

April 17, 2001

The Honorable Mitchell E. Daniels, Jr.
Director, Office of Management and Budget
Eisenhower Executive Office Building, Room 252
17th Street & Pennsylvania Avenue, N.W.
Washington, D.C. 20503

Dear Director Daniels:

CRE is filing the enclosed Petition pursuant to section 3517(b) the Paperwork Reduction Act to correct HHS's failure to prepare required analyses and to provide required notices and comment opportunities in connection with HHS's final rule on Electronic Transactions Standards ("ETS Final Rule") (issued pursuant to the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act). Under section 3517(b) "any person may request the Director to review any collection of information" for compliance with the Paperwork Reduction Act.

The basic problem with the ETS Final Rule is that it was promulgated on August 17, 2000 – some eight months ago – yet as of today HHS has not obtained OMB approval of the information collections contained therein. Furthermore, as is explained in the Petition, HHS does not anticipate submitting a clearance package to OMB until later this year. Even if the clearance package is sent to OMB, OMB will not be in a position to exercise its discretionary authority and issue a control number for the ETS requirements without evaluating clearance packages relating to the information collection requirements in the other Administrative Simplification regulations.

HHS is requiring all respondents subject to the Final Rule to attain full compliance with the information collections by October of 2002. Yet under the Paperwork Reduction Act the information collections are not enforceable until a valid clearance package is submitted and until OMB issues control numbers. As virtually the entire Rule is comprised of "information collections" (*i.e.*, there are no non-informational requirements), it is unreasonable for HHS to require respondents to undertake

compliance efforts before a legally enforceable regulation is in place.

Transcending all the arguments presented in the enclosed Petition is the fundamental statutory requirement that HIPAA requires that the totality of all the regulatory requirements under the Administrative Simplification program be promulgated simultaneously, not on a piecemeal basis. Failure to do this will certainly invite judicial review (see the discussion at sections “I.1 - I.2” of the enclosed Petition).

Consequently, in the enclosed Petition, we request that OMB exercise its authority under the Paperwork Reduction Act to extend the compliance deadline from the current deadline of October 2002 (which was 24 months after the effective date of the original rule) until 24 months after the later of the following dates:

- (i) the date on which all of the Administrative Simplification regulations (except for the unique personal identifier and privacy regulations) are issued as final rules;
- (ii) the date on which control numbers are granted for the information collections in all of the Administrative Simplification final rules (except for the unique personal identifier and privacy regulations);
- (iii) the date on which HHS modifies the ETS regulation to incorporate additional data requirements, currently not in the ETS final rule but which are presently needed by state governments;
- (iv) the date on which HHS modifies the ETS regulation so that it is in conformity with the information collection requirements in the Department of Labor’s final rule on health claims procedures issued pursuant to ERISA; and
- (v) the date on which HHS completes a negotiated rulemaking pursuant to section 1172(c)(2)(A) of the Social Security Act to address gaps in the present version of the ETS rule, as explained in the enclosed Petition.

Sincerely yours,

Jim J. Tozzi,
Member, CRE Board of Advisors

Enclosure