CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

April 26, 2002

Department of Health and Human Services
Office of Civil Rights
Attention: Privacy 2
Hubert H. Humphrey Building
200 Independence Avenue, S.W. - Room 425A
Washington, D.C. 20201

To Whom It May Concern:

The Cancer Leadership Council (CLC) is a forum for education and advocacy among national organizations concerned with cancer. The CLC, which includes cancer patient organizations, professional societies, and research organizations, appreciates the opportunity to offer comments on the March 27, 2002, Notice of Proposed Rulemaking (NPRM) proposing changes in the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule).

Background

The cancer community supports measures that will protect the confidentiality of medical records without creating obstacles to cancer patients' access to quality care or constructing barriers to cancer research. We are concerned about disclosures regarding cancer patients' diagnosis and treatment, but we also want to ensure that the privacy regulatory system does not impede prompt access to cancer care. Achieving the appropriate balance between the protection of individual privacy and other interests, such as a strong biomedical research effort and speedy access to health care, is not an easy task. We recognize the efforts of the Department of Health and Human Services (HHS) to refine the current Privacy Rule.

Consent

For individuals battling cancer, health care is only quality care if it is provided without delay. Unfortunately for some cancer patients, postponing the start of treatment for even a matter of days may have a serious adverse impact on their treatment outcomes. Delays in access to care pose an unacceptable risk for cancer patients, and the current Privacy Rule should be modified to ensure that it does not cause any disruptions in care. Cancer patients are often referred to an oncologist with special expertise in their cancer by another oncologist or a primary care physician, or they may independently seek out a specialist. Treatment - including the receipt and evaluation of medical records, conversations between the physician and the patient, and development of a preliminary treatment plan - is often started before the patient sees the specialist and provides written consent for release of information for treatment. Cancer patients do not wish to disturb the current system of care in which their oncologists initiate treatment before the first face-to-face encounter between patient and oncologist. This system of cancer care works well by facilitating the efficient delivery of care.

The CLC welcomes HHS efforts to address the issue of prior consent and its potential to impede access to quality health care. The Department proposes to replace the requirement that a health care provider receive consent for disclosure and use of information prior to treatment with a requirement of a good faith effort to obtain patients'

acknowledgment that they have received the Notice of Privacy Practices. We believe the proposed modification addresses potential barriers to access to cancer care without compromising privacy.

The CLC is aware, however, that some consumer organizations strongly endorse the retention of the prior consent and that those organizations recommend instead a few targeted modifications to address issues related to the implementation of the prior consent requirement. The cancer community takes a different view of this matter because of the very nature of cancer. Because cancer is a life-threatening disease for which treatment must be begun expeditiously, we endorse a standard that allows more flexibility in the timing of notice to individuals regarding their privacy rights. If HHS chooses to retain the prior consent standard, however, the CLC recommends a modification to allow health care providers to request and receive medical records, consult with patients over the telephone or through e-mail, and develop a treatment plan prior to the first in-person contact with the patient and the receipt of consent.

Health Care Operations

If the final version of the Privacy Rule does not include a prior consent requirement, that modification must be accompanied by a more limited definition of health care operations. In the current version of the Privacy Rule, disclosures for health care operations would be permitted after a provider obtains consent for use and disclosure of information. In addition, health care operations are defined expansively and would permit a number of activities that go beyond treatment and payment for health care. If patients are not afforded notice of these potential uses of our health care information through a prior consent process, we must be guaranteed some protections by restricting the definition of health care operations.

Marketing

The CLC is troubled by the proposed modifications in the standards for the use and disclosure of protected health information (PHI) for marketing activities. Although HHS has proposed that authorization be required for the use and disclosure of information for marketing activities, the Department has so narrowly defined marketing activities that the authorization requirement will have little effect. HHS proposes to exclude from the definition of marketing all communications that encourage the use or purchase of a health-related product or service, even where the covered entity is paid by a third party to make such a communication.

While the CLC supports efforts to ensure open and unfettered communication between physicians and patients regarding treatment options, cancer survivors and their caregivers believe the proposed modifications upset the balance between open communication and disclosure of indirect or direct remuneration for marketing activities.

CLC recommends that HHS leave in place the marketing provisions that are included in the current Privacy Rule. Under those provisions, a physician or other health care provider would be allowed to communicate with patients regarding treatment options or new goods or services but would be required to: 1) disclose the receipt of remuneration from a third party for those communications; and 2) provide individuals the opportunity to opt out of receiving future marketing communications. The cancer community strongly supports the disclosure of third party payment to providers for their marketing activities. This disclosure provides the patient important information for informed decision-making.

Medical Research

The CLC acknowledges the difficulty of balancing the protection of individual privacy and the smooth functioning of the research enterprise. Cancer patients are highly motivated to participate in research. We actively seek opportunities to participate in clinical trials, and we are also willing to deposit our tissue and data into research databases. However, our

willingness to participate in research is influenced by the assurance that our confidential health information will be protected. Achieving the proper balance between appropriate use and disclosure of information and protection against improper breaches of confidentiality is a challenge.

Cancer advocates are concerned that certain provisions of the Privacy Rule would slow the speed of research, including records-based research that may provide important information about the causes of certain cancers.

The CLC urges the Department to consider several research-related modifications to the Privacy Rule:

- ***De-Identification***

  The Department has noted the concerns of the research community regarding the standard for de-identification in the Privacy Rule. Researchers are concerned that the de-identification standard is so stringent that information that meets the standard would be useless to researchers. CLC applauds HHS for its willingness to entertain additional comments on the appropriate standard for de-identification. The Secretary has identified a set of direct identifiers that might be removed to achieve de-identification. CLC recommends the adoption of the standard proposed by HHS.

- ***Public Health Disclosures***

  The proposed modifications would allow covered entities to disclose PHI to private sector registries that are created for activities related to the quality, safety, or effectiveness of products regulated by the Food and Drug Administration (FDA). The Department has noted that there is a great breadth of public health activities undertaken by sponsors of FDA-approved products and that those activities should be encouraged by allowing release of PHI to those registries without authorization.

  Regrettably, HHS does not consider allowing disclosures without authorization to registries and databases that are maintained by research institutions and non-profit organizations, even in situations where those registries and databases have been reviewed and approved by institutional review boards (IRBs). CLC strongly urges HHS to allow disclosures of PHI without authorization to registries and databases that are approved by IRBs. If HHS proposes to allow the release of information without authorization to private sector registries that are maintained by for-profit entities, the same standard for data release should be applied to IRB-approved registries sponsored by non-profit organizations and academic researchers and institutions. Databases and registries of this sort are critically important to the cancer research effort and may yield important information about the causes of cancer and improved treatments for cancer. Their smooth functioning would be aided by allowing them access to data on the same basis as sponsors of FDA-regulated products.

- ***Expiration Date for Authorization Forms***

  CLC welcomes the HHS proposal for open-ended authorizations for disclosure of data to research databases. Researchers had noted the difficulty of establishing a concrete termination date for an authorization for data disclosure to research databases, and the proposed modification appropriately addresses that issue.

  The proposal by HHS still anticipates that separate authorization forms will be necessary for disclosure of data to a research database and for subsequent uses of those data for research purposes. This second authorization form must include an expiration date or event. CLC recommends that HHS consider a single authorization form for the disclosure of data to a research database and for subsequent research uses. It is our experience that cancer patients would be willing to make such authorization to facilitate research utilizing the data in databases.

We understand that authorization for subsequent research uses of data in research databases could be waived through IRB or privacy board review, but we have concerns that IRBs, already overwhelmed by their workload, would be unable to complete timely privacy-related reviews of such proposals.

Conclusion

The CLC is pleased to have this opportunity to offer suggestions regarding modifications and refinements to the current Privacy Rule. We appreciate the difficulty of developing a responsible regulatory scheme to protect medical records privacy. As cancer patients, caregivers, and researchers, we have seen the harm that can be done by the inappropriate disclosure of sensitive medical information. On the other hand, we have also seen the damage that is caused by unreasonable delays in the provision of health care or in cancer research. CLC commends HHS for its efforts to achieve an appropriate balance that is in the best interests of health care consumers.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research Foundation of America
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
Kidney Cancer Association
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
US TOO! International, Inc.
Y-ME National Breast Cancer Organization

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