



Office of Clinical Standards and Quality

April 7, 2003

TO: All Renal Dialysis and Transplant Providers

SUBJECT: Release of Data to ESRD Network Organizations

The purpose of this letter is to address your concerns about releasing protected health information on individual patients to End Stage Renal Disease (ESRD) Network Organizations (usually referred to as ESRD Networks).

Section 1881 of the Social Security Act (the Act) provides Medicare benefits to certain individuals who have end stage renal disease and to kidney donors. For the purpose of assuring effective and efficient administration of the benefits provided under § 1881, the Secretary has established 18 End Stage Renal Disease Network areas, and entered into contracts with the ESRD Network organizations, primarily to perform activities related to ensuring high quality and appropriate care for patients within an assigned area.

In order to conduct their activities, Networks must obtain from ESRD facilities health information that identifies individuals that would be included under the definition of protected health information (PHI) under the "Standards for Privacy of Individually Identifiable Health Information," otherwise known as the "HIPAA Privacy Rule" (45 CFR Parts 160 and 164). The HIPAA Privacy Rule guarantees certain privacy rights to individuals and places certain obligations on health care providers to protect PHI. However, the Privacy Rule provides that PHI may be used and disclosed without the authorization of the subject of that information to the extent a law requires the use or disclosure.

Providers Are Required by Law to Disclose Information to Networks. Networks are required by statute and regulations to gather information from ESRD providers to prepare annual reports to the Secretary covering, among other things, the Network's goals and the Network's performance in meeting those goals. They must also help the Secretary to assure the maintenance of a national end stage renal disease registry that assembles and analyzes data reported by Network organizations, transplant centers, and other sources on all ESRD patients. ESRD providers, in turn, are required by statute and regulations to provide data to the Networks, as the Networks require, in order for the Networks to follow their plans and meet their goals under their agreements with the Secretary. Providers do not have the discretion to withhold information requested by the Networks while the Networks are performing Network activities required by statute or regulation.

ESRD Providers Do Not Need Business Associate Agreements. With respect to the disclosures required by law, ESRD Providers do not need business associate agreements with the Networks. Under the definition of business associate in § 160.103 of the Privacy Rule, Networks are not business associates of a provider or practitioner because they are not performing functions for the provider or practitioner when they collect information as required by law.

The Social Security Act Protects PHI Disclosed to Networks As Well As Persons Who Disclose It. The Social Security Act provides in § 1881(c)(8) that the provisions in §§ 1157 and 1160 of the Act apply with respect to network administrative organizations (including such organizations as medical review boards) with which the Secretary has entered into agreements under § 1881(c). This means that the confidentiality provisions in the law that quality improvement organizations (QIOs) must follow in protecting data under § 1160 of the Act also apply to Networks. Also, the law guarantees certain protections to those who disclose information to the Networks, as described in § 1157 of the Act. Under § 1157, no person providing information to a Network will be held, by reason of having provided such information, to have violated any criminal law or to be civilly liable under any State or Federal law, unless the information provided is unrelated to the performance of the contract of the Network or the information is false and the individual knew or had reason to believe that the information was false.

If you have any questions concerning the information provided above, please feel free to contact your Network.

Sincerely,



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