

M E M O R A N D U M

To: The Center for Regulatory Effectiveness (CRE)
From: Multinational Legal Services (MLS)
Date: April 10, 2001
Re: Non-Paperwork Requirements in the HIPAA ETS Final Rule

Question Presented

Whether the HHS final rule on Electronic Transaction Standards under HIPAA contains any requirements that do not constitute “information collections” within the meaning of the Paperwork Reduction Act (PRA)?

Discussion

The Paperwork Reduction Act defines “collection of information” as:

the obtaining, causing to be obtained, soliciting, *or requiring the disclosure to third parties or the public*, of facts or opinions by or for an agency, regardless of form or format, calling for either—

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons, other than agencies, instrumentalities, or employees of the United States; or

(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes....

44 U.S.C. § 3502 (3)(A)(emphasis added).

The OMB rules implementing the PRA explain that:

“Collection of information” means...the obtaining, soliciting, or requiring the disclosure to an agency, third parties or the public of information by or for an agency by means of identical questions posed to, or identical reporting requirements imposed on, ten or more persons, whether such collection of information is mandatory, voluntary, or required to obtain a benefit. “Collection of information refers to the act of collecting or disclosing information, to the information to be collected or disclosed, to a plan and/or an instrument calling for the collection or disclosure of information, or any of these, as appropriate.

...

“Collection of information” includes the use of report forms, schedules, questionnaires, surveys, reporting or recordkeeping requirements, or other similar methods.

...

A “collection of information” may implicitly or explicitly include related recordkeeping requirements.

5 C.F.R. § 1320.3.

Keeping the above definitions in mind, a review of the HHS final rule for Electronic Transaction Standards reveals 14 substantive requirements, each of which constitutes a “collection of information” under the PRA. Specifically, these requirements include:

- 162.923. Requirements for covered entities.
 - This section states the general duty of entities covered under the Act that conduct health transactions electronically to transmit such data as “standard transactions.”
 - This requirement is a “recordkeeping requirement” within the

meaning of section 3502(13) of the PRA¹ because it requires that covered entities maintain data.

- This is a reporting requirement since it governs how data is disclosed to third parties.
- It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.925. Additional requirements for health plans.
 - This section discusses specific issues related to health plans which requires plans to conduct transactions as standard transactions when requested to do so (i.e. in electronic format), forbids delay or adverse treatment of transactions because they are standard transactions, store standardized coordination of benefits data. Generally, the section prohibits health plans from undertaking actions which would be at cross-purposes with the Act.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.

¹ Section 3502(13) of the PRA states:

“the term ‘recordkeeping requirement’ means a requirement imposed by or for an agency on persons to maintain specified records, including a requirement to –

- (A) retain such records;
- (B) notify third parties, the Federal Government, or the public of the existence of such records;
- (C) disclose such records to third parties, the Federal Government, or the public; or
- (D) report to third parties, the Federal Government, or the public regarding such records;

44 U.S.C. § 3502(13).

- It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.930. Additional rules for health care clearinghouses.
 - This section states that when acting as a business associate for another covered entity, a clearinghouse may translate standard transactions into nonstandard transactions and nonstandard transactions into standard transactions. However, such activities are integrally dependent upon the standard transactions included in the Electronic Transactions Standards rule.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.940. Exceptions from standards to permit testing of proposed modifications.
 - This section discusses the procedures and reporting requirements for organizations which seek an exception for use of a standard in the Electronic Transactions Standards rule in order to test a proposed modification to that standard. Written justification must be provided to HHS, and the Secretary must grant the exception before the entity may deviate from the standard transaction.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how

information is disclosed to the federal government.

- §162.1000. General requirements (Codes Sets).
 - This section states the general duty of covered entities to use medical data code sets and nonmedical data code sets specified in the HHS final rule.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.1002. Medical data code sets.
 - This section lays out the code sets selected by the HHS Secretary as standard medical data code sets. Covered entities must utilize these codes sets in conducting standard transactions under the final rule.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.1102. Standards for health care claims or equivalent encounter information.
 - This section sets forth the four standards selected by the HHS Secretary for reporting of health care claims or equivalent encounter information. Standards are selected for retail pharmacy drug claims,

dental health care claims, professional health care claims, and institutional health care claims. Covered entities are required to utilize these standards to the extent they conduct such transactions.

- This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.1202. Standards for eligibility of a health plan.
 - This section sets forth the two standards selected by the HHS Secretary for the eligibility of a health plan transaction. Standards are selected for retail pharmacy drugs eligibility and for dental, professional, and institutional eligibility. Covered entities are required to utilize these standards to the extent they conduct such transactions.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.
 - §162.1302. Standards for referral certification and authorization.
 - This section sets forth the standard selected by the HHS Secretary for referral certification and authorization. Covered entities are required to utilize these standards to the extent they conduct such transactions.

- This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
- This is a reporting requirement since it governs how data is disclosed to third parties.
- It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.1402. Standards for health care claim status.
 - This section sets forth the standard selected by the HHS Secretary for inquiries and responses regarding status of health care claims. Covered entities are required to utilize these standards to conduct such transactions.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.1502. Standards for enrollment and disenrollment in a health plan.
 - This section sets forth the standard selected by the HHS Secretary for transmitting subscriber enrollment information to either establish or terminate coverage. Covered entities are required to utilize these standards to the extent they conduct such transactions.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.

- It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.1602. Standards for health care payment and remittance advice.
 - This section sets forth the two standards selected by the HHS Secretary for transmitting information regarding payment for health care, information related to payment, or remittance advice. One standard was selected to cover retail pharmacy drug claims and remittance advice, and another was selected to cover dental, professional, and institutional health care claims and remittance advice. Covered entities are required to utilize these standards for payment related transactions.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.
- §162.1702. Standards for health plan premium payment.
 - This section sets forth the standard selected by the HHS Secretary for transmitting information health plan premium payments or related data. Covered entities are required to utilize these standards to the extent they conduct such transactions.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.

- §162.1802. Standards for coordination of benefits.
 - This section sets forth the four standards selected by the HHS Secretary for transmitting information related to coordination of benefits (e.g., claims information or payment information) to determine the relative payment responsibilities of a health plan. Standards are selected for coordination of retail pharmacy drug claims, dental claims, professional health care claims, and institutional health care claims. Covered entities are required to utilize these standards to the extent they conduct such transactions.
 - This requirement is a “recordkeeping requirement” within the meaning of section 3502(13) of the PRA because it requires that covered entities maintain data.
 - This is a reporting requirement since it governs how data is disclosed to third parties.
 - It is also a reporting requirement because it regulates how information is disclosed to the federal government.

In sum, the ETS final rule does *not* appear to include any requirements that are not “information collections.” The above assessment is confirmed by the ETS final rule’s definition of the term “transaction” as “the exchange of information between two parties to carry out financial or administrative activities related to health care.” The definition then proceeds to identify eleven “types of information exchanges” as included within this term. 65 Fed. Reg. 50366-67 (August 17, 2000). Consequently, the mandated electronic standards constitute “collections of information” under the PRA.

Except for Subpart A (Applicability and Definitions) and Subpart J (Code Sets), all parts of the Electronic Transaction Standards rule expressly and only regulate particular types of “transactions” as defined by the rules. 65 Fed. Reg. 50367-72 (August 17, 2000). By their express terms, they only apply to various “types of information exchanges,” all of which are “collections of information” as defined by the PRA and OMB’s rules. Moreover, Subpart J specifies the code sets that must be used when a covered entity is “conducting a transaction covered by” the Electronic Transaction Standards rule. 65 Fed. Reg. 50370 (August 17, 2000). These code set provisions of the rule relate directly to the manner in which information is recorded and

reported to the agency, the public and/or third parties.

Conclusion

In sum, our assessment of the ETS final rule reveals no segregable substantive requirement which does *not* involve a “collection of information” within the meaning of the PRA. Consequently, since HHS has not complied with the PRA and there are no requirements in the final rule for Electronic Transaction Standards which do not constitute “collections of information” under the PRA, regulated persons have no compliance responsibilities and cannot be penalized for noncompliance until and unless the rule and its associated information collections are approved by OMB and issued a valid OMB control number under the PRA.