



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Mar 28, 2003

John R. Seffrin, Ph.D.
Chief Executive Officer
American Cancer Society
1599 Clifton Rd. N.E.
Atlanta, GA 30329-425 1

Dear Dr. Seffrin:

Thank you for your letter regarding implementation of the health information privacy regulation (Privacy Rule) issued pursuant to the Health Insurance Portability and Accountability Act of 1996. I respect the American Cancer Society's (ACS) mission and leadership, and appreciate your strong support of the patient confidentiality protections implemented through the Privacy Rule. I also share your concern that access to quality health care continues unimpeded as these important patient privacy rights are protected.

In your letter, you request the Department to clarify that disclosures of cancer patients' protected health information to ACS for the purpose of delivering the variety of ACS services are permitted under the Privacy Rule. While some of the ACS Assistance Programs described in your letter appear to be for the purposes of providing health care and related services, we cannot confirm that each of the specific services ACS offers are "treatment". This is both because we do not have sufficient facts to make an adequate judgment, but also because the Department cannot provide advisory opinions about the myriad of services that are made available for patients. We trust, however, that the enclosed clarifications will be helpful to you in making these determinations.

You also inquire whether a business associate contract is required when a health care provider discloses, as part of treatment, protected health information to a third party like the ACS. Under the Privacy Rule, a business associate contract is not needed, if the disclosure for purposes of treating an individual is made to a health care provider. In other cases, a business associate contract (or other arrangement, if applicable) is needed only if the recipient of the disclosure meets the definition of a "business associate" in 45 CFR 160.103.

I appreciate you keeping me aware of your concerns. If your internal counsel working on this matter has any further questions, please contact Paula Stannard, Deputy General Counsel, at (202) 690-7741. If you have any further concerns or questions, please feel free to contact me.

Sincerely,

Tommy G. Thompson

Enclosure

- There are a number of circumstances under which covered entities may disclose patient information to the ACS. As you know, the Privacy Rule permits a covered entity, such as a health care provider, to disclose protected health information for treatment purposes without the individual's authorization. As defined by the Privacy Rule, "treatment" purposes include the provision, coordination or management of health care and related services for an individual. A covered health care provider may disclose protected health information for its own treatment purposes or to another health care provider for that provider's treatment purposes.
- A covered health care provider may disclose protected health information to a third party that is not a health care provider, provided that the disclosure is for the provider's own treatment of the individual. For instance, under these provisions a covered entity may, for its treatment purposes, disclose protected health information that would enable a third party such as ACS to provide health care related cancer education, assistance and support services to a particular patient. If the third party is not a health care provider, such disclosures are subject to the minimum necessary standard, but the covered entity is not required to obtain the individual's authorization to make the disclosure.
- Of course, not all services constitute "treatment" under the Privacy Rule. Some of the ACS assistance services described in your letter may come within the definition of treatment; but we cannot say, as a general matter, that each of the described services always come within the definition of treatment under the Rule. For instance, lodging or transportation services offered for general purposes, and not related to the provision, coordination or management of the individual's health care, would not be treatment under the Rule. As I am sure you appreciate, the Privacy Rule requires patient authorization for a covered provider to disclose lists of patient names that would enable third parties to contact the patients about a range of services not related to individualized health care needs. Ultimately, the provider or other covered entity must evaluate whether a use or disclosure is for treatment purposes under the Rule, and thus would not require the express authorization of the patient.
- Another provision of the Privacy Rule also permits a covered entity to disclose, to a person identified by the individual, protected health information directly relevant to such person's involvement in the individual's care or payment for health care. Such disclosures are permitted without the individual's written authorization as long as the individual has an opportunity to agree or object. See 45 CFR 164.510(b). Thus, for instance, under this provision, a health care provider could explain ACS' patient services and ask a patient if she wishes the provider, on her behalf, to have ACS involved in her care. If the patient agrees, the provider could then provide information directly relevant to ACS' involvement in the patient's care, and no further patient authorization would be required by the Privacy Rule.

Further Clarifications for your Consideration

- We know that you recognize that patients should be able to exercise control over their health information. Thus, as discussed above, where the services further the treatment needs of individual patients, no specific authorization is needed. As we indicate, the Rule also permits, under certain conditions, communications to persons identified by the patient as assisting in his or her care. Or, the health care provider can disclose protected health information if the individual expressly authorizes the disclosure in writing.