the individual's policy (even though the health plan cannot use the manifestation of a disease or disorder in one individual as genetic information about other individuals to further increase premiums or contribution amounts for those other individuals).

VII. Additional Final Rule Provisions

In addition to the changes to the HIPAA Rules noted in this E*Bulletin as well as in our previous E*Bulletin, we wish to note certain other changes contained in the Final Rule. For example, the Final Rule modifies the current rule to limit the period for which a CE must protect an individual's health information to 50 years after the individual's death. HHS notes that this will reduce the burden on both CEs and those seeking the PHI of persons who have been deceased for many years by eliminating the need to search for and find a personal representative of the decedent, who in many cases may not be



known or even exist after so many years, to authorize the disclosure. HHS also notes that it believes the change will benefit family members and historians who may seek access to the medical information of these decedents for personal and public interest reasons.

In addition, the Final Rule permits CEs to disclose a decedent's PHI to family members and others who were involved in the care or payment for care prior to the decedent's death, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the CE. HHS notes its belief that this change will reduce burden by permitting CEs to disclose PHI about a decedent to family members and other persons who were involved in an individual's care while the individual was alive, without having to obtain written permission in the form of an authorization from the decedent's personal representative, who may not be known or even exist, and may be more difficult to locate as time passes.

Further, the Final Rule creates a new public health provision to permit disclosure of proof of a child's immunization by a CE to a school in States that have school entry or similar laws. HHS notes that this allows a covered health care provider to release proof of immunization to a school without having to obtain a written authorization, provided the provider obtains the agreement, which may be oral, to the disclosure from a parent, guardian or other person acting in loco parentis for the individual, or from the individual, if the individual was an adult or emancipated minor. HHS also notes this change obviates the need for a CE to receive formal, executed HIPAA authorizations for such disclosures. Further, while the Final Rule requires CEs to document the agreement, HHS explains that the Final Rule is flexible, does not prescribe the nature of the documentation, and does not require a signature by the parent. This allows CEs the flexibility to determine what is appropriate for their purposes. For example, HHS notes that if a parent or guardian submits a written or email request to a CE to disclose their child's immunization records to the child's school, a copy of the request would suffice as documentation of the agreement. Likewise, if a parent or guardian calls the CE and requests over the phone that their child's immunization records be disclosed to the child's school, a notation in the child's medical record or elsewhere of the phone call would suffice as documentation of the agreement.

VIII. Next Steps

As is evident from the above, the Final Rule makes a number of changes that will require CEs to make revisions to, among other things, their NPPs and other significant documents, to conform to the Final Rule's requirements. Policies and procedures will need to be reviewed and substantially revised to include, without limitation, revised provisions regarding marketing, fundraising, the sale of PHI, research (as applicable), individual requests for access to PHI, and requests for restrictions on uses and disclosures of PHI. The foregoing changes will clearly also require entities to quickly train all workforce personnel with respect to the new requirements contained in the Final Rule. Such personnel include, without limitation, individuals in business development, marketing, fundraising, and research, as well as individuals in administration, compliance, and audit services. Entities will have to ensure that systems, including appropriate checks and balances, are in place to ensure compliance with the myriad changes resulting from the Final Rule.

Jones Walker has significant expertise in HIPAA issues and is available to assist with any and all of the steps that need to be taken as a result of the changes set forth in the Final Rule, including, without limitation, drafting new NPPs and other documents, revising policies and procedures, and providing comprehensive training to all workforce personnel. For any



questions regarding this E*Bulletin or how we may assist with the many steps that will need to be taken as a result of the Final Rule, please contact Lynn M. Barrett, Esq. at lbarrett@joneswalker.com

Please join us for our Health Care seminar titled, "Recent Health Care Trends from a Legal and Compliance Perspective," which will be held at the Westin Diplomat Resort & Spa, Golf Location in Hallandale Beach, Florida, on Friday, March 15, 2013. We, together with government representatives and other industry experts, will discuss, among other topics, government trends from an enforcement and auditing perspective, the role of quality in government cases, legal issues in referral source and physician arrangements, ZPICs and other audits, reviews, and the "down and dirty" on the new HIPAA Final Rule.

— [Lynn M. Barrett, Esq.](#)



Jones Walker offers a broad range of legal services to health care industry clients, including regulatory compliance, litigation, investigations, operations, and transactional matters. These legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:

Myla R. Reizen

Jones, Walker, Waechter, Poitevent, Carrère & Denègre L.L.P.

Miami Center, Suite 2600

201 S Biscayne Boulevard

Miami, FL 33131-4341

305.679.5716 tel

305.679.5710 fax

mreizen@joneswalker.com

Health Care Attorneys

Lynn M. Barrett

Allison C. Bell

George F. Bloss, III

David P. Borghardt

Amy C. Cowley

Mark A. Cunningham

Nadia de la Houssaye

Kathryn W. Drey

Stephanie C. Edgar

S. Trent Favre

Pauline F. Hardin

Kathleen A. Harrison

Kathryn H. Hester

Robert B. House

Mary Margaret Kuhlmann

Joseph J. Lowenthal, Jr.

J. Leray McNamara

James C. Percy

David G. Radlauer

Rudolph R. Ramelli

Myla R. Reizen

Krystal Pfluger Scott

Donald W. Washington

Amy M. Winters

This newsletter should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult your own attorney concerning your own situation and any specific legal questions you may have.

To subscribe to other E*Bulletins, visit <http://www.joneswalker.com/ecomunications.html>.