Honigman Miller Schwartz and Cohn's *April 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

INTRODUCTION

On March 21, 2002, the Department of Health and Human Services ("DHHS") released a Notice of Proposed Rulemaking ("NPRM") that is intended to amend the regulatory "Standards for Privacy of Individually Identifiable Health Information" (the "Privacy Rule" or the "Rule"). The Rule was issued in December of 2000 pursuant to the Health Insurance Portability and Accountability Act ("HIPAA"), and implements the privacy requirements of the Administrative Simplification Subtitle of HIPAA. The stated purpose of the proposed changes is to simultaneously "maintain strong protections for the privacy of individually identifiable health information" while "clarifying misinterpretations, addressing the unintended negative effects of the Privacy Rule on health care quality or access to health care and relieving unintended administrative burden created by the Privacy Rule." The NPRM was published in the Federal Register on March 27, 2002. A copy of the NPRM is available at http://www.hhs.gov/ocr/ hipaa/

The NPRM proposes numerous changes to the Privacy Rule. Some significantly modify the Rule, others make minor adjustments and others simply propose conforming modifications to make the entire Privacy Rule internally consistent. It is important to remember that these changes are only "proposed." There is a 30 day comment period, after which final rules will be issued. Some of the proposed changes have been controversial, *e.g.*, the proposal to eliminate the requirement that providers obtain consent for treatment, payment or health care operations. Therefore, it is not certain which, if any, parts of the NPRM will survive in their current formulations. Each of the proposed changes is described below.

ELIMINATION OF CONSENT REQUIREMENT.

The most significant change, and certainly the most controversial, is the elimination from the Privacy Rule of the requirement that providers obtain consent for uses and disclosures of protected health information ("PHI") for treatment, payment and health care operations ("TPO"). In response to provider comments that they (i) often need PHI for TPO purposes before the first face-to-face contact with an individual, (ii) were uncertain how consent could be obtained in circumstances where treatment was not provided in person (from simple telephonic contact to Internet telemedicine consultations), and (iii) wished to avoid the draconian consequence of having to refuse treatment should consent be withheld, the Rule was modified so that providers need <u>not obtain consent</u> for TPO purposes. Covered entities may still voluntarily request patient consent, and those that do so would have complete discretion in designing their consent policies and forms. The proposed change now makes obtaining consent optional for all covered entities, and creates a uniform rule for all providers, health plans and clearinghouses.

<u>HMSC Observation</u>. *The removal of the consent requirement has been labeled as everything from a non-event to a retrograde step that effectively removes the patient from having any control over the uses and disclosures of his or her own PHI. Neither extreme characterization seems entirely accurate. In fact, it should be remembered that the initial NPRM for HIPAA's Privacy Rule did not require that health care providers obtain consent, as it was felt that the process of obtaining consent had become a mere formality and did not effectively communicate to patients the substance of how their PHI was to be used. Moreover, most patients would likely sign the form whatever it said, if the consequence of refusal was for the provider to withhold treatment. We believe that the change does not substantially impair a patient's privacy expectations under the Rule, and does ameliorate the administrative burden for health care providers. In short, it maintains the balance between individual and institutional interests that the drafters of the Rule sought to achieve and which will be necessary for the effective application of the Rule. In many instances, providers will, however, continue to seek patient consent for disclosure of their PHI. Additionally, even if HIPAA does not require consent, state law consent requirements will still apply.*

ACKNOWLEDGEMENT OF NOTICE OF PRIVACY PRACTICES.

Importantly, the NPRM requires health care providers with a direct treatment relationship with patients to make a "good faith" effort to obtain the patient's written acknowledgment that he or she has received a copy of the provider's Notice of Privacy Policies and Practices. The written acknowledgement would be obtained when the Notice must be provided, *i.e.*, at the time of the first service delivery, or what the

NPRM terms the "initial moment" of interaction between a covered health care provider and an individual, unless the treatment is emergency treatment. In emergencies, the effort to obtain written acknowledgement must be made as soon as reasonably practicable after the treatment. The NPRM emphasizes that this "initial moment" also provides the individual an opportunity to request additional restrictions on the use or disclosure of his or her PHI, or to request from the provider additional confidential treatment of communications containing PHI.

The NPRM does not propose any requirements for the form of the written acknowledgement, and the individual is not required to sign the acknowledgement. If the individual refuses to sign, the provider must, nevertheless, document the good faith efforts it undertook to obtain the signature, and the reason why the signature was not obtained (which could simply be a statement to the effect that the individual refused to sign). The documentation of this good faith effort must be retained pursuant to the documentation requirements of the current Final Rule.

HMSC Observation. *Taken together, the proposal to remove the consent requirement for TPO and the lack of a requirement to obtain a written acknowledgment of the Notice are significant dilutions of the requirements in the existing Privacy Rule, but are unlikely to significantly alter existing practices of providers.*

DISCLOSURES FOR PAYMENT AND HEALTH CARE OPERATIONS

The NPRM also modifies the Rule to permit a covered entity to disclose PHI to another covered entity for the payment activities of the other covered entity and for certain health care operations of the other covered entity (*i.e.*, quality assessment, credentialing, training, fraud and abuse detection and compliance). Under the Privacy Rule in its current final form, a covered entity could only use or disclose PHI pursuant to consent for its own TPO purposes, though it could share PHI with another provider for treatment purposes. The NPRM clarifies that covered entities participating in an organized health care arrangement ("OHCA") also may share PHI for the health care operations of the OHCA.

MINIMUM NECESSARY REQUIREMENT, ORAL COMMUNICATIONS AND INCIDENTAL USES AND DISCLOSURES

The NPRM proposes to classify certain incidental uses and disclosures of PHI that occur as a result of an otherwise permitted use or disclosure under the Privacy Rule as permissible, so long as reasonable safeguards are utilized, and the minimum necessary standards are observed, where applicable. Incidental uses and disclosures are those that cannot reasonably be prevented, are limited in nature and occur as a by-product of an otherwise permitted use or disclosure. By way of illustration, the NPRM would not permit a covered entity to seek a patient's health history on a waiting room sign in sheet. The NPRM also notes that mistake and neglect would not justify treating a disclosure as incidental. Thus, when PHI is sent via e-mail to the wrong recipient or made accessible to others via the entity's website, a violation of the Privacy Rule would occur. Additionally, the NPRM proposes to exempt from the minimum necessary standard any uses or disclosures for which a covered entity has received a proper authorization. (See page 3).

Finally, the NPRM reiterated provisions from the July, 2001 Guidance indicating that the minimum necessary standard is subject to a criterion of reasonableness. Facility redesigns and expensive computer upgrades are not specifically required by the standard, even though covered entities may need to make certain adjustments to their facilities as are reasonably necessary to minimize access or provide additional security (*e.g.*, isolating and or locking file cabinets or records rooms, using passwords, *etc.*)

The NPRM reaffirms that the Privacy Rule is not intended to impede access by health care professionals to information necessary for treatment; however, the DHHS remains concerned that covered entities not disclose an entire medical record when only a few items of information are necessary for purposes of payment and health care operations. Thus, the DHHS concludes that the privacy benefits of maintaining the minimum necessary standard outweighs the burdens involved for these purposes. The NPRM indicates that further guidance on the minimum necessary standards to clarify issues causing confusion and concern to the industry will be provided along with technical assistance materials.

HMSC Observation. *While the DHHS promised additional technical assistance, it did not respond in the NPRM to the suggestion by the National Committee on Vital Health Statistics that the DHHS issue advisory opinions with respect to Privacy Rule issues.*

BUSINESS ASSOCIATES

DHHS has clarified the Rule to emphasize that (i) a covered entity need not enter into a business associate ("BA") agreement to disclose PHI to a health care provider for treatment purposes, and (ii) a contract between providers and a PPO network does not of itself implicate a BA relationship, but a BA relationship may arise if the PPO receives PHI to perform certain functions

on behalf of its network providers (*e.g.*, provides billing or re-pricing services). In that case, a BA relationship would exist, and a contract that includes the required provisions for a BA agreement under the Privacy Rule would be necessary.

Most importantly, in certain circumstances, the NPRM gives covered entities, other than small health plans, at least an additional year, until April 14, 2004, in which to review and modify existing written agreements to comply with the BA requirements. This extension would apply as follows:

- A written contract with a BA that is in effect on the effective date of these proposed amendments to the Rule (a date which has not yet been determined) and that is not renewed or modified between that date and April 14, 2003, will be deemed compliant until April 14, 2004.
- A written contract with a BA that is in effect on the effective date of these proposed amendments to the Rule and that is renewed or modified between the effective date of the proposed amendments to the Rule and April 14, 2003, must be compliant by April 14, 2003.
- A written contract with a BA that is in effect on the effective date of these proposed amendments to the Rule and that is renewed or modified on or after April 14, 2003 will be deemed compliant until the earlier of the date of its renewal or modification (at which time it is expected the contract will have been made compliant) and April 14, 2004.
- A written contract with a BA that is entered into after the effective date of these proposed amendments to the Rule, but prior to April 14, 2003, must be compliant by April 14, 2003.
- Written contracts with BAs entered into on or after April 14, 2003, must be compliant from their initial effective date.
- Oral contracts with BAs, if any, must be compliant by April 14, 2003.

Evergreen contracts (contracts which automatically renew by their terms) would not be considered to have "renewed" for purposes of these transition provisions. DHHS has included in the NPRM model language for BA agreements. Covered entities are not required to use the model language, nor does the model language itself constitute a binding agreement. Rather, as the NPRM commentary indicates, the sample language is merely provided to help covered entities comply with the BA requirements.

HMSC Observation. *While the extension is being proposed to give covered entities additional time to identify, review and negotiate contracts with BAs, it is prudent for covered entities to begin that process sooner rather than later.*

USES AND DISCLOSURES PURSUANT TO AN AUTHORIZATION

The NPRM seeks to simplify the authorization requirements in the Privacy while ensuring that decisions authorizing the use and disclosure of PHI are voluntary and informed. All of the provisions governing authorizations will be consolidated in one section under the Rule.

Core Elements: Every authorization would be required to include certain core elements, including:

- a description of the information to be used or disclosed,
- the identification of the persons or class of persons authorized to make the use or disclosure of the PHI,
- the identification of the persons or class of persons to whom the covered entity is authorized to make the use or disclosure,
- a description of each purpose of the use or disclosure,
- an expiration date or event,
- the individual's signature and date, and
- if signed by a personal representative, a description of his or her authority to act for the individual

The NPRM also provides for an authorization to be initiated by an individual for purposes designated by the individual. For such individually-initiated disclosures, the purpose of the requested disclosure would not have to be revealed.

Contents of Authorizations. In addition to the core elements noted above, all authorizations would be required to include the following notifications:

- a statement that the individual may revoke the authorization in writing, and either a statement regarding the right to revoke, and that includes instructions on how to exercise such right, or to the extent this information is included in the covered entity's notice, a reference to the notice;
- a statement that treatment, payment, enrollment, or eligibility for benefits may not be conditioned on obtaining an authorization if such conditioning is prohibited by the Rule, or, if conditioning is permitted, a statement about the consequences of refusing to sign the authorization; and

- a statement about the potential for PHI to be subject to re-disclosure by the recipient.

Marketing Authorizations. Authorizations for marketing purposes also would have to include a statement that the covered entity will receive remuneration with respect to the marketing effort, if that is in fact the case.

Exceptions and Revocations of Authorizations. The exceptions to permitted revocation of authorizations would be modified to add an exception with respect to an insurer's right to contest the insurance policy under other law. This modification would recognize an insurer's right to contest a policy under existing law but would not expand that right.

The Impact of Minimum Necessary Standard. Significantly, an authorization for any purpose would be exempt from the minimum necessary standard for uses and disclosures of PHI. With respect to psychotherapy notes, proposed modifications would clarify that such information may not be used or disclosed for purposes of another entity without individual authorization. Finally, DHHS proposes to delete provisions conditioning payment of a claim on the provision of an authorization. This requirement would be rendered moot in light of the proposed changes to the consent requirements in the Privacy Rule.

HMSC Observation. *Although the consolidation of the authorization requirements will make compliance easier, there are still nuances to the authorization that must be considered. For example, as discussed below, while authorizations will generally require an expiration date, authorizations for research purposes need not specify a precise date of expiration.*

RESEARCH

The NPRM proposes changes to the waiver criteria and research authorization provisions of the existing Privacy Rule.

Waiver Criteria. The NPRM recognizes that much of the biomedical and behavioral research in this country is governed by the "Federal Policy for the Protection of Human Subjects (the "Common Rule"), and/or by the Food and Drug Administration's human subject protection regulations. It also notes that while the Common Rule and FDA regulations provide for informed consent and include some provisions regarding the confidentiality of health care information, the Privacy Rule was intended to supplement those protections by requiring specific measures to safeguard the privacy of individually identifiable health information. Commenters found the waiver criteria in the Privacy Rule confusing, redundant and internally inconsistent and requested that they be simplified. Commenters also expressed concern that the de-identification requirements in the Rule are too strict and subject more research to IRB review than is currently the case, and that they preclude sharing of data with researchers.

DHHS now proposes that the following waiver criteria replace the existing waiver criteria in the Privacy Rule:

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

  (i) an adequate plan to protect the identifiers from improper use and disclosure;

  (ii) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

  (iii) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

- The research could not practicably be conducted without the waiver or alteration; and

- The research could not practicably be conducted without access to and use of the PHI.

DHHS indicates that these proposed modifications to the waiver criteria in the Privacy Rule would eliminate both redundancies in the waiver criteria and conflicts regarding research conducted pursuant to the Common Rule.

With respect to concerns about the de-identification criteria in the Privacy Rule and research, the DHHS noted that the Privacy Rule's de-identification safe harbor was not intended to be used for research purposes. Accordingly, it requested comments on an alternative approach that would permit uses and disclosures of a limited data set for research purposes that does not include facially identifiable information, but in which certain identifiers remain.

HMSC Observation. *While the clarifications proposed in the NPRM alleviate some confusion, it still will be necessary for those involved in research activities to ensure compliance with each of the regulations applicable to their research. In other words, compliance*

with the waiver criteria in HIPAA is not tantamount to compliance with the Common Rule or FDA regulations.

Research Authorizations. As noted above, DHHS proposes a single set of requirements that generally will apply to all types of authorizations, including those used for research. Thus, provisions in the existing Privacy Rule calling for unique authorizations for uses and disclosures of PHI created for research that includes treatment of the individual would be eliminated. By making conforming changes elsewhere in the Rule, a covered health care provider would be able to condition the provision of research-related treatment on provision of an authorization for the use and disclosure of PHI for the particular research study. The proposed changes also would clarify that an authorization for the use or disclosure of PHI for research could be combined with any other legal permission related to the research study, including another authorization or consent to participate in the research (*e.g.*, an informed consent).

Significantly, DHHS also proposes to include provisions specific to research authorizations that would allow researchers to specify that the expiration date of the authorization is: "at the end of the research study." Such a statement also would be sufficient to allow additional time, after completion of the research, for the use of the PHI as necessary to meet the researcher's record retention requirements. The NPRM further notes that a statement, "none" would suffice in the expiration provisions of a research authorization when a covered entity uses or discloses PHI solely for the creation or maintenance of a research database or repository. In effect, for such purposes, no expiration date or event would be required. The NPRM emphasizes, however, that if the information in the database is to be used later for additional research, an authorization specifying an end date, such as "end of the research study" would be required.

Research Transition Provisions. To assure that ongoing vital research will not be impeded, DHHS reassessed relevant provisions regarding what authorization is required before and after the compliance date of the Privacy Rule for research that involves treatment (*e.g.*, clinical trials), and research that does not involve treatment (*i.e.*, records research). DHHS now proposes that there be no distinction between research that includes treatment and research that does not include treatment, and no distinction between requirements for research conducted with a patient's informed consent versus research conducted with an IRB-approved waiver of a patient's informed consent. Thus, under the NPRM, a covered entity could use or disclose for a specific research study PHI created or received either before or after the compliance date (absent any restrictions agreed to by the covered entity), if the covered entity has obtained (prior to the compliance date) an authorization or other express legal permission from an individual to use or disclose PHI for the research study. Additionally, DHHS proposes to "grandfather" research for which the individual has signed an informed consent to participate in the research study, or for which an IRB has waived the informed consent for the research study, in accordance with the Common Rule or FDA's human subject protection regulations. These changes are intended to apply once any of these permissions have been obtained, irrespective of whether the research study actually begins by the compliance date for the Privacy Rule, as long as the permission was obtained prior to the compliance date. These transition provisions also will apply to informed consents obtained for privately funded research.

MARKETING

The NPRM proposes to redefine marketing as follows: "to make a communication about a product or service to encourage recipients of the communication to purchase or use the product or service." This change focuses on the effect of the communication rather than on its intent. Thus, if the effect of the communication is to encourage recipients of the communication to purchase or use a product or service, the communication would be marketing irrespective of the intent of the person making the communication.

The NPRM also proposes to simplify and clarify the marketing provisions in the Privacy Rule. The changes respond to comments that the existing marketing provisions are complicated and confusing, and to concerns by consumers about unwanted solicitations and disclosures of PHI to commercial entities. Under the proposed changes, an authorization for any use or disclosure of PHI for marketing purposes would be required. Additionally, if the marketing is expected to result in direct or indirect remuneration to the covered entity from a third party, the authorization would be required to state that fact. As noted below, however, certain communications would continue to be excluded from the definition of marketing (in which case authorizations for marketing would not be required). The NPRM proposal to require an authorization for any activity that constitutes marketing (in effect, an "opt in" procedure) is believed to afford greater consumer privacy protection than the opt-out procedure in the existing Privacy Rule.

Finally, the NPRM proposes to retain the exclusions from the definition of marketing, with certain clarifications. These exclusions, as clarified, are:

- to describe the entities participating in a health care provider network or health plan network, or to describe, if and the extent to which, a product or

service (or payment for such product or services) is provided by a covered entity or included in a plan of benefits,

- for treatment of that individual, or
- for case management or care coordination for that individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to that individual.

Under the current Rule, exceptions to the definition of marketing only apply if the communication is oral or written and no remuneration is paid to a covered entity by a third party for making the communication. The NPRM would eliminate this distinction. Thus, pursuant to the third exception noted above, a health care provider would not have to obtain an authorization to send out a prescription refill reminder, even if the provider is compensated by a third party for the activity. The NPRM further clarifies that certain other disease management activities, wellness programs and appointment notifications that individuals expect to receive as part of their health care are excepted from the definition of marketing in the Privacy Rule and, therefore, may continue

PARENTS AS THE PERSONAL REPRESENTATIVES OF UNEMANCIPATED MINORS

The NPRM states that the provisions in the Privacy Rule pertaining to parents and minors have been reassessed and that no substantive changes are proposed. Rather, DHHS will continue to defer to state and other applicable law with respect to important health care decisions about minors. The DHHS reached this conclusion because it wants to ensure that the Privacy Rule does not interfere with a minor's ability to consent to and obtain health care under current state or other applicable law. Additionally, DHHS does not want to interfere with state or other applicable laws relating to competency or parental rights, generally, or the role of parents in making health care decisions about their minor children, in particular. Finally, DHHS does not want to interfere with the professional requirements of state medical boards or other ethical codes of health care providers with respect to confidentiality of health information or health care practices of such providers as it relates to adolescent health care. The NPRM notes that this approach works to the extent that state law is definitive and requires or prohibits disclosure or access to health care information. The NPRM changes the current final Rule to clarify and ensure that state and other applicable law also govern when such law, whether based on statute, regulation or established case law, grants discretion to a provider regarding disclosure or access to health care information. Providers may disclose PHI to parents or guardians of minors when in their professional judgment it is reasonable to do so, and state or other applicable law allows such an exercise of discretion.

Finally, the NPRM proposes to add a new paragraph to the Privacy Rule that would establish a neutral policy regarding the right of access by a parent to health information about a minor in the rare circumstance when the parent, technically, is not the personal representative of the minor under the Privacy Rule. This policy would apply, especially when the state or other law is silent or unclear. The new paragraph would simply provide that exercise of the right of access to health information under the Privacy Rule by parents who are not personal representatives must be consistent with their access rights under the state or other applicable law. This assures that the Privacy Rule would not prevent a covered entity from providing such access, in accordance with the Privacy Rule, to a parent, who is not the personal representative of the minor child, if access would be otherwise consistent with state or other applicable law.

DE-IDENTIFICATION

In the area of de-identification, DHHS proposes a clarification and requests comments. First, it clarifies that it did not intend any codes established to re-identify de-identified information be one of the enumerated identifiers that must be removed in order for information to be deemed de-identified under the Privacy Rule. Therefore, it proposes to except from that list any re-identification code or other means of record identification otherwise permitted under the Privacy Rule.

Second, DHHS received many comments regarding de-identification requirements as they relate to using and disclosing information for research, public health purposes, or for certain health care operations. Commenters complained that the de-identification requirements were so stringent as to require removal of many data elements essential to relevant analyses being undertaken. DHHS notes that while there was little consensus as to which data elements were most important, there was general consensus among covered entities that the statistical method alternative for de-identification in the existing Privacy Rule was beyond their capabilities.

In particular, state hospital associations expressed concern that the Privacy Rule prevents them from collecting patient information from area hospitals to conduct and disseminate analyses that are useful for hospitals in making decisions about quality and efficiency improvements. The stringent de-identification requirements preclude collection of necessary data elements for such analyses. Additionally, the Privacy

Rule's provisions for data aggregation would permit such associations to collect and aggregate identifiable data from multiple hospitals for quality and efficiency purposes; however, they would not allow the associations to disclose all of the desired analyses back to the contributing hospitals because some identifiers would remain in the data. These limitations impede the ability of hospitals to have access to information about community health care needs and the ability to compare their community to others in the state. Finally, commenters noted a problem with hospitals themselves sharing aggregated information with other hospitals for health care operations purposes. This problem arises because the existing Privacy Rule prohibits covered entities from disclosing PHI for the health care operations purposes of other covered entities.

DHHS proposes to modify this restriction to allow covered entities to disclose PHI for another covered entity's health care operations under some circumstances; however, two conditions on the sharing of this information may continue to pose problems. The proposed modifications would condition the sharing of PHI on both entities being covered entities, and both entities having a relationship with the individual. DHHS recognizes that hospitals that want to exchange patient information with each other or with other community health care providers would not meet these conditions in all cases. It also recognized that these requirements would result in more research being done on identifiable health information being subject to IRB review than is presently the case. Additionally, while not noted in the NPRM, state hospital associations that collect, aggregate and analyze health care data and trends would not meet these requirements because they are not covered entities and do not generally have relationships with the individuals who are the subject of PHI in the data being collected.

In response to these and other concerns expressed by commenters, DHHS indicated that, despite the importance of the activities involved, it is not currently convinced of the need to modify the safe harbor for de-identified information. Instead, DHHS solicits comments on an alternative approach that would permit uses and disclosures of a limited data set that would not include "facially identifiable" information, and in which certain identifiers would remain. Such use and disclosure would be limited to research, public health and health care operations purposes. Direct identifiers, such as name, street address, telephone and fax numbers, e-mail address, social security number, certificate/license number, vehicle identifiers and serial numbers, URLs and IP addresses and full-face photos and comparable images would not be permitted. Rather, the limited data set would include admission, discharge, service dates, date of death, age (including those 90 and over) and a five-digit zip code. DHHS is soliciting comments on whether another one or more geographic units smaller than a state, such as a city, county, precinct, neighborhood or other unit, would be needed in addition to or in preference to a five digit zip code. Comments are also requested as to whether the date of birth is needed, and if so whether the entire date versus month and year is needed. Finally, DHHS would condition the disclosure of the limited data set on covered entities obtaining from the recipients (i) a data use or similar agreement in which the recipient agrees to limit the use of the limited data set to the specified purposes in the Privacy Rule and to specified users or recipients of data, and (ii) obtaining an agreement not to re-identify the data or contact the individuals.

HMSC Observation. *While the proposed modification is an improvement, the requirement that both entities be covered entities and that both have a relationship with the individual whose PHI is to be shared minimizes the improvement. The proposed modification discussed above to permit the use of limited data that is not "facially-identifiable" could offset this problem.*

HEALTH PLANS AND EMPLOYERS

The NPRM does not make any substantive changes to the obligation employers/plan sponsors have to their group health plans (and insurers and HMOs providing benefits under those plans) other than to clarify that enrollment and disenrollment information, by itself, can be exchanged between the employer and the plan, insurer or HMO without amending any plan documents. The NPRM also gives hybrid entities discretion in determining which components perform "covered functions," thereby subjecting those components to the obligations imposed by the Privacy Rule.

CONCLUSION

While it is impossible to predict what the final rule will include, further changes are likely to be made. Given the controversy sparked by the NPRM, the volume of comments anticipated to be submitted and the standard administrative processes necessary to effectuate change, any reliance on the NPRM at this time is, of course, premature.

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 policies, contracts, forms and other documents needed under the Rule, and assessing legal requirements beyond the 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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