DEPARTMENT OF HEALTH & HUMAN SERVICES



Office of the Secretary

DEC 23 2004

Director Office for Civil Rights Washington, D.C. 20201

Ms. Joyce Young, HIPAA GIVES Coordinator Department of Human Services, DIRM 695 Palmer Drive Raleigh, North Carolina 27603

Reference Number: 04-23200

Dear Ms. Young:

Thank you for your letter to Secretary Thompson and me on behalf of HIPAA Government Information Value Exchange for States (GIVES), concerning the health information privacy regulation (Privacy Rule) issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Office for Civil Rights (OCR) is responsible for implementing and enforcing the Privacy Rule, and our office has undertaken a wide range of efforts to assist covered entities in voluntarily complying with their obligations under the Rule. We at the Department also recognize the important and helpful service that HIPAA GIVES performs in promoting effective HIPAA compliance.

Your letter raises a number of concerns about the interaction of the Privacy Rule and Child Protection Services and Adult Protection Services (CPS/APS). In particular, you describe resistance by covered entity medical providers in releasing up-to-date medical information without an authorization or court order; delays that arise because some covered entities have adopted procedures that allow only their privacy officers to disclose this information; that covered entities must account to an individual or an individual's personal representative for disclosures to a CPS/APS agency even when the covered entity has exercised discretion not to inform the individual or the individual's personal representative of the report; and that covered entities may identify a reporter in an accounting for disclosure, despite state laws that strictly prohibit release of identification of a reporter of suspected abuse or neglect. Your letter also seeks an amendment to the Privacy Rule that would exempt disclosures to CPS/APS from the accounting requirements of the Privacy Rule, and defer to State mandatory reporting, investigation and confidentiality laws pertaining to CPS/APS. As explained below, the Privacy Rule is balanced in a way that generally allows the purposes of both the Privacy Rule and CPS/APS to be effectuated.

With respect to the first of these issues – whether some health care providers resist disclosing protected health information to CPS/APS agencies without an authorization from the individual or a court order -- the Privacy Rule recognizes that protected health information can be essential to agencies charged with protecting individuals against abuse and neglect and domestic violence. To allow covered entities to appropriately share information in this context, and to harmonize the

Page 2 - Ms. Joyce Young

Privacy Rule with existing state and federal laws mandating uses and disclosures of protected health information, 45 CFR § 512(a) permits covered entities to comply with laws requiring the use or disclosure of protected health information, provided the use or disclosure meets and is limited to the relevant requirements of such other laws. Where and to the extent that such disclosures are required by law, no authorization or court order is required for the disclosure. 45 CFR § 512(a). Further, to the extent that such disclosures are required under State law, as described at 45 CFR § 164. 512(a), the minimum necessary standard does not apply. (45 CFR § 164.502(b)(2)(v)). While the Rule itself does not require disclosures in compliance with State laws, neither does it interfere with such State law requirements.

In addition, under the Privacy Rule covered entities may disclose protected health information without the authorization of the individual, or the individual's personal representative, to an appropriate government authority authorized to receive reports of child abuse or neglect (45 CFR \S 164.512(b)) or reports of abuse, neglect, or domestic violence (45 CFR \S 164.512(c)). In response to your concern that CPS/APS providers often need to seek repeated access to individual medical records during the course of an investigation, we note that pursuant to 45 CFR \S 164.512(b) or 164.512(c), a covered entity may, pursuant to the Rule, continue to disclose to such government authorities repeatedly over the duration of an investigation when making disclosures to public officials. Covered entity making such disclosures must comply with the requirement that the disclosure be limited to the minimum necessary amount for the purpose; but the Privacy Rule also allows a covered entity to reasonably rely on the representations of such officials that the information requested is the minimum necessary for the stated purpose(s) when making disclosures to public officials. (45 CFR \S 164.514(d)(3)(iii)(A)).

With respect to your concern that some covered entities delay disclosures because they permit only their designated privacy officials to make them, we note that while 45 CFR § 164.530(a) requires covered entities to designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity, it does not require or suggest that the designated privacy official is the only person authorized to make discretionary disclosures. The Privacy Rule is designed to be flexible and scalable, and does not dictate who within the covered entity should evaluate requests for disclosures. Rather, a covered entity is free to determine which of its personnel should be authorized to make discretionary disclosures in accordance with the Rule; and in doing so, the covered entity can, of course, take into account factors such as size and complexity of the organization.

Your letter also is concerned that under 45 CFR § 164.512(c)(2), a covered entity has discretion, under certain conditions, to refrain from informing the individual or the individual's personal representative in the cases of a report to a CPS/APS agency, if the notification would either place the individual at risk of serious harm or would not be in the best interests of the individual; but that under 45 CFR § 164.502(g) and 164.528(a) a personal representative has broad rights to demand an accounting of disclosures. In this regard, we note that there are important limitations on the right to receive an accounting of disclosures. For example, the accounting may be suspended for a period of time if the disclosure is to a health oversight agency or a law

Page 3 - Ms. Joyce Young

enforcement official, for the time specified by such agency or official, if the accounting would be reasonably likely to impede the agency's activities. (45 CFR § 164.528(a)(2)). Moreover, if the request is by the individual's personal representative and the covered entity has a reasonable belief that such person is the abuser or that providing the accounting to such person could endanger the individual, the covered entity continues to have the discretion in § 164.502(g)(5) to decline such a request. Given these limitations on the general requirement to treat an individual as the personal representative, the Rule is structured to minimize the conflicts your letter anticipates.

Another issue raised in your letter involves issues of tracking disclosures of protected health information, presumably for the accounting requirement, and the concern that this requirement preempts State confidentiality law which prohibits the release of the identification of a reporter of suspected abuse or neglect. *The Privacy Rule does not require disclosure in an accounting of the identity of the person who initiated the report of suspected abuse or neglect.* To the extent that 45 CFR § 164.528 applies, the only information that needs to be disclosed is the date of the disclosure, the recipient, a brief description of the information disclosed (which does not need to identify the reporter) and the purpose of the disclosure. Therefore, the accounting for disclosure provisions of the Privacy Rule are not contrary to State laws that prohibit release of the identity of reporters of such information and preemption does not apply. See, 45 CFR §160.203(c).

Turning to various recommendations in your letter for modification to the Privacy Rule, we point out that as the Privacy Rule was being developed, the issues raised by your letter concerning exempting CPS/APS disclosures from the accounting requirements of the Privacy Rule were carefully considered. As stated in sections of the December 28, 2000 and the August 28, 2002 preambles (and restated below), providing such an exemption to the right to accounting for disclosures would also have the effect of cutting off victims of abuse, neglect, or domestic violence from information about the extent of disclosures of their protected health information. Ultimately, the Rule was structured to balance appropriate access to this information by requiring the accounting, while affording appropriate discretion to covered entities to refrain from disclosures that might be harmful in certain circumstances:

Comment: One commenter stated that under Minnesota law, providers who are mandated reporters of abuse are limited as to whom they may reveal the report of abuse (generally law enforcement authorities and other providers only). This is because certain abusers, such as parents, by law may have access to a victim's (child's) records. The commenter requested clarification as to whether these disclosures are exempt from the accounting requirement or whether preemption would apply.

Response: While we do not except mandatory disclosures of abuse from the accounting for disclosure requirement, we believe the commenter's concerns are addressed in several ways. First, nothing in this regulation invalidates or limits the authority or procedures established under state law providing for the reporting of child abuse. Thus, with respect to child abuse the Minnesota law's

Page 4 - Ms. Joyce Young

procedures are not preempted even though they are less stringent with respect to privacy. Second, with respect to abuse of persons other than children, we allow covered entities to refuse to treat a person as an individual's personal representative if the covered entity believes that the individual has been subjected to domestic violence, abuse, or neglect from the person. Thus, the abuser would not have access to the accounting. We also note that a covered entity must exclude a disclosure, including disclosures to report abuse, from the accounting for specified period of time if the law enforcement official to whom the report is made requests such exclusion.

65 Fed. Reg. 82741 (2000)

Comment: One commenter sought an exemption from the accounting requirement for disclosures to adult protective services when referrals are made for abuse, neglect, or domestic violence victims. For the same reasons that the Rule permits waiver of notification to the victim at the time of the referral based on considerations of the victim's safety, the regulation should not make such disclosures known after the fact through the accounting requirement.

Response: The Department appreciates the concerns expressed by the commenter for the safety and welfare of the victims of abuse, neglect, or domestic violence. In recognition of these concerns, the Department does give the covered entity discretion in notifying the victim and/or the individual's personal representative at the time of the disclosure. These concerns become more attenuated in the context of an accounting for disclosures, which must be requested by the individual and for which the covered entity has a longer time frame to respond. Concern for the safety of victims of abuse or domestic violence should not result in stripping these individuals of the rights granted to others. If the individual is requesting the accounting, even after being warned of the potential dangers, the covered entity should honor that request. However, if the request is by the individual's personal representative and the covered entity has a reasonable belief that such person is the abuser or that providing the accounting to such person could endanger the individual, the covered entity continues to have the discretion in § 164.502(g)(5) to decline such a request.

67 Fed. Reg. 53246 (2002)

Again, with regard to your request that the Privacy Rule be amended to defer to state mandatory reporting, investigation and confidentiality laws, we emphasize that the Privacy Rule does authorize a covered entity to comply with State laws in that a covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law. The specific, additional, requirements for disclosures about an individual whom the covered entity believes to be a victim of abuse, neglect or domestic violence, found at 45 CFR §164.512 (b) and (c), must be complied with, as applicable. Requirements for disclosures for judicial and administrative proceedings can be found at 45 CFR §164.512(e); and requirements for

Page 5 - Ms. Joyce Young

disclosures for law enforcement purposes can be found at 45 CFR §164.512(f). See also the attached FAQ, summarizing the various ways in which disclosures for law enforcement purposes may occur. In general, these various provisions reflect the balance in the Privacy Rule to protect health information, and to afford individuals their rights to access their information and to an accounting for certain disclosures of their information while deferring to State mandatory reporting, investigation and confidentiality laws pertaining to CPS/APS.

The Department is continuing its effort to develop and distribute helpful guidance on a wide range of Privacy Rule topics, and your input is helpful to us as we evaluate the effectiveness of the Rule, and focus on efforts to assist covered entities in complying with the Privacy Rule. A significant array of these guidance materials is available at the Office for Civil Rights website, <u>www.hhs.gov/ocr/hipaa/</u>. Among these resources are the full text of the Privacy Rule, a HIPAA Privacy Rule Summary, hundreds of answers to frequently asked questions, Privacy Rule fact sheets, sample Business Associate contract provisions, extensive guidance on key Privacy Rule topics, a "covered entity decision tool" that helps entities determine whether they are covered by the Privacy Rule, and links to additional Department websites that provide information about other aspects of HIPAA. In addition, the website provides assistance, which can be accessed in both English and Spanish, regarding how to file a Privacy Rule complaint. We are continuing to update and add to these materials to assist covered entities in their efforts to comply with the Privacy Rule.

I trust the information and clarification in this letter are helpful. We very much appreciate the careful thought and important concerns reflected in your letter, and continue to monitor the experience of covered entities and others affected by the Privacy Rule to ensure that the balance of protecting health information without impeding access to quality care is appropriately struck. Please feel free to contact us as HIPAA GIVES and its members have further experience with these and other provisions of the Rule.

Richard M. Campanelli, J.D. Director