Honigman Miller Schwartz and Cohn's *December 2002*

HIPAA LAW FOCUS

A Special Joint Newsletter on the HIPAA Privacy Rule
Prepared by the
Health Care and Employee Benefits Departments of HMS&C

Guidance for the Standards for Privacy of Individually Identifiable Health Information

Introduction

On December 4, 2002, the Office of Civil Rights (OCR) within the United States Department of Health and Human Services (DHHS) released further guidance (Guidance) on the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) issued pursuant to HIPAA. The Guidance first provides an overview of the Privacy Rule and its evolution. It then explains select elements of the Privacy Rule and provides answers to frequently asked questions. The Guidance contains new information and expands on previous explanations that were the subject of prior OCR guidance. Highlighted below are the key aspects of the Guidance.

Incidental Uses and Disclosures

The Privacy Rule permits incidental uses and disclosures of protected health information (PHI), as long as a covered entity applies reasonable safeguards and, where applicable, the minimum necessary standard.

Reasonable safeguards are those administrative, technical and physical safeguards that protect against uses and disclosures not permitted by the Privacy Rule. They are *not* intended to compromise quick, effective and quality health care. Reasonable safeguards will vary for each covered entity, depending on the size and nature of its business. In establishing reasonable safeguards, a covered entity must weigh the potential risks to patient privacy, the effects on patient care and related financial and administrative burdens. Examples of reasonable safeguards include:

- Using a lowered voice when discussing PHI in public areas;
- Avoiding use of patient names in public hallways or elevators, and posting signs to remind employees to protect patient confidentiality;
- Isolating or locking file cabinets or record rooms;
- Limiting non-employee access to areas containing PHI;
- Placing patient charts facing the wall or covering them to limit the visibility of PHI;
- Requiring an escort for non-employees through areas containing PHI;
- Using passwords on computers maintaining PHI;
- Having patients stand a few feet back from a pharmacist counter used for patient counseling;
- Using cubicles, dividers, shields, curtains or similar barriers where multiple staff-patient communications occur;
- Limiting PHI disclosed on a patient answering machine or over an intercom system; and
- Not showing the purpose of a physician visit on patient sign-in sheets.

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Reasonable safeguards do *not* necessarily require structural or system changes, such as soundproofing rooms or encrypting telephone systems or medical radio communications. The Privacy Rule does not require that all risk of incidental uses and disclosures be eliminated.

Minimum Necessary Standard

The Guidance reiterates that covered entities must take reasonable steps to limit the use or disclosure of, and requests for, PHI to that which is the minimum necessary to achieve the intended purpose. OCR plans to provide additional guidance on this standard in the future and will monitor its workability to ensure that it does not impair timely access to health care.

The Guidance notes that the minimum necessary standard does not apply to:

- Disclosures to or requests by a health care provider for treatment purposes;
- Disclosures to the individual who is the subject of the PHI;
- Uses or disclosures based on the individual's authorization;
- Uses or disclosures required for compliance with HIPAA;
- Disclosures to DHHS when required under HIPAA for enforcement purposes; and
- Uses and disclosures required by other law.

Case by case review of each use of an entire medical record is unnecessary. Instead, the covered entity's policies and procedures must indicate those circumstances when disclosure of the entire record is appropriate and why. Individual review of each routine or recurring disclosure or requests is also unnecessary; rather, standard protocols limiting the PHI disclosed or requested to that minimally necessary are appropriate. In contrast, non-routine or non-recurring disclosures and requests should be reviewed individually to determine the applicable minimum necessary PHI to be disclosed in accordance with established criteria.

Generally, covered entities may reasonably rely on the judgment of the party requesting the disclosure of PHI as a request for the minimum amount of PHI needed. The Privacy Rule, however, does not require this reliance, and a covered entity always has the discretion to make its own minimum necessary determination.

OCR provides the following additional clarifications:

- Covered entities must determine what PHI is reasonably necessary for a particular purpose based on their business and workforce, and implement polices and procedures accordingly. There is no "one size fits all" approach. The standard is described as a "reasonableness" standard rather than a "best practices" standard, and covered entities should be guided by their professional judgment and standards.
- The standard does not apply to *disclosures or requests* for treatment purposes, but does apply to *uses* of PHI for treatment purposes. Covered entities are given significant discretion on how to implement the standard, through role-based access policies and otherwise.
- Since medical training programs are part of health care operations, covered entities can formulate their minimum necessary policies and procedures to allow access to PHI as needed for health care training needs.
- Health care providers are not required to make a minimum necessary determination to disclose PHI to Federal or State agencies (*e.g.*, the Social Security Administration) or its affiliated State agencies, in connection with an individual's application for Federal or State benefits.

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- Health care providers can accept a Federal or State agency's authorization form as long as it meets the requirements of the Privacy Rule. Accordingly, it is likely that we will see modifications made to agency authorization forms to ensure compliance with Privacy Rule requirements.

- The minimum necessary standard does not conflict with HIPAA's electronic transaction standards information requirements because it only applies to the optional data elements and not to required or situational data elements.

- A covered health care provider may disclose medical records, including PHI in those records created by other providers, for permissible purposes (*e.g.*, treatment).

- A covered entity may reasonably determine that a request for PHI by a researcher who has an Institutional Review Board or Privacy Board waiver of authorization meets the minimum necessary standard.

- A covered entity may reasonably rely on requests from a business associate of another covered entity as being compliant with the minimum necessary standard because the business associate contract must limit the business associate's uses and disclosure of (as well as requests for) PHI to those consistent with the covered entity's minimum necessary policies and procedures.

Personal Representatives

The Guidance, for the most part, reiterates the deference granted under the Privacy Rule to the determination under State or other applicable law of who may be treated as a personal representative. State or other applicable laws regarding health care powers of attorney continue to apply, and the scope of personal representation will depend on the authority granted under the State or other law.

The Guidance clarifies when family members may access PHI of other family members, as described below:

- Disclosure of PHI for treatment purposes does not require authorization – even when the disclosure is for the treatment of another individual. A covered entity may, therefore, disclose PHI of one family member if necessary for the treatment of another family member.

- A covered entity must treat a deceased individual's legally authorized executor or administrator as a personal representative with respect to PHI relevant to such representation.

- The Privacy Rule imposes no specific additional requirements on covered entities for identifying or verifying a personal representative. Since this is a matter for State or other law, covered entities should continue to identify such persons as they do now.

The Guidance reiterates that parents generally have access to the medical records of their minor children except: (1) when the minor consents and consent is required under State or other law, (2) when the minor obtains care at the direction of a court or person appointed by a court, and (3) when, and to the extent, the parent agrees that the minor and health care provider may have a confidential relationship. The Guidance emphasizes that:

- A parent may have access even in these exceptional situations when State law either requires or permits such parental access.

- The health care provider must get the child's permission to notify the parent where State or other law is silent about whether the provider may allow parent access to PHI when the child has previously consented to treatment without parental consent.

- Generally, parents may also access their child's medical records when the child

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received emergency medical care without parental consent.

Business Associates

After reviewing what a business associate is and providing some examples, the Guidance explains what must be included in a business associate agreement and refers to sample business associate contract language that can be found at *http://www.hhs.gov/ocr/hipaa/contractprov.html.* The Guidance then reviews the applicable compliance dates for business associate contracts, including the transition provisions, which grant an extra year for compliance with business associate contract requirements for certain contracts. All of these provisions have been described in prior editions of HIPAA LAW FOCUS, which can be found at *www.honigman.com.*

The Guidance notes that a business associate contract is not required in the following situations:

- When a health care provider discloses PHI to a health plan for payment purposes or merely accepts a discounted rate to participate in the plan's network. In those circumstances, each party is acting on its own behalf and not on behalf of the other covered entity. The same is true when a covered entity buys a health insurance product from another covered entity.

- When access to PHI is incidental, such as in connection with janitorial services, and certain contractors, such as electricians, plumbers, or copy machine technicians. In those cases, contact with PHI is limited in nature, does not occur as part of the regular performance of duties and cannot reasonably be prevented.

- When a person or entity is acting merely as a messenger for PHI such as the United States Postal Service, private couriers and their electronic equivalents. In that case, no disclosure of PHI is intended by the covered entity and the probability of exposure of PHI to these entities is very small.

- When covered entities participating in an organized health care arrangement (OHCA) make disclosures of PHI that relate to the joint health care activities of the OHCA.

- When PHI is disclosed to a researcher for research purposes based on a patient authorization, waiver of authorization, or in the form of a limited data set.

- When a financial institution processes consumer-conducted financial transactions by debit, credit or other payment card, or clears checks, initiates or processes electronic fund transfers or other activities that facilitate or effect the transfer of funds to pay for health care or health plan premiums.

The Guidance also clarifies the following:

- A covered entity with a contract eligible for the one-year extension for compliance with the business associate requirements must still fulfill its other duties under the Privacy Rule, even if those duties require assistance from its business associates.

- Business associates may not self-certify or be certified by a third party as compliant with HIPAA instead of entering into a business associate contract.

- Accreditation organizations are business associates of the covered entities that they accredit. If, however, only a limited data set is disclosed to the accreditation agency, only a data use agreement is required.

- While no business associate contract is required between health care providers for treatment purposes, a health care provider can be a business associate of another health care provider (*e.g.*, when a physician is hired by a hospital to assist in the training of medical students at the hospital).

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- A covered entity may make permitted disclosures to another covered entity's business associate.

- Physicians with hospital privileges are part of an OHCA and may disclose PHI for the joint health care activities of the OHCA without entering into a business associate contract.

- In some cases, an entity that performs business associate services can be deemed part of a covered entity's work force and exempt from the business associate requirements. For example, when a shredding company performs its services on site at a hospital, and is under the direct supervision and control of the hospital, no business associate contract is required.

- The Privacy Rule governs covered entities, not business associates. To ensure its compliance with the individual rights requirements of the Privacy Rule, however, a covered entity may contract with its business associate to ensure that Privacy Rule requirements are met. This may be particularly relevant when the business associate is the only holder of a designated record set.

- Electronic business associate contracts with electronic signatures are permitted as long as such contracts meet the requirements of applicable State law.

- A covered entity may contract with a business associate to create a limited data set in the same way that it can contract with a business associate to create de-identified information. The business associate must agree to return or destroy the information that includes the direct identifiers once it has finished the conversion for the covered entity. If the only PHI that is disclosed to a business associate is a limited data set, only a data use agreement is required.

- A re-insurer is not a business associate of a health plan because each entity is acting on its own behalf when the health plan buys the reinsurance benefits and when the plan submits a claim to the re-insurer and the re-insurer pays the claim. It is possible for a business associate relationship to arise if the re-insurer performs other services for the health plan or if it performs certain functions unrelated to the reinsurance benefits.

- Software vendors may or may not be business associates of covered entities. The mere act of selling software to a covered entity does not create a business associate relationship if the vendor does not have access to PHI of the covered entity. If the software vendor needs access to such PHI, however, it would be a business associate. This situation could arise when a software vendor hosts the software containing PHI on its own server or accesses PHI when trouble-shooting. When an employee software vendor (or other contractor) is stationed primarily on site at a covered entity, that person may be treated as a member of the covered entity's workforce, rather than as a business associate.

Use and Disclosure for Treatment, Payment and Health Care Operations

The Guidance highlights the government's intent to avoid interfering with an individual's access to quality health care and the efficient payment for such health care, and provides the following examples:

- A hospital may use PHI to provide health care and to consult with another health care provider.

- A health care provider may disclose PHI as part of a claim for payment to a health plan.

- A health plan may use PHI to provide customer service to enrollees.

- A primary care doctor may send a patient's medical record to a specialist who needs the information to treat that patient.

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- A hospital may send a patient's health care instructions to a nursing home to which the patient is transferred.

- A doctor may send an individual's plan coverage information to a laboratory that needs the information to bill for services provided at the request of the doctor for that individual.

- A hospital emergency department may give a patient's payment information to an ambulance service that transported and/or treated that patient so that the ambulance service may bill the patient.

- A health care provider may disclose an individual's PHI to a health plan for the plan's Health Plan Employer Data and Information Set purposes, as long as the health plan had or has a relationship with that individual.

The Guidance also highlights the following:

- If a State law requires consent to the use or disclosure of PHI, the Privacy Rules does not prohibit a covered entity from obtaining that consent.

- The Privacy Rule does not change informed consent and consent for treatment laws because the Privacy Rule relates to the use and disclosure of PHI and not to consent to treatment.

- A pharmacist can use a patient's PHI without written consent to fill a prescription that was telephoned in by the patient's doctor as this use is for treatment purposes.

- Health care providers to whom a patient is referred for the first time can use that patient's PHI to set up appointments and schedule surgery because this use is for treatment, payment or health care operations.

- A health care provider may consult with other providers without a patient's authorization for treatment purposes.

- A pharmacist may provide advice over the counter to a customer.

- Patients may have a friend or family member pick up prescriptions, but a pharmacist should use professional judgment and experience to make reasonable inferences about the patient's best interest.

- The disclosure by an eye doctor to a distributor of contact lenses to confirm a contact lens prescription is a permitted treatment disclosure.

- A covered health care provider can disclose PHI to a professional liability insurer or a similar entity to obtain or maintain medical liability coverage or to obtain benefits from insurer because such disclosures are for health care operations.

Marketing

The Guidance makes the following observations regarding marketing under the Privacy Rule:

- A hospital may use its patient list to announce the arrival of a new specialty group or the acquisition of new equipment through a general mailing.

- A pharmacy or other health care provider can mail a prescription refill reminder. A prescription refill reminder does *not* become a marketing communication even if a third party pays for the reminder; the receipt of remuneration does not transform a treatment communication into a commercial promotion of a product or service.

- Communications about replacements of, or enhancements to, a health plan are not marketing. For example, a health plan can mail information about Medicare supplemental

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insurance to its subscribers approaching Medicare eligibility.

- Notices about changes in deductibles, co-pays and types of coverage are not marketing.

The definition of marketing also excludes value-added items or services if the communication is health-care related and the items or services demonstrably "add value" to the plan's membership. A managed care organization may offer its members a special discount for eyeglasses without prior authorization if the discount is only available to members, and not to consumers on the open market. If members could obtain the discount directly from the eyeglass store, an authorization would be required.

Communications in connection with case management, case coordination or recommendations about alternative treatments, therapies, health care providers or settings of care conducted by or on behalf of a covered entity are not marketing. Thus, a hospital's wellness department could send flyers about its weight loss program to all obese hospital patients over the past year, even if those individuals were not specifically seen for obesity when they were at the hospital. Communications that promote health generally, such as annual mammogram reminders or organ donation cards, do not meet the definition of marketing and do not require prior authorization.

A communication does *not* require an authorization, even if it is marketing, if the communication occurs face-to-face or involves a promotional gift of only nominal value. Examples of face-to-face communications or gifts of nominal value are:

- A hospital providing a free package of formula and other baby products to new mothers upon discharge;

- An insurance agent selling insurance policies in person to a customer;

- A health plan sending its subscribers pens embossed with the health plan's logo; and

- A physician providing patients free pharmaceutical samples.

The Guidance notes that the marketing provisions of the Privacy Rule do not amend, modify or change any other rule or requirement to authorize any activity or transaction currently proscribed by Federal or State law. Thus, while a communication may not require patient authorization because it is not marketing, the arrangement nevertheless may violate other Federal or State law.

Public Health

The Guidance provides helpful information regarding disclosures for public health activities under the Privacy Rule. On the whole, covered entities should interpret this part of the Privacy Rule as encouraging full and timely disclosure. In particular:

- A health care provider or other covered entity need not obtain permission from a patient before notifying public health authorities of the occurrence of a reportable disease.

- The Guidance emphasizes the permissive nature of the Privacy Rule's public health disclosure provisions. Covered entities are advised to continue current voluntary reporting practices germane to public health and safety. Disclosures for public health purposes pursuant to State or other law are permitted.

- Facially identifiable PHI may be disclosed when needed for public health purposes. Where the reporting is not required by law, such disclosure of PHI must comply with the minimum necessary standard.

- For matters relating to FDA-regulated products, a covered entity may report PHI to any person or entity identified on a product label or in literature accompanying a product,

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or to a contact listed in another widely-used information source. These disclosures are permitted even when the link between the product and an adverse event is only suspected. The disclosure, however, must be only that which is minimally necessary to make a report.

- Health care providers may disclose PHI to the individual's employer without the individual's authorization, but only under the following limited, employment-related circumstances: the health care provider must provide a health care service to the individual at the request of the individual's employer, or as a member of the employer's workforce (*e.g.*, as a staff nurse or physician), or the health care service must relate to medical surveillance of the workplace or a work-related illness or injury. Finally, the employer must have a duty to keep records of such matters under Federal or State law (*e.g.*, OSHA). In all other circumstances, disclosure to the individual's employer would require an authorization.

Research

The following clarifications are included in the Guidance regarding research:

- Where the Privacy Rule, Common Rule and/or the Food and Drug Administration's human subject protection regulations (FDA Regulations) apply to a research study, all applicable regulations must be followed.

- The authorization required by the Privacy Rule is for the use and disclosure of PHI for research purposes, whereas the informed consent required by the Common Rule and the FDA Regulations is to consent to participate in the research study. The authorization may be combined with the required informed consent into a single form.

- If a researcher is a member of the covered entity's workforce, the researcher can use PHI to identify and contact prospective research subjects. If not, the researcher cannot contact prospective research subjects without prior authorization or waiver of authorization.

- A limited data set that omits specified direct identifiers may be used and disclosed if a data use agreement is executed. Unlike de-identified information, the use and disclosure of a limited data set remains subject to the Privacy Rule.

- It is unlikely that information maintained by a researcher would constitute a "designated record set." Therefore, individual access to PHI maintained for research purposes may be limited.

- A researcher, who conducts a clinical trial involving the delivery of health care services and transmits information electronically in connection with a transaction covered by HIPAA's electronic transaction standards would be a covered entity, and research participants would have a right to access their PHI.

- An individual's right of access to PHI may be suspended while a clinical trial is in progress, provided the participant agreed to the suspension when consenting to participate in the clinical trial. The participant must be informed that the right of access will be reinstated at the end of the clinical trial.

Disclosures for Workers' Compensation

The Privacy Rule permits covered entities to disclose PHI to workers' compensation insurers, State administrators, employers and other persons or entities involved in workers' compensation systems, in the following circumstances:

- To comply with workers' compensation laws or similar programs established by law that provide benefits for work-related injuries or illness;

- As required by State or other law; and

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- For purposes of obtaining payment for any health care provided to injured or ill workers.

Covered entities may reasonably rely on the State or public official's request for information as the minimum necessary for the intended purpose. Covered entities may disclose PHI for such purposes to the full extent authorized by State or other law. Covered entities may also disclose the type and amount of PHI necessary to receive payment for any health care provided to an injured or ill worker. Covered entities should not, however, disclose PHI to employers for workers' compensation purposes without the individual's authorization, unless such disclosure is required under State law.

The Guidance also highlights the following:

- Individuals do not have a right under the Privacy Rule to request that a covered entity restrict a disclosure of PHI for workers' compensation purposes when that disclosure is required or authorized by law.

- A covered entity may disclose PHI without authorization to adjudicate a workers' compensation claim.

- Written releases from the worker required under workers' compensation laws must be in the form of an authorization that meets the requirements of the Privacy Rule.

Notice of Privacy Practices

With respect to the Notice of Privacy Practices (Notice), the Guidance provides the following:

- Direct treatment providers, other than in emergency situations, must provide the Notice at or before the first service delivery date, and must make a good faith effort to obtain a written acknowledgment. Health plans do not need to obtain a written acknowledgment.

- When the first treatment encounter is not face-to-face, providers may mail the Notice and provide a tear-off sheet to be returned as an acknowledgement.

- Covered entities may distribute their Notice through the mail as part of other mailings.

- Health plans may distribute the Notice with the distribution of Summary Plan Descriptions.

- The Notice may not be combined in a single document with an authorization form.

- Where the Notice is delivered electronically, an electronic return receipt or other return transmission is considered valid written acknowledgment.

- Business associates do not need to create a Notice, but their uses and dislosures of PHI must be consistent with those of the covered entity.

- Participating members of an OHCA may rely on a single Notice. Provision of the Notice by any covered entity participating in the OHCA satisfies the requirement for all. But, where members of an OHCA use individual Notices, then each covered entity must provide it in accordance with the Privacy Rule. Non-direct treatment providers participating in an OHCA need not obtain an acknowledgment of the Notice.

- Health plans must provide the Notice only to the policy holder or participant, and not to all covered dependents individually.

- Health plans may distribute their Notices through a plan administrator, but if that person fails to do so, the health plan will be in violation of the Privacy Rule.

- If the patient is a minor child, Notice can be given to the parent, guardian or person acting in *loco parentis.*

- When changes are made in the Notice, a revised Notice need not be mailed or

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distributed. Rather, the revised Notice must be provided upon request, and posted where the provider has a physical service delivery site.

- Pharmacists may have the customer sign a log book acknowledging receipt of the Notice.

Government Access

The Guidance indicates that the Privacy Rule is not a tool for the government to gain additional access to individuals' PHI and notes:

- The only new governmental access to PHI is granted to DHHS for the specific purpose of enforcing the Privacy Rule. Such access is limited to information that is "pertinent to ascertaining compliance" and is subject to controls safeguarding PHI.

- The Privacy Rule does not create a Federal government database with all individuals' PHI.

- The Privacy Rule does not provide a backdoor allowing covered entities that are Federal agencies or contractors to disclose PHI that would otherwise be protected by the Privacy Act of 1974. Such covered entities must comply with that law as well as the Privacy Rule.

Miscellaneous FAQs

OCR wraps up the Guidance with information about certain aspects of the Privacy Rule's day-to-day application. The key points are:

- Activities occurring before the Privacy Rule's effective date (April 14, 2003, for most covered entities, and April 14, 2004, for small health plans) are not subject to the Privacy Rule.

- The Privacy Rule covers genetic information when that information meets the definition of PHI.

- To the extent that a State, county or local health department performs functions as a covered entity (or hybrid entity), it (or, if a hybrid entity, its designated component) must comply with the Privacy Rule.

- Generally, a third party administrator providing services to or acting on behalf of a group health plan is not a covered entity. It is a business associate of the group health plan.

- Guidance is provided to determine if a health plan meets the $5 million in annual receipts for "small health plan" status under the Privacy Rule. For ERISA group health plans that do not report receipts to the IRS, proxy measures are allowed and a link to further information on these rules can be found at *http://cms.hhs.gov/hipaa/hipaa2/default.asp*.

- Oral communications are not included in an individual's designated record set, unless they are transcribed or taped and used to make decisions about the individual. Oral communications of disclosures (*e.g.*, orally reporting an individual's communicable disease to a public health authority) must be documented as required by the Privacy Rule.

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Honigman Miller Schwartz and Cohn's HIPAA Compliance Team

Honigman Miller Schwartz and Cohn has assembled a HIPAA Compliance Team, led by the attorneys listed below from our Health Care and Employee Benefits Departments, and has developed a number of tools to facilitate compliance. We stand ready to help with any aspect of your compliance planning, from developing a compliance checklist to drafting or reviewing Notices of Privacy Practices, policies, contracts, forms and other documents needed under the Privacy Rule, and assessing legal requirements beyond the Privacy Rule (*i.e.*, State law and other requirements). We would be delighted to answer your questions or otherwise assist you and your colleagues in this important process.

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For further information regarding any of the matters discussed in this newsletter, or a brochure that more specifically describes our practices in health care law or employee benefits law, please feel free to contact any of the attorneys listed above by calling our Detroit office at (313) 465-7000, our Bingham Farms office at (248) 566-8300 or our Lansing office at (517) 484-8282.

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