Attachment 2

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: **Compatibility of the Paperwork Reduction Act and HIPAA**

Question Presented

Whether there is any basis for concluding that the Administrative Simplification regulations issued under HIPAA are exempted from, or inconsonant with, the PRA?

Discussion

As HHS states in its final rule for HIPAA Electronic Transaction Standards, "The Office of Management and Budget ... has determined that this regulatory requirement (which mandates that the private sector disclose information and do so in a particular format) constitutes an agency sponsored third-party disclosure as defined under the Paperwork Reduction Act of 1995 (PRA)." (65 Fed. Reg. 50350, August 17, 2000.) The HHS rule is subject to and must meet all requirements of the PRA, unless there is a specific exemption from such requirements arising either from the HIPAA statute or the PRA itself. As a thorough review of both statutes revealed no basis for such exemption, HHS must fully comply with statute, and OMB must fully enforce the PRA provisions, pursuant to the reasoning set forth below.

The PRA unambiguously states that any federal government "collection of information" must comply with the PRA before it can be conducted, unless it is covered by one of the express exemptions in the statute (discussed below). In making this broad assertion of authority, the PRA clearly states:

> Except as otherwise provided in this chapter, the authority of an agency under any other law to prescribe policies, rules, regulations, and procedures for Federal information resources management activities is subject to the authority of the [OMB] Director under this chapter [the PRA]. 44 U.S.C. § 3518(a).

The PRA establishes requirements, including prior OMB review and approval, governing the federal government's "collection of information." See 44 U.S.C. § 3507(a); 5 C.F.R. §§ 1320.1, 13201.4, 1320.5. The PRA defines "collection of information" as meaning

> 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.

The HHS Electronic Transaction Standards rules require, in a specified manner, the collection, recording and reporting of health care transaction information to HHS, the public, and/or third parties. They impose identical requirements on ten or more persons. Consequently, they are a "collection of information" under the PRA. In fact, they are nothing but a "collection of information" because no aspect of the Electronic Transaction Standards rules can be segregated from their information collection requirements.

Congress exempted several types of federal government action from the PRA's requirements, including information collections related to federal criminal investigations/prosecutions, civil actions involving the federal government, administrative actions or investigations involving specific parties, and intelligence activities as defined under Executive Order No. 12333 (December 4, 1981). See 44 U.S.C. §§ 3502(3)(B); 3518(b), (c), (d), (e) for a complete discussion of PRA exemptions. However, the HHS Electronic Transaction Standards rules are not among these exemptions, and no other PRA provision exempts the HHS final rule from compliance with the PRA. Nor do OMB's rules exempt the Electronic Transaction Standards rules from PRA compliance. See 5 C.F.R. § 1320.4 (OMB rules governing PRA coverage).

The last basis for overcoming the applicability of the PRA to the Electronic Transaction Standards would be the existence of an express provision in the HIPAA statute providing such an exemption. A careful review of the statute does not demonstrate that Congress intended to limit applicability of the PRA in this context. There is no conflict between the two statutes, so it is possible to read the two acts consistently and to give effect to all relevant provisions.

In fact, the two laws are highly consistent from a public policy perspective. The PRA seeks to improve the quality of government-mandated information collections and at the same time to reduce the financial and administrative costs of gathering and

maintaining this data. HIPAA's Administrative Simplification provisions seek to standardize various health-related transactions through the use of common forms and codes, with the stated intention to reduce costs in the nation's health care system. To the extent that both statutes are focused on promoting efficiency and reducing burdens, the laws are totally consistent.

Finally, the HIPAA statute itself does not envision the HHS Secretary taking a hands-off approach in terms of adoption or maintenance of the electronics standards accepted under the rule. While expressing a preference for standards developed by standard setting organization, Congress recognized in section 1172 of the HIPAA statute that there may be instances where no such standard exists or where the HHS Secretary determines that a different standard should be developed in order to reduce administrative costs; in such cases, HHS may develop or promote the development of such a standard using specified rulemaking procedures. Clearly, HHS would have significant involvement in the standard itself in such a case.

Furthermore, section 1174 (b)(1) of HIPAA deals with modification of the standards selected by HHS, stating:

> Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1173, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance.

Thus, Congress clearly contemplates HHS review and modification of the standards for electronic transactions. These standards are in no way immutable, either now or in the future, so it makes no sense to place the standards beyond the reach of the public protections contained in the PRA, during either the initial selection or modification phase of the HIPAA Electronic Transaction Standards rule. There is no legal or practical justification for doing so.

Conclusion

Based upon the above reasoning, including the applicability of the PRA and the lack of exemption in either the PRA or HIPAA itself, HHS must develop and promulgate the HIPAA Electronic Transaction Standards rules in accordance with the PRA and

OMB's rules because the rule's substantive requirements are "collections of information."