A. Introduction.

Petitioner The Center for Regulatory Effectiveness ("CRE") hereby submits this Petition to the Office of Management and Budget ("OMB") to correct a number of statutory violations committed by the Department of Health and Human Services ("HHS"). These violations involve noncompliance with the Paperwork Reduction Act of 1995 (44 U.S.C. §§ 3501 *et seq.*) ("PRA") and OMB Circular A-119 (which was issued pursuant to the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) ("Technology Transfer Act")). This Petition is filed pursuant to 44 U.S.C. § 3517(b).

HHS has committed, and continues to commit, the violations set forth in this Petition in connection with its rulemaking proceeding to promulgate a final rule governing "Standards for Electronic Transactions" (published at 65 Fed. Reg. 50,312 (Aug. 17, 2000)) ("the ETS Final Rule") pursuant to the "Administrative Simplification" provisions of the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) ("HIPAA") (found at §§ 1171-1179 of the Social Security Act ("SSA"), 42 U.S.C. §§ 1320d - 1320d-8).

In particular, and as is set forth with greater specificity in the "Specific Relief Requested" at "L.3" (pages 76-79 below), Petitioner requests in this Petition that OMB comply with its own legal obligation to enforce agency compliance with the PRA by:

(a) Requiring HHS to submit a complete and valid clearance package to OMB, including a complete Supporting Statement;

(b) Refraining from deciding whether to approve, modify or disapprove the information collections in the ETS Final Rule until the clearance package demonstrates that HHS has met all of the substantive standards of the PRA, as described in this Petition;

(c) Refraining from reviewing the ETS clearance package until HHS has promulgated the remaining Administrative Simplification final rules (except for the unique personal identifier and privacy rules), so that OMB can assess the impact that other Administrative Simplification components will have on whether the ETS requirements will ultimately comply with the PRA;

(d) Requiring HHS to provide complete and accurate burden estimates in its Supporting Statement; and

(e) Directing HHS to extend the initial compliance deadline under the ETS Final Rule, as well as for the other Administrative Simplification final rules (except for the unique personal identifier and privacy regulations), until two years from 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) have been issued as final rules;

(ii) the date on which OMB has granted control numbers for all of 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 has published in the Federal Register a notice of its determinations as to which modifications will be made to the ETS Final Rule to accommodate state-law requirements (as discussed at "J.1" (pages 65-66) below);

(iv) the date on which HHS has modified the ETS regulation to incorporate the information collection requirements in the Department of Labor's ("DOL") final rule governing claims procedures of ERISA-covered plans ("DOL Claims Procedure Final Rule") pursuant to the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. §§ 1001-1461) ("ERISA"); and,

(v) the date on which HHS has completed a negotiated rulemaking pursuant to SSA § 1172(c)(2)(A) to correct practical implementation problems identified by covered entities and other stakeholders.

B. Factual and Procedural Background.

HIPAA was enacted on August 21, 1996. Title II, Subtitle F of HIPAA enacted a program known as "Administrative Simplification," under which HHS was required to have adopted standards on the following:

(1) Electronic transactions standards and code sets ("ETS");

(2) National provider identifiers;

(3) National employer identifiers;

(4) National personal identifiers;

(5) Security standards;

(6) Privacy; and,

(7) Claims attachments.

See SSA § 1173 (42 U.S.C. § 1320d-2); see also "Tentative Schedule for Publication of HIPAA Administrative Simplification Regulations," *at* http://aspe.os.dhhs.gov/. As of the date of this Petition, HHS has promulgated final rules addressing ETS/code sets and Privacy. However, the other elements of Administrative Simplification have not yet been promulgated as final rules.

Under HIPAA, HHS was supposed to have promulgated the complete set of final standards no later than February 21, 1999. See SSA § 1174 (42 U.S.C. § 1320d-3). Despite the fact that only half of the regulatory regime is in place – so that major compliance requirements have yet to be promulgated into law – HHS is requiring one of the largest sectors of the U.S. economy – virtually the entire health care industry – to engage in wasteful, piecemeal efforts, which, by HHS's own admission, will have to be redone as soon as the entire regulatory regime is in place.

HHS's failure to promulgate a complete set of regulations within the time framework established by Congress has significantly prejudiced the information collection respondents under the ETS Final Rule. Congress intended that these

respondents be given a full 24 month period to attain initial compliance. This was based on Congress' recognition of the sweeping nature of the changes required by the new regulatory regime. Congress intended that HHS would issue the complete set of regulations on or about February 21, 1999, and that, in working toward initial compliance with one constituent standard, respondents would have reference to the complete body of interrelated standards. See discussion at "I.1" - "I.2" (pages 54-60) below.

HHS has been unable to meet the congressional timetable. Instead of issuing all of the regulations by February of 1999, HHS has issued only two regulations as of April 16, 2001. Moreover, these two regulations are not really "final," because they are *unenforceable* and *incomplete*:

- They are *unenforceable*, because they are comprised solely of information collection requirements for which HHS has not sought approval under the PRA. Therefore, the supposed 24 month compliance-attainment period set forth in the ETS Final Rule is *illusory: first*, because as of April 16, 2001, there are no enforceable requirements with which to comply; and *second*, because the ETS requirements cannot be performed until informational requirements in the as-of-yet-unissued regulations become final and are also reviewed under the PRA by OMB.
- They are *incomplete*, because they do not establish standardized codes for a significant percentage of the health care transactions that occur every day (*e.g.*, local codes, codes for state programs, *etc.*). See discussion at "G.2" (pages 41-45)

and “J” (pages 65-68) below.

The procedural history of Administrative Simplification has been marred by two broad categories of procedural violations:

(1) ***PRA Violations:*** As is set forth in greater detail at “E” and “F” (pages 16-40) below: (i) HHS failed to submit a clearance package to OMB at the time it published its NPRM for the ETS regulation; (ii) HHS failed to submit a clearance package when it published the ETS Final Rule; (iii) HHS still has not submitted a clearance package to OMB as of the date of this Petition; and (iv) HHS has not provided OMB or the public with accurate estimates of the burdens imposed by the information collections in the ETS Final Rule.

(2) ***Circular A-119 Violations:*** As is set forth at “K” (pages 69-72) below, HHS did not adequately consider U.S. and international consensus standards as alternatives to those adopted in the ETS Final Rule.

HHS’s failure to fulfill its legal obligations to Congress, OMB and the public are not merely technical or academic. Virtually all segments of the health care industry, as well as state Medicaid officials, have stated that the two-year compliance period in the ETS Final Rule is grossly inadequate due to the absence of a complete set of requirements, and also due to the need to purchase and install new systems, train employees in operating the new systems, and correct transactions that are mishandled during the transition.

Legal Arguments

C. The ETS Final Rule Is Subject to the Paperwork Reduction Act.

HHS and OMB both acknowledge that the ETS Final Rule is subject to the Paperwork Reduction Act, because virtually all of the standards in the Final Rule constitute "third-party disclosures":

> we solicited comment on whether a regulation that adopts an EDI standard used to exchange certain information constitutes an information collection [that] is subject to the PRA. Public comments were presented which suggested that the use of an EDI standard is not an information collection and under the PRA. The Office of Management and Budget, however, 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 Federal Register at 50,350.

The language of the statute similarly shows that the PRA applies, because certain requirements in the Electronic Transactions Standards come within the PRA's definition of "collection of information." Under the PRA:

> the term collection of information...means 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...identical reporting or recordkeeping requirements imposed on ten or more persons...

44 U.S.C. § 3502(3). The term "reporting requirement," in turn, 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...

Id. § 3502(13).

In sum, there are three subcategories of "collections of information": (i) record retention requirements; (ii) third-party notification or disclosure requirements; and (iii) requirements to report information to the federal government. The information collections in the ETS Final Rule fall within all three categories for the following reasons:

(i) The ETS information collections contain record retention requirements, because the standards regulate the type of data entities must maintain on their premises, as well as how the records of such data must be maintained.

(ii) The ETS information collections contain third-party disclosure requirements, because the standards regulate how data is to be transmitted to other covered entities.

(iii) The ETS information collections contain federal government reporting requirements, because covered entities must comply with the standards when they transmit data to the federal government for Medicare and other purposes. See Attachment 1.

D. There Is a Dichotomy in the Paperwork Reduction Act Between Procedural Requirements (Which Are Mandatory and Nondiscretionary) and OMB Review Authority (Which Is Discretionary). OMB Lacks the Authority to Engage in Discretionary Review Unless and Until HHS's Procedural Violations Are Corrected.

1. HHS's and OMB's Duties Under the Paperwork Reduction Act Are Mandatory and Nondiscretionary, and Are Conditions Precedent to OMB's Review on the Merits.

The procedure in the PRA for reviewing and approving a "sponsoring agency's" (*e.g.*, HHS's) "proposed information collections" is based on a dichotomy between: (i) procedural requirements which must occur before OMB can undertake its review; and (ii) OMB's review of the proposed information collections on the merits. When procedural requirements governing rulemaking are mandated by Congress, compliance with such procedural requirements is mandatory, ministerial and nondiscretionary, and agencies subject to such procedural requirements lack the legal authority to waive compliance. See, *e.g.*, National Mining Ass'n v. Sec'y of Labor, 153 F.3d 1264 (11th Cir. 1998) (holding that procedural requirements in Federal Mine Safety and Health Act requiring federal agency to adopt finding of economic feasibility before adopting safety standard were mandatory and nondiscretionary, so that standard promulgated in violation of the procedural requirement was invalid).

Compliance with the procedural requirements of the PRA is evidenced through the submission of a complete clearance package (containing, *inter alia*, a "Supporting Statement"). Compliance with the procedural requirements is a condition precedent to

the second part of the PRA dichotomy, *i.e.*, OMB's review of the clearance package. See 44 U.S.C. § 3507(a)(1)(A), (a)(1)(B), (a)(1)(C), (a)(1)(D), (a)(2), (a)(3) (sequencing of procedural steps).

Congress established these procedural preconditions to OMB review on the merits with two things in mind:

(i) Ensuring that the sponsoring agency provides OMB with the statutorily required information and analyses OMB will need before it can intelligently "exercise its discretion" by deciding to approve or disapprove the information collection request; and

(ii) Providing members of the public with adequate notice of the agency's clearance package, so that the public can review the clearance package and submit informed comments to OMB.

These nondiscretionary duties are set forth at PRA §§ 3506 and 3507 and in OMB's implementing regulation (5 C.F.R. §§ 1320.5, 1320.8(d)(1) and 1320.11), and can be summarized as follows:

a. ***Complete Clearance Package.*** HHS was required to have submitted a clearance package to OMB simultaneously with publication of the ETS NPRM. In preparing the clearance package, HHS was supposed to have sought and obtained public comments addressing the substantive criteria that OMB will then consider in deciding whether to issue a control number. These requirements are found in a number of interlinked provisions of OMB's implementing regulation: Under 5 C.F.R. § 1320.11(a), HHS was required to have complied with § 1320.5(a)(1)(iv). In order to comply with

subsection (a)(1)(iv), HHS was required to have "published...a notice in the Federal Register...stating that the agency has made such submission," *i.e.*, the submission required by subsection (a)(1)(iii). Subsection (a)(1)(iii), in turn, required HHS to have "submitted to the Director" a clearance package containing, *inter alia*, the following:

(a) "the certifications required under § 1320.9";

(b) "a summary of the public comments received under § 1320.8(d), including actions taken by the agency in response to the comments"; and,

(c) "such related supporting materials as OMB may request".

b. ***Ten Statutory Certifications.*** Under PRA § 3506(c)(2) and (c)(3) and § 1320.9 of the implementing regulation, HHS was supposed to have made ten certifications regarding its compliance with the PRA, and provided documentation (in the form of extracts from public comments received by HHS) in support of those certifications. Key certifications that HHS has not yet provided to OMB include:

(a) Whether the proposed information collections in the ETS Final Rule meet the *"practical utility"* test (44 U.S.C. § 3506(c)(3)(A));

(b) Whether the proposed information collections *reduce burdens* to the full extent practicable (id. § 3506(c)(3)(C));

(c) Whether the proposed information collections are *consistent with existing reporting and recordkeeping practices* of respondents (id. § 3506(c)(3)(E));

(d) Whether the sponsoring agency has *"allocated resources for the efficient and effective management and use of the information"* (id. §

3506(c)(3)(H)); and,

(e) Whether the proposed information collections *"use information technology to reduce burden and improve data quality."* Id. § 3506(c)(3)(J).

c. *Submission of Accurate Burden Estimates.* HHS was required to prepare "a specific, objectively supported estimate of burden." 5 C.F.R. § 1320.8(a)(4). HHS was also required to provide an opportunity for public inspection and comment regarding the burden estimates sufficient to allow the public to "*evaluate the accuracy* of the agency's estimate of the burden of the proposed collection of information, *including the validity of the methodology and assumptions used*." Id. § 1320.8(d)(1)(ii) (emphasis added). OMB enforces these requirements by requiring the agency's clearance package to include a Supporting Statement setting forth the burden estimates and the underlying data, analyses, assumptions and methodologies. See OMB Draft Guidance, Exhibit 1.[1]

d. *Reduction of Burdens Through Use of Electronic Technologies.* Information collections using electronic technologies must use those technologies in a manner that *reduces, not increases* burdens. 44 U.S.C. § 3506(c)(3)(J); see also id. § 3501(10) (PRA's goal is to "ensure that information technology is acquired, used, and managed to improve performance of agency missions, including the reduction of information collection burdens on the public"). Congress clearly understood the danger

[1] OMB issued draft guidance for use by agencies in preparing and reviewing PRA clearance packages on February 3, 1997. Although OMB has not issued this guidance document in final form, it nevertheless represents OMB's only publicly available interpretation of the PRA.

that new computer technologies could be imposed by agencies on the regulated community in a manner that would be counterproductive in light of transition costs, as well as due to the constantly changing nature of the technologies.[2]

All of the above can be summarized very simply: The PRA requires that, at a minimum, the agency "sponsoring" an information collection submit a *complete* clearance package to OMB. The clearance package must contain the Ten Certifications and a Supporting Statement containing comprehensive and accurate burden estimates. The clearance package cannot be treated as a *pro forma* exercise; rather, it must demonstrate that each of the agency's *proposed* information collections meet all of the substantive criteria established by Congress and enacted into the PRA.

2. HIPAA Is Consonant With, and Does Not Override, the Paperwork Reduction Act.

Reference is made to the two legal opinions of Multinational Legal Services, PLLC (Attachments 1 and 2 to this Petition), which demonstrate that:

(a) Virtually all of the substantive requirements in the ETS Final Rule are also "information collections" within the meaning of the PRA (Attachment 1); and,

(b) HIPAA and the PRA are complementary, so that in enacting HIPAA

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[2] Unfortunately, HHS does not appear to understand this requirement. Thus, HHS treats increased revenues to software vendors (a cost to the health care industry which will be passed onto consumers!) as an economic benefit of the ETS Final Rule, despite the HIPAA mandate to reduce *health care* costs. See 65 Fed. Reg. at 50,360.

Congress did not exempt HHS from complying with the PRA (Attachment 2).

HHS wrongly states in the preamble to the ETS Final Rule that complying with the PRA would not be consonant with the requirements of HIPAA. See 65 Fed. Reg. at 50,350. HHS's rationale is that it is required to adopt existing consensus standards, and that scrutinizing a selected standard for the validity of information collection requirements therein could entail modifying the language of the initial standard. In other words, HHS is saying that it has no choice but to adopt a consensus standard *verbatim*, and that, because the standard must be adopted *verbatim*, there is no point in separately reviewing (and thereby possibly modifying) the reporting or recordkeeping requirements within the standard.

This position is based on an incorrect interpretation of both the PRA and HIPAA. The PRA applies to any proposed or final rule containing information collections. Therefore, HHS and OMB are obligated to undertake the analyses, certifications and approvals required by the PRA. If the standard adopted by HHS contains proposed information collections that do not meet the requirements of the PRA in every respect, then OMB's obligation is to "disapprove" or to instruct the "sponsoring agency" (*i.e.*, HHS) as to how to modify the requirements, regardless of what implications such disapproval or modifications might have for the non-information collection requirements elsewhere in the rule. See discussion at "H" (pages 52-53) and "F.3" (pages 39-40) below.

In enacting HIPAA, Congress did not grant HHS an exemption from compliance with the PRA, which Congress knew would apply to a regulatory regime covering virtually all data transactions within an entire industry. Thus, under HIPAA, if a consensus standard does not comply with the PRA, HHS has two options:

First, under SSA § 1172(c)(2)(A) (42 U.S.C. § 1320d-1(c)(2)(A)), HHS could start with the initial consensus standard, but then modify it pursuant to a negotiated rulemaking, until the resulting, modified standard complies with the PRA. This option would have been particularly feasible had HHS submitted a complete clearance package to OMB at the time the ETS NPRM was published in the Federal Register, as was required under 5 C.F.R. § 1320.11. This is still a viable option, and is in fact requested in the "Specific Relief Requested" at "L.3" (pages 76-79) below.

Second, under SSA § 1174(b)(2)(A) (42 U.S.C. § 1320-3(b)(2)(A)), Congress expressly authorizes HHS to modify the ETS Final Rule on or after 12 months from the adoption date the final standard. The ETS final standard was adopted on August 17, 2000, so that HHS has the authority to correct any PRA problems on or after August 17, 2001. See 65 Fed. Reg. 50,312 ("This rule *adopts standards* for eight electronic transactions...") (emphasis added). As HHS has already indicated that it does not intend to submit a clearance package to OMB until sometime between June-September 2001 (see Exhibit 2, ¶ 6), it is eminently feasible for OMB and HHS to work with the stakeholders to correct the legal violations set forth in this Petition. As stated above, negotiated rulemaking is still a feasible option.

E. HHS Has Violated Procedural Requirements of the Paperwork Reduction Act Which Must Occur Before OMB Can Review the Merits of an Information Collection Request.

1. HHS Has Not Submitted a Valid Clearance Package to OMB.

HHS has not filed any clearance package whatsoever with OMB. HHS, however, has stated that it intends to file a joint clearance package for information collections in the ETS and Privacy regulations. See Exhibit 2, ¶ 5. HHS's delay places respondents – virtually the entire health care industry – in an untenable position. On the one hand respondents must engage in expensive compliance implementation procedures (*e.g.*, computer upgrades, training, *etc.*). Yet on the other hand, some or all of the requirements could change depending upon the results of OMB's review under the PRA.

Another problem stems from the fact that HHS is 'clustering' two, but not all six, of the Administrative Simplification rulemakings. Respondents will not have a full set of requirements with which to comply until all of the Administrative Simplification regulations (listed at pages 3-4 above) have gone final, and until all of the information collection requests in each of those regulations have been approved by OMB.

Even if the ETS Final Rule is viewed in isolation, HHS's failure to submit a clearance package means that neither OMB nor members of the public, such as Petitioner CRE, have had an opportunity to meaningfully assess such questions as: (i) exactly what burdens would result from the new rule; (ii) whether those burdens are appropriate in light of the benefits; and (iii) whether HHS's information collection requests comport

with the PRA requirement that effective, efficient and state-of-the-art electronic technologies be promoted.

2. HHS Has Failed to Provide the Public with Notice of, and an Opportunity to Review and Comment on, a Complete Clearance Package.

HHS openly acknowledges that it: (i) has no intention of publishing a notice in the Federal Register when, later this year, a clearance package is belatedly submitted to OMB; and (ii) does not believe that any additional public comment is called for. See Exhibit 2, ¶ 10. The problem here is that HHS's Federal Register notices concerning the proposed and final rules for both ETS and Privacy were inadequate from a PRA standpoint, because there was never a clearance package for the public to review and comment on.

F. The Burden Estimates Provided by HHS Are Incomplete and Grossly Inaccurate.

1. HHS's Burden Estimates Are Incomplete.

HHS identified 31 categories of respondents who will be required to comply with the information collections in the ETS Final Rule.[3]

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[3] These categories are: (1) large physician practices; (2) small physician practices; (3) dental practices; (4) podiatrists; (5) chiropractors; (6) optometrists; (7) hospices; (8) federal hospitals; (9) large non-federal hospitals; (10) small non-federal hospitals; (11) large nursing facilities; (12) small nursing facilities; (13) home health agency; (14) residential mental health/ retardation/substance abuse facilities; (15) outpatient care centers; (16) pharmacies; (17) medical labs; (18) dental labs; (19) DMEs; (20) osteopaths; (21) large commercial health plans; (22) small commercial health plans; (23) BlueCross/BlueShield; (24) third-party administrators; (25) HMOs/PPOs; (26) self-administered plans; (27) employer plans (not self-administered); (28) clearinghouses; (29) billing companies/billing associates; (30) materials management/supply

For each of the 31 respondent categories, HHS was required to estimate costs with respect to the following six types of burden: (i) reviewing instructions; (ii) acquiring, installing, and utilizing technology and systems; (iii) adjusting the existing ways to comply with any previously applicable instructions and requirements; (iv) searching data sources; (v) completing and reviewing collections of information; (vi) transmitting, or otherwise disclosing the information." See 44 U.S.C. § 3502(2).[4]

To assist "sponsoring agencies" such as HHS in preparing their burden estimates, OMB has prepared instructions (and accompanying worksheets) to ensure that all of the burden categories are estimated for each type of respondent. See Exhibit 3. These instructions and worksheets reflect the type of analyses that HHS was supposed to have already made available for review by the public and OMB.

HHS has not prepared or provided the required estimates. In the preamble of the ETS Final Rule, HHS provides summary, conclusory, aggregate estimates for some of the respondent categories. However, HHS has not: (i) provided data for each of the six types of burden for each respondent category; (ii) explained where the data came from; (iii) explained what methodologies HHS utilized in arriving at the final estimates; or

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ordering software companies (VANs); and (31) state Medicaid agencies.

[4] Based on the statutory requirement, and as applied to the ETS Final Rule, HHS has distilled the following types of burden: (i) system conversion/upgrade; (ii) start-up cost of automation; (iii) training; (iv) implementation problems. See 65 Fed. Reg. at 50,353. HHS's burden categories do not appear to cover all of the types of burdens required to be addressed by the PRA.

(iv) explained what assumptions were used.

To make matters worse, HHS has already indicated that, when it submits its combined clearance package for the ETS and Privacy Final Rules, HHS does not intend to provide any burden data that has not already been included in the preambles to the Final Rules. See Exhibit 2, ¶ 9.

As is set forth in greater detail at "F.3" (pages 39-40) below, OMB's legal obligation and ongoing practice is to reject clearance packages that do not contain complete and accurate burden estimates, and to defer consideration of the merits of a clearance package until the sponsoring agency submits a corrected clearance package.

2. HHS's Burden Estimates Are Based on Incorrect Assumptions, So That HHS Has Grossly Understated Aggregate Burdens.

Although HHS has failed to provide a complete clearance package with justifications of its burden estimates, it is nevertheless possible to critique the HHS estimates by comparisons to health care industry assessments of implementation costs. Such a comparison demonstrates several key points:

- Compliance costs will be significantly higher than HHS estimates.
  - Based upon figures contained in a 2001 report by the Robert E. Nolan Company ("Nolan Report"), in the first five years, *industry implementation costs for HIPAA will likely exceed savings*. See Robert E. Nolan Co., Inc., An Analysis of the August HHS Estimates Regarding HIPAA Administrative Simplification 7 (First Quarter, 2001), Exhibit 4 ("Nolan

Report").

- Benefits/savings under the final rule are likely to be less than HHS predicts.
- HHS relied upon a number of invalid assumptions in estimating implementation costs.

To demonstrate HHS's underestimations of burdens, this discussion compares HHS's cost estimates with data from respondents on current and planned expenditures for attaining initial compliance. HHS's numbers are then reviewed both in the aggregate and for key sectors (*i.e.*, health plans, hospitals and physicians). At the outset, the following global cost and savings estimates of HHS should be kept in mind:

HHS Estimated Cost to Implement HIPAA (over 10 years)	HHS Estimated Savings from HIPAA (Over 10 years)	Net Savings Estimate (over 10 years)
$7 billion	**$36.9 billion**	**$29.9 billion (undiscounted) ($19.9 billion discounted)**

Id. at 3. If the HHS savings figures are used over the initial five-year period, instead of over ten years, then HHS's savings estimate would be $3.4 billion (see table below). As can be seen from this table, the $3.4 billion figure reflects savings based on HHS's assumptions over a five-year period (*i.e.*, no other changes were made by Nolan):

HHS Estimates over a Five Year Period (Using HHS Assumptions) as Restated by Nolan		
Estimated Cost Over Five Years (Discounted)	**Estimated Savings Over Five Years (Discounted)**	**Net Savings Estimate Over Five Years (Discounted)**
$6.8 billion	**$10.2 billion**	**$3.4 billion**

Note: **The Nolan Report calculated the Net Present Value (NPV) of the 5-year savings using a basic spreadsheet formula and a 7 percent discount rate, which is what HHS says it used in calculating its NPV.**

Id. at 5.

a. HHS's aggregate figures underestimate costs (burdens).

As discussed in the Nolan Report (at pages 3-5), HHS has underestimated implementation costs due to the following factors:

- Initial implementation costs are grossly underestimated. (Details provided below.)
- HHS does not acknowledge significant *ongoing* implementation costs. For example:
  - Standards may be modified once per year, and such changes will translate into additional costs for covered entities. (In addition, the Towers Perrin Report, discussed below, expects a shift in requirements of covered entities to the international standards in several years.)
  - As-of-yet unissued Administrative Simplification regulations related to HIPAA will require further investment in time and resources.
- There will be costs to "paper" transaction providers, since they will be dealing with other entities which are subject to the ETS Final Rule.
- Code development costs will probably be encountered as covered entities migrate from "local codes" to standardized, national codes. Such efforts will be required to capture all health care services (*e.g.*, nursing homes, home health and durable medical equipment). HHS does not recognize these costs.

As HHS itself admits, implementation costs for state Medicaid agencies (HHS estimate of $1 million each) have been substantially underestimated at least 10-fold. For example:

- Maryland has estimated HIPAA Medicaid costs of $9-$36 million. See Maryland Department of Health & Mental Hygiene, Fiscal Year 2002 Budget Planning Memorandum ¶ 16 (May 3, 2000), *at* http://www.dhmh.state.md.us/HIPAA/html/hipaamemo.htm, Exhibit 5.
- Wisconsin estimates implementation costs of $18 million. Nolan Report, Exhibit 4 at 4.[5]
- Arizona's Department of Health Services, which interfaces with the state's Medicaid agency, has requested $4.5 million to cover implementation costs over a two-year period. Further funds will be requested in the next budget cycle as well. Testimony of Arizona Dep't of Health Servs. before the Workgroup for Electronic Data Interchange ("WEDI") HIPAA Success Task Group (2001), Exhibit 7.

b. HHS's aggregate figures overestimate benefits (savings).

The Nolan Report calculated the anticipated savings attributable to the ETS Final

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[5] The Nolan Report considers Wisconsin's full implementation costs for the ETS Final Rule. Additional confirmation may be found in the state's budget materials, which request over $13 million for implementation for fiscal years 2002 and 2003, an amount in addition to prior funds already spent on HIPAA implementation efforts. See Wisconsin Department of Health and Family Services, Biennial Budget Request 2001-2003 at 90 (September 15, 2000), *at* http://www.dhfs.state.wi.us/aboutdhfs/OSF/DINS56-113.pdf, Exhibit 6.

Rule, and concluded that HHS has significantly overestimated savings for a number of reasons. These include the following:

- The ten-year time frame of the HHS calculation improperly assumes that technology purchased for initial implementation will be usable for more than five years. HHS fails to factor in ongoing technology costs during the second five-year period of the initial ten years. However, additional costs for rapidly changing software and other technologies will be required. Most businesses justify capital expenditures on a three to five-year payback period, so five years is really the maximum extent to which technology savings can be reasonably calculated. Nolan Report, Exhibit 4 at 5.
- HHS has made unrealistic assumptions about the growth of electronic data interchange ("EDI") absent promulgation of the ETS Final Rule. EDI has already increased from 12% of claims in 1993 to 53% of claims in 2000. However, HHS assumes a slower rate of growth absent regulatory intervention. Utilizing current trends reduces the savings associated with implementation of the ETS Final Rule. Id.

  Other unrealistic assumptions on the part of HHS include:

  – HHS assumes a 10% increase in physician EDI in the first year, even though the ETS Final Rule would not become operative until October of that year. Id.

  – HHS disregards the fact that some physicians will revert to paper

transactions due to their financial inability to conform to the Final Rule within the existing deadline. Id.

– The HHS expectation of reaching 94% EDI usage by 2011 is overly optimistic. A natural cap of 80%-85% is considered more likely due to technological and other barriers. Id. at 5-6.

According to the Nolan Report, changes in these assumptions alone could cause HHS savings estimated to decline by over $9 billion.

• Perhaps because it relies so heavily on the 1993 WEDI report, HHS fails to consider a generation of new technologies which health plans and providers have adopted without the impetus of government regulation, and which have significantly increased efficiency and lowered costs. As a result, the incremental gains from EDI will be lower than HHS estimates. Examples include the following:

– Non-EDI technology has already reduced the cost of claims (*e.g.*, the widespread adoption of optical character recognition or scanning). Thus, the HHS savings estimate of $1 per claim is overstated. Claim cost reductions actually attributable to the Final Rule are expected to be only about 30-50 cents per claim. Id. at 6.

■ According to the Nolan Report, a change in this assumption alone would decrease potential savings under the Final Rule by $5 billion. Id.

– Non-claim transaction costs have also dropped through the use of advanced telecommunications technologies, including the Internet. These technologies have already reduced costs by about 25-50 percent, which means that HHS's expectations for additional savings are overstated. Id.

  - According to the Nolan Report, adjusting estimates associated with this assumption would decrease HHS savings estimates by $4.2 billion.

– HHS overestimates current physician claim costs. HHS estimates physician savings at $1.49 per claim, but Nolan's labor cost workflow analysis estimates the total current cost of a physician submission to be only $0.95. Id.

  - According to the Nolan Report, correcting HHS's invalid assumption reduces HHS's saving estimates by about $2 billion.

• Despite incorporation of a small amount of more recent data, the HHS analysis still relies primarily on the nearly decade-old WEDI report dated 1993. As a result, HHS's ignore virtually an entire generation of technology. This runs counter to the express legislative purposes of both the PRA and HIPAA to utilize the best technology to improve efficiency and reduce cost burdens.

c. HHS has underestimated costs for major segments of the health care industry.

Once HHS's invalid assumptions are corrected, new calculations demonstrate that

HHS has underestimated costs to key segments of the health care industry for initial implementation of and ongoing compliance with the ETS Final Rule. The following table from the Nolan Report illustrates the significantly divergent estimates for costs to health plans, hospitals, physicians, and other providers:

Summary of Differences in Initial Implementation Costs				
HHS Cost-Benefit Analysis Table	**Segment**	**HHS ($ billions)**	**Nolan Estimate ($ billions)**	**Difference ($ billions)**
Table 1	Health plans	3.5	11.4	7.9
Table 2	Hospitals	1.4	3.5	2.1
	Physicians	.4	1.4	1.0
	Other providers	1.8	1.8	0.0 (Not re-estimated)
Totals ($ billions)		**$7.1**	**$18.1**	**$11.0**

Id. at 17.

The discussion at "d," "e" and "f" immediately below addresses HHS's underestimation of costs for two key respondent categories, health plans and hospitals. *However, it is important to note that HHS has failed to provide complete, broken-down data for each of the six burden categories (listed at "F.1" (page 18) above) for the other 28 respondent categories listed in footnote 3 above.* This, in and of itself, is a serious violation of the PRA. Moreover, it would appear that if HHS has underestimated costs for health plans and hospitals, similar inaccuracies could be expected for the other 28 respondent groups.

d. Costs to health plans have been underestimated.

Specific problems have been identified with HHS's estimates of implementation costs for health plans. For example, HHS did not adequately address the substantial reprogramming costs to large health plans with older "legacy systems." HHS also underestimated the costs of new technology to support non-claim transactions and to develop related processes. The ETS Final Rule will increase costs by requiring the early purchase of new systems that would otherwise have had additional 2-5 year life spans. Nolan Report, Exhibit 4 at 4.

The following tables present a corrected picture of health plan implementation costs. The HHS table, corresponding to Table 1 in the preamble to the Final Rule, uses formulas to discount costs to plans by EDI percentages. However, industry experts point out that systems investments are not volume related, so the comparative table from the Nolan Report provides a more accurate real-world technology cost figure. Id. at 14.

HHS TABLE 1. - HEALTH PLAN IMPLEMENTATION COSTS AND SAVINGS [2002-2011]

Type of health plan	Number of health plans	Average Cost	% EDI	Total Cost (in Millions)	Savings (in Millions)
Large commercials	250	$1,000,000	90	$350	
Small commercials	400	500,000	50	200	
Blue Cross/Blue Shield	48	1,000,000	100	98	
Third-party administrators	750	500,000	50	375	
HMO/PPO	1,630	250,000	60-85	487	
Self-administered	50,000	50,000	25	1,875	
Other employer health plans	2,550,000	100	00	127	
Total (Undiscounted)	.....	.....	.....	$3,512	$16,600
Total (Discounted)	.....	.....	.....	$3,300	$11,600

65 Fed. Reg. at 50,356.

Nolan Report Table of Health Plan Costs

Segment	**Nolan Estimated Average Cost**	**Estimated Number of Entities in Category**	**Total Category Cost**
Large commercials and BlueCross/ BlueShield Plans	$10 million	298	$3.0 billion
Small Commercials and HMOs	$1.2 million	1,060	$1.3 billion
PPOs and TPAs	$.6 million	1,720	$.97 billion
Self Administered	$.1 million	50,000	$5.5 billion
Total			**$10.8 billion**
Nolan Report's Assumptions: The Nolan Report did not discount costs by EDI percentages as HHS did based on the Nolan Report's assumptions that systems investments are not volume related.			

Nolan Report, Exhibit 4 at 13.

Nolan Report Table of Employer Plan Costs			
Employer size	**Number**	**Investment**	**Explanation**
Large (1,000 or more employees)	6,719	$7,500	Purchase software and hardware; assign additional staff; perform training; redesign processes; write system interface (Assume two new PCs and software to support EDI enrollment; installation cost; train operators; program interface with HR system)
Medium (100-999 employees)	71,761	$1,750	Purchase software and hardware; develop additional training or staff (Assume one PC and hardware; install hardware; train operator)
Small (5-99 employees)	1,797, 622	$250	Additional training, negotiate contract relationships with vendors, install software or hardware
Weighted average cost	**1,876,102***	**$332**	**$624 million**
Average PC cost = $1,250; software cost of $249 if purchased off the shelf; $4,500 if partial application written with IT or external programming; $2,000 if using just the internal staff. * Source of company data: 1992 Census Bureau (Company Statistics) updated in 1999; does not add to totals used in HHS' cost/benefit Table 1; the Nolan Report assumed fewer employers and ignored subsidiaries and locations.			

Nolan Report, Exhibit 4 at 14.

The following additional real-world costs to health plans were not taken into account by HHS:

- One large New England managed care plan reported in comments to WEDI that it hired an external third party to assess its compliance implementation costs for the HIPAA transaction standards. Those costs were estimated at $15 million, exclusive of software and hardware costs. See Testimony of Harvard Pilgrim

Health Care before WEDI (2001), Exhibit 8. This figure is significantly greater than the $1 million estimated by HHS.

- Figures from another large health plan suggest that implementation of the ETS Final Rule will ultimately run from $20 million to $25 million. (Compliance with the Privacy regulation is expected to add another $10 million to that figure.) These estimates, significantly higher than the HHS estimate of $1 million, take into account a variety of costs not acknowledged by HHS:
  - Project management (estimated at between $2 million and $3 million);
  - Pilot projects to test program features which would then become part of implemented solutions (estimated at $1 million);
  - Computer hardware/software costs (estimated at over $2 million);
  - Employee and consultant costs;
  - Remediation activities (*e.g.*, code renovations, translation/mapping) and new functions (estimated at over $8 million); and,
  - Testing and implementation.

  The following table, provided by this same health plan, provides a summary of the costs associated with ETS implementation. To the extent that this health plan is typical, these figures demonstrate that HHS has greatly underestimated the costs to health plans as a respondent category under the PRA.

Summary of Initiative Costs	
Initiative	Translation Centric Cost ($, rounded total)
PMO	2,610,000
PROJECT MANAGEMENT TOTAL:	**$2,610,000**
Pilot Project	1,047,200
Phase 2 (Detail Design)	950,000
Remediation/New Functions	5,577,300
EDI Processing	900,000
Hardware/Software	2,225,000
Remediation/New Functions	8,371,000
EDI Processing/EAI	1,440,000
SYSTEM REMEDIATION TOTAL:	**$20,510,500**
PRIVACY/SECURITY TOTAL:	**$9,666,000**
Business Process Changes	**$4,005,000**
GRAND TOTAL:	**36,791,500**

- Another large health plan has estimated its implementation costs for the ETS Final Rule to be at least $11 million. However, this plan is budgeting an additional 25% for contingency costs to account for rule amendments and other anticipated changes/modifications to the regulations. This would cause expected implementation costs to rise to a level of over $13 million. Such contingency budgeting is undoubtedly prudent in light of the incomplete status of the

Administrative Simplification rulemakings.

The chart below details this health plan's anticipated costs associated with HIPAA implementation, for both the ETS and Privacy regulations. This data provides yet another real-world example demonstrating that HHS has greatly underestimated the cost burden of Administrative Simplification implementation on health plans.

HIPAA Activity	IS	IS Subtotal	Non-IS
1. Project Management	468,000	468,000	
2. Translator Resource	499,200	499,200	
3. Translator Infrastructure (servers & translator)	575,000	575,000	
4. Transactions:			
a. Claims /Encounter (837)	508,800		
b. Claims Payment (835)	381,600		
c. Claims Status (276/277)	381,600		
d. Referral/Authorization (278)	758,400		
e. Enrollment/Disenrollment (834)	758,400		
f. Eligibility (270/271)	381,600		
g. Premium Payment (820)	381,600		
h. Claim Attachment (275)	On Hold		
i. First Report of Injury (148)	On Hold		
Transaction Subtotal		3,552,000	
5. Code Sets:			
a. Claim Adjustment Reason Codes	504,000		
b. Health Care Claims Status Codes	753,600		
c. HCPCS	967,200		844,800
d. National Drug Code (NDC)	1,226,400		
e. Provider Taxonomy Code	691,200		
f. CDT (implemented in HCPCS)	0		
g. ICD-10	On Hold		
Code Sets Subtotal		4,142,400	
6. Identifiers:			
a. National Provider ID (NPI)	314,400		
b. National Health Plan ID (Plan ID)	374,400		
c. National Employer ID	223,200		
d. National Member ID	On Hold		
Identifier Subtotal		912,000	
7. Security & Privacy:			
a. Administrative Procedures			
i. Certification		244,000	1,545,600
ii. Chain of Trust			72,000

iii. Contingency Plan			36,000	
iv. Formal Mechanism for Records		96,000	108,000	
v. Information Access Control		34,400	48,000	
vi. Internal Audit		1,312,800	100,800	
vii. Personnel Security		160,000	202,000	
viii. Sec. Config. Mgmt.		219,200		
ix. Sec. Incident Procs.			496,000	
x. Sec. Mgmt. Process		50,400		
xi. Termination Procedures			16,000	
xii. Training			96,000	
b. Physical Safeguards				
i. Assigned Sec. Responsibility		9,600	28,800	
ii. Media Control		6,000	56,000	
iii. Physical Access Control			4,000	
iv. Policy on Workstation Use		12,000	48,000	
v. Secure Workstation Location		396,000		
vi. Security Awareness Trng.		24,000		
c. Technical Security Services				
i. Access Control		32,000		
ii. Audit Control		24,000		
iii. Authorizations Controls		10,400		
iv. Data Authentication				
v. Entity Authentication		8,000		
d. Technical Security Mechanisms				
i. Comm. Network Controls		352,000		
e. Electronic Signature				
i. Digital Signature		48,000		**TOTALS**
SUBTOTALS		**13,187,400**	**3,702,000**	**16,889,400**
+25% Contingency		3,296,850	925,500	4,222,350
Total:		**16,484,250**	**4,627,500**	**21,111,750**

- At least one large health plan has indicated that it will be forced to "wrap" its current systems into a "short-term fix" alternative. This short-term solution is expected to cost between $60 million and $100 million. Eventually, this temporary system will have to be discarded, once all of the Administrative Simplification final rules are promulgated and a permanent system can then be put in place – a squandering of health care dollars that will have to be diverted away from the provision of services to beneficiaries.

e. Costs to hospitals have been underestimated.

Industry estimates suggest that HHS has underestimated implementation costs to hospitals by a factor of two- or three-to-one. HHS estimated conversion costs for large hospitals (100+ beds) to be $250,000 each, but the Nolan Report found the average cost to be closer to $900,000, with some hospitals facing costs of $2-$5 million. Nolan Report, Exhibit 4 at 14.[6] As the tables below demonstrate, the difference between these two estimates for hospitals suggests that costs will be at least $2 billion greater than HHS estimates.

Hospital Cost Estimate: HHS vs. Nolan Report

Hospital Category	Number of Providers	HHS Average Cost ($)	Nolan Average Cost ($)	Nolan Total Cost ($ millions)	HHS Total Cost ($ millions)	Difference ($ millions)
Federal Hospitals	266	250,000	846,563	225	92	133
Non-Federal Hospitals <100 beds	2639	100,000	340,000	897	364	533
Non-Federal Hospitals 100+ beds	2780	250,000	846,563	2,353	960	1,393
Imputed Hospital Totals	**5,685**			**$3,475**	**$1,416**	**$2,059**

Id. at 15.

[6] In reaching the higher-end figure, the Nolan Report cites the analysis of Phoenix Health Systems in their Quarterly Industry HIPAA Survey Results (Winter 2001), *at* http://www.hipaadvisory.com/Survey/winter2001.htm, Exhibit 9.

A March 2001 study by Tillinghast-Towers Perrin concurs with the Nolan Report, finding HIPAA implementation costs for a mid-sized hospital (200-300 beds) to range from $775,000 to over $3 million. See Tillinghast-Towers Perrin, Final Report: Provider Cost of Complying with Standardized Electronic Formats 3 (Mar. 2001), Exhibit 10 ("Towers Perrin Report"). Again, this is significantly higher than the $250,000 estimate of HHS. According to the Towers Perrin Report, costs to develop standardized transaction formats for a particular hospital are highly dependent upon a number of factors, including:

- Degree of electronic data interchange already in place and level of current compliance;
- Hardware configuration and age of system;
- Software packages and degree of integration between business platforms;
- Data warehouse capacities;
- Use of data translators or clearinghouse functions;
- Use of billing agencies and ability of these organizations to comply with standardization within current cost structures; and,
- Other factors.

Id. The following table from the Towers Perrin Report offers a breakdown of the implementation costs for the hypothetical hospital discussed above:

Representative Hospital Electronic Format Remediation Budget	
Area/Gap	**Estimated Cost**
Reprogramming billing systems	$100,000 to $1 million
Purchasing a HIPAA compliant data translator (necessary investment for most hospitals)	$100,000 to $250,000
Business office and provider training (new codes, new formats, new identifiers, etc.)	$50,000
Charge slip and charge master (changes in how charge slips are designed and charge masters maintained)	$25,000
EDI upgrade for eligibility and claim status check (migration from non-compliant dial-up systems to new platforms)	$50,000 to $100,000
Consulting (including estimate revenue impact of standardized code sets)	$100,000
Data mapping and data warehouse upgrade (most hospitals must map current transactions to standard formats. Those that operate data warehouses for analytic purposes mus revise layouts and map old fields to new)	$100,000 to $1 million
MSO/PPO/PHO remediation (virtually all hospitals now have affiliated organizations that bill on behalf of staff physicians and other organizations)	$250,000 to $1 million
Estimated total:	**$775,000 to $3,525,000**

Id.

The Towers Perrin Report notes that teaching hospitals and other integrated delivery systems will require significantly greater investments, as they often include insurance functions, physician office administration, facilities and ancillary services. Costs for these institutions may average $1.5 million to over $6 million. Id. at 4.

f. Costs to physicians have been underestimated.

According to health industry sources, HHS has also underestimated the implementation costs for physicians, particularly with respect to non-claim transactions. Nolan Report, Exhibit 4 at 15. If physician offices are to process such non-claim transactions, they will need to invest in new technologies, including new computer

software, hardware and communications capabilities, and upgrades of existing systems.

HHS does not provide a breakdown of physician costs, as required by the PRA. However, the following figures from the Nolan Report provide an indication of these costs. Totals are then contrasted with the HHS estimates:

Nolan Estimate of Physician Costs

Provider Category	Number of Providers	Hardware ($)	Software ($)	Communication Upgrade ($)	Training ($)	Other Expense ($)	Subtotal* ($)	Total ($ millions)
Physicians: solo and groups less than 3	193,000	2,500	500	600	1,500	500	5,600	1,080
Physicians: groups 3+ with computers	20,000	7,500	750	1,800	4,500	1,500	16,050	321
Physicians: 3+ no automation	1,000	Not Re-estimated						
Total physician estimate				**$1,401,000,000**				

***** Represents an average expenditure per physician; some physicians will spend less, others more.

Cost Summary for Physicians: Nolan vs. HHS Estimate

Provider Category	HHS Average Cost	Number	Nolan Average Cost ($)	Nolan Total Cost ($ Millions)	Total HHS Estimate ($ Millions)	Difference ($ Millions)
Physicians: solo and groups less than 3	$1,500	193,000	5,600	1,080	290	790
Physicians: groups 3+ with computers	$4,000	20,000	16,050	321	112	209
Physicians: groups 3+ no automation	0	1,000	Not Re-estimated	Not Re-estimated	0	Not Re-estimated
Total				**$1,401**	**$402**	**$999**

Id. at 16.

The Towers Perrin Report also provides data which suggests that HHS has underestimated implementation costs for physicians. According to this report, retooling the electronic billing system for a solo physician practice would require an investment of $3,000-$5,000 (compared to an HHS estimate of $1,500). The study adds that costs for a typical 50-physician practice could run between $75,000-$250,000. Towers Perrin Report, Exhibit 10 at 4.

The Medical Group Management Association concurs with the Nolan Report, the Towers Perrin Report and Petitioner CRE that HHS's burden estimates are grossly understated:

> We are gravely concerned, however, that the implementation cost for this and the remaining HIPAA regulations will be substantial and far in excess of that predicted by HCFA. Group practice compliance with HIPAA will potentially include expensive software/hardware upgrades and modifications, extensive and ongoing staff training, and costly legal and consultative fees....
>
> We believe that in the cost/benefit table provided in this rule, HCFA has significantly underestimated the expense for group practices to implement this complex regulation. HCFA also does not appear to be offering the same level of education and implementation assistance to group practices as it did for the Year 2000.

Statement of Medical Group Mgmt. Group before WEDI (2001), *at* http://www.mgma.com/news/releases/, Exhibit 11.

3. OMB Is Obligated to Reject a Clearance Package Containing Grossly Inaccurate Burden Estimates.

The requirement that HHS submit accurate burden estimates for OMB and public review is not a mere technicality; it goes to the heart of Congress' purposes in enacting the PRA, which include: (i) minimiz[ing] the paperwork burden...resulting from the collection of information by or for the Federal Government"; and (ii) "ensur[ing] that information technology is acquired, used, and managed to improve performance of agency missions, including the reduction of information burdens on the public." 44 U.S.C. § 3501(1), (10).

Moreover, the submission by HHS of accurate burden estimates is a precondition without which HHS and OMB cannot fulfill their own respective statutory obligations to certify that the information collection burdens are appropriate (*i.e.*, reasonable and proportionate) in light of the benefits to be obtained. *In other words, because HHS has not submitted accurate burden estimates, any certification by HHS that the burden levels are appropriate (i.e., under 44 U.S.C. § 3506(c)(3)(C)) cannot be accepted.* Nor is it possible for HHS to credibly publish a statement in the Federal Register "setting forth...an estimate of the burden that shall result from the collection of information" (as required under PRA § 3507(a)(1)(D)) in the absence of accurate burden estimates.

OMB has long recognized that accurate burden estimates are a precondition to consideration of the merits of a clearance package. Accordingly, it has been OMB's longstanding practice to reject a clearance package with procedural deficiencies, and to

require the agency to resubmit a corrected clearance package before OMB will conduct any review. See Exhibit 12.

G. Even If OMB Engages in an Exercise of Discretion at the Present Time, HHS's Information Collection Request Should Be Disapproved on the Merits.

1. HHS Fails the "Purpose" Test Under the Paperwork Reduction Act, Because Piecemeal Implementation of Administrative Simplification Violates HIPAA.

In accordance with OMB's interpretation of the PRA, OMB cannot approve an information collection request that violates the "purpose" test:

> "purpose" means that the collection of information will, or is expected to, achieve a result within the statutory... requirements of the sponsoring agency...and will be used on a timely basis. The purpose often suggests the general benefit to be served by the collection of information. *Proposed information collections that do not have a purpose, as defined, will be disapproved by OMB.*

OMB Draft Guidance, Exhibit 13 (emphasis added); see also 44 U.S.C. § 3506(c)(1)(A)(i), (c)(3)(A). As is discussed in detail at "I" (pages 54-65) below, HHS's "piecemeal" or "staggered" promulgation of only portions of the Administrative Simplification regulatory scheme violates HIPAA. This violation of HIPAA means that the "purpose" test under the PRA cannot be met. HHS could correct this violation by establishing one compliance deadline applicable to the completed Administrative Simplification regulatory scheme, as outlined in the "Specific Relief Requested" at "L.3" (pages 76-79) below.

2. The Information Collections in the ETS Final Rule Fail the "Practical Utility" Test.

Under OMB's most recent interpretation of the "practical utility" requirement:

> The term "practical utility" refers to the usefulness of information (considering its accuracy, adequacy, and reliability) to carry out the agency's functions in a timely manner. A collection of information may meet the purpose and need criteria, but fail the criterion for practical utility because the agency using the information (or the third-party to whom it is disclosed) is not able to use the information obtained (or to receive, understand, process, and make use of the information disclosed) in a timely and useful fashion in a reasonable, practical, workable, and reliable way.

Exhibit 13. The following examples demonstrate that the ETS Final Rule fails the "practical utility" test, because under the Final Rule it will be impossible for "covered entities" and state governments to perform routine data transactions that are now performed thousands of times per day and are necessary for the provision of basic health care services:

- HHS staff have failed to clarify the extent to which, under the ETS Final Rule, a data transmitter will be permitted to provide <u>*more*</u> information than is required by a standardized format, as may be needed to effectuate a health care transaction or provide a service pursuant to legal and binding payer-provider contracts or pursuant to terms required by a state (*e.g.*, Medicaid) or federal (*e.g.*, Medicare, TRICARE, DOL, *etc.*) law or regulation.
- HHS staff have failed to clarify the extent to which existing "direct data entry"

("DDE") practices will still be allowed once the ETS Final Rule goes into effect. DDE systems are an electronic transmission practice under which the transmitter keys into a "dumb" remote terminal of the receiver only the actual data elements needed by the receiver (*e.g.*, the three, four or a handful of data actually desired by the user), as opposed to the complete set of approximately 270 data elements called for in the ETS Final Rule. If a provider needs only one or two pieces of data (*e.g.*, pertaining to coverage), requiring the transmitter to transmit 268 additional data points violates "practical utility."

- HHS staff have failed to clarify the extent to which existing "screen scraping" practices will still be allowed once the ETS Final Rule goes into effect. "Screen scraping" (or "keystroke emulation") is an efficiency whereby multiple similar tasks need only be performed once, and the electronic program repeats what would otherwise be a repetitive manual task. For example, instead of requiring an employee of a hospital make 50 eligibility inquiries to a plan for data on the coverage status of 50 hospital patients-insureds, a screen scraping system allows the hospital employee to input the 50 names and then let the software add patient I.D. numbers, do the searching, "scrape" the payer screens, and "populate" the provider's system with the scraped data from the payer's files.
  - Screen scraping is also one of the few ways to enable the X12 HIPAA transactions to be utilized in a non-batch mode. Eliminating the allowability of screen scraping could result in payers being only able to

operate in batch modes, which could mean delays of one to three days for a provider to receive responses to the types of inquiries for which screen scraping could return answers in a matter of seconds.

To the extent that the ETS Final Rule would disallow this kind of cost saving mechanism, the Final Rule lacks "practical utility."

- As is discussed at "G.4" (page 47 below), the ETS Final Rule would prohibit "real-time adjudication" of coverage and claims.
- As is discussed at "G.4" (page 47 below), the ETS Final Rule would prohibit mobile physician access.
- The ETS Final Rule would prevent state governments from collecting data now required to implement state Medicaid and other health programs. Thus, the Indiana Health Coverage Programs (including that state's Medicaid program) submitted testimony to WEDI stating that the ASC X12N 278 review and response format in the ETS Final Rule does not accommodate Indiana's need for data that would enable the state to process provider reimbursements for supplies, equipment and services specific to certain beneficiaries, and that such providers would be forced under the ETS Final Rule to revert from nonconforming electronic transactions to paper transactions. Exhibit 14; see also discussion at "J.2" (pages 67-68) below.
- State governments have also testified before WEDI that the elimination of local code usage will increase the number of claims that will revert to manual review,

"thereby increasing processing time and payment delay to the provider." See, *e.g.*, id.

- According to the Mayo Clinic, the ETS Final Rule requires covered entities to gather and transmit substantial amounts of data that are unnecessary for most health care transactions:

> A major issue that arises from the universal transaction philosophy is that the burden then falls on the provider for reporting all the requirements in the claim transaction. *A given provider is now obligated to provide required elements, on all claims, to all payers even though none of the provider's business partners may need the element. Those payers who don't need the element for processing the claim will need to maintain the data element so they can either pass it back on a remittance advice or pass it on to a secondary payer as part of the COB process.*
>
> Our provider group believes that if the elements in question are not currently necessary for the billing of services, the elements should not be required for HIPAA implementation. It appears that some of these data elements do not reflect a universal need for the healthcare industry or they are the requirements expressed by a single payer or state agency.
>
> Our group believes *it is unreasonable to expect that every provider in the nation will be required to modify their system and collect and report certain data in order to accommodate a single or small number of payers. We found that in many of the cases, it may be impossible to collect the required data element information.*

Exhibit 15 (emphasis added).

These examples demonstrate that the ETS Final Rule fails the practical utility test, because: (i) it will be impossible for covered entities to provide/obtain needed

information; (ii) covered entities will be required to transmitted unneeded data; (iii) key health care transactions, such as claims adjudication and provision of information to/from physicians, will be impeded; and (iv) state programs will not have access to necessary information.

Given the number and seriousness of these examples, it is imperative that OMB exercise its oversight obligation with HHS and grant the "Specific Relief Requested" at "L.3" (pages 76-79 below) that will enable covered entities to attain compliance without inflicting undue financial harm on covered entities or impeding the efficient flow of information which is so necessary for the proper functioning of the health care industry.

3. The Burdens of the Information Collections Are Unreasonably Excessive, and Outweigh the Benefits.

Congress enacted HIPAA with the intent that the net savings from data standardization would justify the initial compliance costs. See discussion at "I.2" (pages 58-60 below). However, during the initial five years during which covered entities will have to attain compliance, the burdens will greatly outweigh the benefits. Moreover, HHS's decision to require compliance with Administrative Simplification on a staggered, piecemeal basis will add to the compliance burdens without providing any corresponding benefits whatsoever.[7]

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[7] Thus, to cite one of many examples, the American Association of Health Plans submitted testimony to WEDI stating that its 1,000 HMOs, PPOs and other health plans will be unable to meet the initial compliance deadline due to HHS's failure "develop related requirements (such as those dealing with employer, provider and plan identifiers)." Exhibit 16.

4. HHS Has Violated the Statutory Requirement That Electronic Technologies Be Used so as to ***Reduce, Not Increase,*** the Burdens of Compliance.

HHS was required to certify that the information collections in the final rule "to the maximum extent practicable, uses information technology to reduce burden and improve data quality, agency efficiency and responsiveness to the public." 44 U.S.C. § 3506(c)(3)(J). HHS has not to date made this certification. Nor can HHS make this certification in light of the barriers the ETS Final Rule would impose to the use of existing state-of-the-art electronic technologies. A few examples include:

- *"Data warehousing"/"data mining".* Data warehousing refers to the electronic storage and immediate retrieval technologies that allow data transmitters (such as plans, providers, clearinghouses) to make data available to data users wherever, whenever, and to whatever extent the need arises via the Internet or other telecommunications mechanisms. For example, one service allows a provider to click onto a screen that provides a number of options, including the patient's copayment status. The data user may need the copayment screen but not other screens available on the system (such as coverage, enrollment, address, *etc.*). Yet under the ETS Final Rule, the data user would be required to access a massive screen containing all the HIPAA-specified data, regardless of how irrelevant. The ETS Final Rule, as presently written and interpreted by HHS staff, would prohibit users from accessing limited data (subsets of the HIPAA-specified maximum data

sets) on user-friendly screens. This would significantly increase the time, expense, complexity and degree of difficulty involved for the user to access the data and proceed to provide the health care service. This would also significantly enhance the danger that some data users will select the wrong data point from the virtually hundreds of data points on a given screen, which would in turn significantly increase the chances of medical misadventures or incorrect coverage or payment determinations.

- *"Real time adjudication."* "Real time adjudication" refers to Internet information products that essentially allow the instantaneous, "real time" exchange of specific data related to specific coverage and payment issues, so as to allow key determinations to be made instantaneously. Under HHS's present interpretation of the ETS Final Rule, this service would no longer be allowed.
- *Mobile physician access.* New technologies are being implemented that provide physicians with instant access to patient data in hand-held devices. These devices will allow physicians to provide critical medical assistance virtually at any time and in any place. The ETS Final Rule, however, would disallow this new service, because the complete data set, comprising hundreds of data points, would not fit onto the small, hand-held screen, and would exceed the memory capability of the hand-held device. This again could significantly increase the chances of medical misadventures or incorrect coverage or payment determinations.

These are but a few examples of HHS's failure to grasp that electronic technologies are

not to be imposed blindly or in a manner that would decrease efficiencies and cost effectiveness. HHS has clearly failed to address the legitimate practical concerns of the regulated community, so that imposition of the information collections in the ETS Final Rule would increase costs to consumers and disrupt the provision of health care services. OMB intervention is necessary to work with HHS and the regulated community to determine, as a practical matter, how the Administrative Simplification regulations can be implemented without unnecessarily impeding the provision of health care services to consumers or doing harm to the stability of "covered entities" providing such services.

5. HHS Has Violated the Statutory Requirement That HHS Allocate Sufficient Resources to Manage the New Requirements.

Under PRA § 3506(c)(3)(H), HHS was required to have certified to OMB that the information collection requests in the ETS Final Rule:

> ha[ve] been developed by an office that has planned and allocated resources for the efficient and effective management and use of the information to be collected, including the processing of the information in a manner which shall enhance, where appropriate, the utility of the information to agencies and the public.

Petitioner CRE has identified at least three examples of HHS's failure to comply with this prerequisite for OMB issuance of a control number:

- The first example is provided by Lisa Doyle, Medicaid Information Specialist with the Wisconsin Department of Health and Family Services and Chair of the NASMD National Medicaid EDI HIPAA Workgroup, who testified before the

National Committee on Vital & Health Statistics ("NCVHS") that:

> If all of the Medicaid procedures currently being supported by local codes must be included in the level II HCPCS the demand on the HCFA HCPCS workgroup will be immense. We question whether the existing quarterly review process and HCFA resources will be adequate to meet this demand. We are concerned that unless there is adequate staffing for the review each quarter, states will have no alternative but to use local codes beyond the date that HIPAA compliance is mandatory.

Exhibit 17.

- The second example is HHS's failure to provide covered entities with definitive responses to inquiries on such critical questions as: (i) whether information systems can be formatted to allow the transmittal of more data than minimally required by the ETS Final Rule; (ii) whether confirmation or elaboration of transmitted data is allowed; and (iii) whether "direct data entry" and "screen scraping" (as discussed at "G.2" (pages 41-42) above) will be allowed. These are key questions that covered entities need answers to ***before*** they commit financial and staffing resources to the overhaul of entire information systems.
- The third example is provided by the Illinois Department of Human Services, which testified before WEDI that HHS has not allocated adequate funding to assist state agencies in making the transition away from the present system, which is based on "local codes":

> while it is widely recognized that HIPAA compliance will be expensive, no funding is available to states to make necessary changes in state-funded health care programs. Typically, 85

> to 90 percent of the operating expenses of these programs is direct health care. These programs have no cash reserves, and they cannot pass expenses along to consumers who are primarily indigent and uninsured. While state Medicaid programs may benefit from federal matching funds covering 75% to 90% of HIPAA costs, no similar source of funding is available for primarily state-funded programs. These programs will not comply with HIPAA until they can afford it.
>
> Because of these problems....[d]eadlines for HIPAA compliance should be extended to October 2004.

Exhibit 18. These examples make it abundantly clear that HHS has not "allocated resources for the efficient and effective management" of the information collections comprising the ETS Final Rule.

Congress enacted the requirement in § 3506(c)(3)(H) precisely to prevent agencies such as HHS from imposing reporting requirements on respondents when the agencies have failed to provide the infrastructure and staffing necessary in order for the agencies to fulfill their basic regulatory oversight obligations with respect to the reporting requirements. In particular, HHS has not: (i) allocated the sufficient staffing (or addressed the question of providing for state funding) to provide state agencies with the support they will need to achieve initial compliance within the time frame set in the ETS Final Rule; or (ii) allocated sufficient staffing to respond to implementation inquiries from covered entities. Accordingly, OMB cannot lawfully approve the information collections in the ETS Final Rule unless and until HHS resolves the problems in the three examples set forth above.

6. HHS Has Violated the Statutory Requirement That New Information Collections Be Consistent and Compatible with Existing Reporting and Recordkeeping Requirements.

Under PRA § 3506(c)(3)(E), OMB cannot approve the information collections in the ETS Final Rule unless and until HHS certifies that the proposed information collection:

> is to be implemented in ways consistent and compatible, to the maximum extent practicable, with the existing reporting and recordkeeping practices of those who are to respond;...

HHS is not in a position to make this certification for two reasons. The first reason is that HHS has failed to adequately consider how the new ETS (and other Administrative Simplification regulatory) requirements will affect the information collection requirements in the DOL Claims Procedure Final Rule. The DOL Final Rule imposes information collection requirements on all ERISA-covered health plans, and compliance with these requirements must be reflected in electronic transmissions subject to any regulations of HHS.

The second reason why HHS cannot make the certification required by § 3506(c)(3)(E) is that the information collections in the ETS Final Rule are so fundamentally interconnected with the information collections in the other Administrative Simplification regulations (some of which have not yet been issued as final rules), that OMB cannot assess the real impact of the ETS requirements until these other 'pieces of the puzzle' (such as unique provider and plan identifiers and claims attachment

requirements) are in place. These 'missing pieces' are integral to the formatting, content and electronic systems adjustments that covered entities will have to undertake in order for standardized electronic transactions to go into operation.

DOL obtained an OMB control number in timely fashion for the information collections in the DOL Claims Procedure Final Rule. See 65 Fed. Reg. 70,245, 70,258 (Nov. 21, 2000) (awarding control number 1210-0053), so that the DOL information collections constitute "existing reporting and recordkeeping requirements" with respect to HHS, even though the DOL regulation was promulgated after the HHS regulation. Accordingly, before HHS can obtain an OMB control number, HHS must establish that the ETS requirements are "consistent and compatible" with the DOL Health Claims requirements.

H. HHS's Failure to Submit a Clearance Package Prior to the Effective Date of the Final Rule Mandates That the Compliance Deadline Be Extended.

OMB has broad authority under the PRA to correct problems with information collections in a manner that accommodates the legitimate requirements of both regulators and stakeholders. OMB's authority in reviewing a clearance package is not limited to approving or disapproving an agency's proposed information collection *in toto*. For example, the statute provides that "[a]ny decision by the Director...to disapprove a collection of information, *or to instruct the agency to make substantive or material change to a collection of information*, shall be publicly available and include an explanation of the reasons for such decision." 44 U.S.C. § 3507(e)(1) (emphasis added).

Thus, the statute expressly recognizes OMB's authority to materially change an agency's initial "information collection *request*."

Similarly, "OMB may instruct an agency to make a substantive or material change to a collection of information if...[t]he agency did not submit the clearance package for OMB review on or before the date the NPRM was published in the Federal Register." OMB Draft Guidance, Exhibit 19.

OMB has in the past freely exercised its authority to modify agencies' initial information collections in connection with health care data regulations. Thus, on June 30, 1995, OMB "approved" an HHS information collection request allowing the use of ICD-9 codes in connection with HCFA Forms -1500, -1490U and -1490S, but *modified and limited* the approval to correct the fact that HHS had failed to establish the "practical utility" of requiring respondents to use certain "e codes." OMB made its approval *conditional* on HHS's: (i) notifying respondents that compliance with the e code portion of the reporting requirement would be solely voluntary; and (ii) subsequently developing a plan for differentiating e codes that did and did not have "immediate practical utility." See Exhibit 20.

In light of the statutory authorization and OMB's past practice, it is clear that OMB has ample legal authority to work with HHS to correct the legal violations and practical compliance issues set forth in this Petition, and to grant the "Specific Relief Requested" at "L.3" (pages 76-79) below.

I. The ETS Final Rule Cannot Be Implemented Until the Other Administrative Simplification Regulations Have Been Promulgated.

1. The Administrative Simplification Subtitle of HIPAA Contains Interrelated Provisions That Cannot Be Implemented in a Piecemeal Manner.

a. Congress intended for the complete set of regulations to be issued at roughly the same time.

Both the statutory language and underlying purposes of HIPAA indicate that Congress intended for HHS to promulgate all of the Administrative Simplification regulations simultaneously. SSA § 1174 (timetables for adoption of initial standards) provides that "[t]he Secretary shall carry out section 1173 not later than 18 months after the date of the enactment of [HIPAA]...except that standards relating to claims attachments shall be adopted not later than 30 months after such date." In other words, all of the Administrative Simplification rulemakings (with the exception of claims attachments) were required to have been completed by February 21, 1999. Given the number and technical complexity of the issues involved, as well as the number of stakeholders, it is clear that Congress intended for the regulated community to have a complete set of interrelated requirements by the end of this 2½ year period.

In other words, Congress intended that a covered entity, in overhauling its entire information management system to attain compliance with one standard, would *simultaneously* be working on compliance with the other interrelated standards. Congress did *not* intend for a covered entity to have to go through the expense of creating a new

information management system by one deadline, only to be told that the new system must be *overhauled again* due to the fact that HHS failed to adhere to Congress' rulemaking schedule. In accordance with this interpretation, a number of Senators have informed HHS Secretary Thompson that they "do not believe that the current staggered release of regulations, each with its own two-year implementation requirement, is consistent with Congressional intent." See Exhibit 21 (discussed at "I.3" (page 64) below).

If HHS was unable to meet Congress' requirement to provide the health care industry with a complete body of regulatory requirements by a date certain, then the regulated community should not be penalized for HHS's failure. *The issue here is not merely HHS's failure to meet its February 1999 deadline, but, more importantly, the fact that Congress did not intend for promulgation of the final standards to be spread out over a period of more than a year. It is this failure to have a complete, coherent set of regulatory requirements finalized under both the Administrative Procedure Act and the PRA by a given date which has placed the regulated community in the unreasonable position of being told to undertake massively expensive restructurings only to be told that much of the work will have to be redone as other should-have-already-been-issued regulations become available.*

This problem is magnified by HHS's failure to comply with the PRA in the required time and manner. HHS was required to have submitted a clearance package for information collections in the ETS regulation on or before May 7, 1998, the publication

date of the NPRM. At the very latest, a clearance package should have been transmitted to OMB by August 17, 2000, the date of the final rule. *HHS's failure to even seek OMB approval of the information collections until half of the compliance period has elapsed, reduces the effective compliance period to a year or less.* This is because there will not be a valid set of requirements with which to comply until OMB has conducted its review, and possibly modified or disapproved, some or all of the requirements.

The amounts of money that will be wasted due to HHS's timing mishaps are staggering, cut across virtually all segments of the health care industry, and will be passed onto consumers. Given the fact that this problem was created by HHS, it would be manifestly unjust to penalize the health care industry, and by extension health care consumers, for the inability of an agency to meet a deadline. If the *first deadline* (*i.e.*, promulgation of a complete set of final rules) has been missed, then an adjustment of the *second deadline* (*i.e.*, initial compliance deadline for all standards) – which is conditioned on compliance with the first deadline – should also be allowed, especially when the costs to society of not doing so are so great.

b. Congress, HHS and NCVHS have all indicated that the Administrative Simplification regulations are so substantively interrelated that one standard cannot be implemented without reference to the others.

Congress' intent that the Administrative Simplification standards be issued together – and not spread out over more than a year – is reflected in the statutory language and is acknowledged by HHS. The following statutory provisions are so

integrally interrelated, that one cannot be fully implemented without reference to the other elements:

- The code set rules adopted under SSA § 1173(c) must be "appropriate" for the data elements adopted in the electronic transactions rules adopted under § 1173(a);
- § 1173(b) calls for the adoption of unique health identifiers to be used in the electronic transactions pursuant to § 1173(a);
- § 1173(d) requires that the security standards "take into account" "records systems" and "audit trails in computerized record systems" that must in turn be valid under the electronic transactions standards of § 1173(a);
- § 1173(e) requires that electronic signature standards be adopted expressly for use "with respect to the transactions referred to in (a)(1)," *i.e.*, the electronic transactions; and,
- The standards to be promulgated under § 1173(f), pertaining to data transfers among health plans for coordinated benefits and for individuals covered by more than one plan, will entail modifications to the electronic transactions standards.

HHS itself has acknowledged through its statements and actions that the above-described regulations are interrelated from an implementation/compliance standpoint:

> Although only the electronic transactions standards are being promulgated in this regulation, *the Department expects affected parties to make systems compliance investments collectively because the regulations are so integrated....it is not feasible to identify the incremental technological and computer costs for each regulation...*

65 Fed. Reg. at 50,351 (emphasis added). This statement is quite revealing: HHS is stating very clearly that all of the Administrative Simplification regulations need to be implemented together as a package. Yet the agency is nevertheless imposing the opposite result by requiring expensive, piecemeal "compliance investments" by causing the compliance clock to run before all of the regulations have been issued, and by HHS and approved by OMB.

It is also highly significant that NCVHS, in its First Annual Report to Congress on the Implementation of HIPAA (1998), acknowledged "the linkage of the individual identifier standard to privacy protections, the need for privacy protections to deal with fair information practices as well as antidiscrimination provisions, and the need for better implementation of security standards." Exhibit 22.

In sum, HHS treats the various standards as being integrally related when it is convenient for the agency to do so (*e.g.*, seeking joint PRA review of the ETS and Privacy regulations), but treats the same standards differently for compliance purposes, despite the increased costs to the health care industry and consumers that will result.

2. The Imposition of Piecemeal Compliance Deadlines Would Violate HIPAA's Fundamental Requirement of "Reducing the Administrative Costs of Providing and Paying for Health Care."

The centerpiece of Administrative Simplification is the use of uniformity and electronic technologies to cut administrative costs to the health care industry, and by extension to the public at large. Section 1172 thus contains the following "General

Requirement," which Congress intended to govern all of HHS's rulemaking activities:

> (b) REDUCTION OF COSTS – Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

42 U.S.C. § 1320d-1(b). All of the other Administrative Simplification provisions must be applied in the light of this requirement. At the very least, implementing regulations and information collection requirements should not be imposed in a manner that directly defeats this General Requirement.

Health plans have informed CRE that HHS's policy of "staggering" the regulations, *i.e.*, of imposing piecemeal compliance before all of the requirements and regulations are in place, will double the costs of attaining initial compliance. One plan has estimated that the ***added cost*** of implementing each new Administrative Simplification regulation after attaining initial compliance with the ETS Final Rule will be 20%-35%. In other words, in addition to the initial costs of complying with the ETS requirements in the form they were in as of August 17, 2000 (and which were seriously underestimated by HHS, see discussion at "F" (pages 17-39) above), this plan will have to incur an additional 20%-35% cost to implement the "audit trail" and "disclosure trail" requirements (whenever HHS promulgates these), and an additional 20%-35% cost to "retroactively rework" earlier compliance work to attain compliance with the signature standards, claims attachments standards, and unique identifier requirements (whenever

these are promulgated). These added 20%-35% "retroactive rework" costs will cumulatively double the compliance cost to this plan.

It can thus be seen that HHS's policy of requiring "staggered" compliance not only violates Congress' initial intent, but will easily double the costs of compliance to covered entities. The imposition of such unnecessary, added burdens violates both HIPAA and the PRA.

3. Members of Congress, State Health Agencies, Providers and Plans Have All Stressed That an Extension of the Compliance Deadline Is Necessary.

There is a broad consensus among Members of Congress, state health agencies, providers and plans that the initial compliance deadline in the ETS Final Rule is unreasonable in light of: (i) HHS's failure to promulgate a complete set of regulations; (ii) HHS's failure to obtain control numbers under the PRA for those rules promulgated to date; (iii) HHS's underestimation of the costs of attaining initial compliance; (iv) HHS's failure to provide definitive answers to requests for clarifications from covered entities attempting to attain initial compliance; (v) HHS's failure to address how covered entities are to transmit data points not covered in the final standards; (vi) the problematic trade-offs between NDC codes and J codes; (vii) the dependence of many smaller providers on noncompliant vendors; (viii) the imposition of single user and single state codes on a nationwide basis; and (ix) the failure of the ETS Final Rule to allow for state-of-the-art web-based data transmissions.

It would be impossible to cite all of the testimony before WEDI calling for an

extension of the deadline; however, the following list of commenters (Exhibit 23) provides some sense of the diversity of the groups that have found the current time framework impracticable:

- *American Medical Association; American Public Human Services Association (organization representing all state Medicaid directors); Blue Cross Blue Shield Association* ("[t]he current schedule does not provide adequate time for vendors to provide HIPAA compliant software and for trading partners to test the new transactions") ("[t]he staggered release, and implementation, of HIPAA administrative simplification regulations will require multiple system upgrades and undermines efficient planning and budgeting").
- *National Association of Governors* ("[s]ince enactment of HIPAA in 1996, it has become clear that the length and structure of its implementation period is unrealistic and untenable....it will be impossible for states to comply effectively with any part of HIPAA until all relevant regulations have been finalized and their implications can be assessed as a whole").
- *National Association of State Medicaid Directors* ("[g]iven the volume of activities, the uncertainty of the standards, and changes required by the elimination of local codes, compliance...cannot be achieved by the current deadline...We propose that the deadline for the elimination of local codes be extended to at least October 2004").
- *American Association of Health Plans* ("[i]n a recent AAHP survey, a substantial

majority of member plans suggested that the compliance date be delayed") (see Exhibit 16).

- *Illinois Department of Human Services* ("[d]eadlines for HIPAA compliance should be extended to October 2004") (see Exhibit 18).
- *Washington State Healthcare Forum; Association of Washington Business* ("[w]e believe an extension of the implementation time period is imperative").
- *Oregon Medical Association* ("[w]e propose a compliance extension that will... spread the cost of compliance over a longer period of time").
- *Alaska State Hospital & Nursing Home Association* ("[t]he current two-year period forcing employers, hospitals, doctors, insurers and everyone to comply compromises HIPAA's goals of administrative simplification and protecting privacy").
- *Colorado Association of Commerce and Industry* ("the current two-year time frame will create a financial strain which, we believe, will severely impact insurance carriers' ability to comply with the new rules and ultimately delay the positive effect of these rules").
- *Oklahoma Hospital Association; Oklahoma State Medical Association; Blue Cross and Blue Shield of Oklahoma* ("[a] four-year time frame is...necessary").
- *Arizona Department of Health Services* ("[t]here is simply not enough time for each of the groups listed above to...change their systems") (Exhibit 7).
- *California Department of Health Services* ("[w]ith all of the tasks that must be

accomplished for so many codes, we are concerned that we will not be able to implement the National Codes by the October 16, 2002 deadline").

- *Delta Dental Plan of California* ("the overall time line to implement each of the Administrative Simplification final rules should be much longer than the 24-month time frame set forth in the regulation").
- *Providence Health Plan* ("[v]endor delays will impact implementation") ("insufficient time to upgrade, convert data and test transactions prior to the final compliance date").

See Exhibit 23.

The following congressional statements also indicate the magnitude of concern regarding the rigid adherence to the two-year deadline despite HHS's own failure to comply with its own rulemaking deadline and the financial waste that would result from an inflexible approach:

- On February 9, 2001 Senator Patty Murray (D-WA) and Members Brian Baird (D-WA), Norm Dicks (D-WA), Jennifer Dunn (R-WA), Doc Hastings (R-WA), Jay Inslee (D-WA), Rick Larsen (D-WA), Jim McDermott (D-WA), George Nethercutt, Jr. (R-WA) and Adam Smith (D-WA) sent a letter to HHS Secretary Thompson stating that "[w]e...are concerned about the ability of health organizations to comply with regulations issued at different times. We request that you review the implementation of HIPAA including providing greater flexibility from the two-year compliance requirement and issuance of comprehensive and

coordinated regulations."

- On March 30, 2001, Senators Michael Enzi (R-WY), Bill Frist (R-TN), Jim Jeffords (R-VT), Judd Gregg (R-NH), Tim Hutchinson (R-AR), Pat Roberts (R-KS) and John Warner (R-VA) sent a letter to HHS Secretary Thompson stating that "[w]e do not believe that the current staggered release of regulations, each with its own two year implementation requirement, is consistent with Congressional intent."
- On April 5, 2001 Senator Russ Feingold (D-WI) and Members Jerry Kleczka (D-WI), Paul Ryan (R-WI), Tom Barrett (D-WI), Tammy Baldwin (D-WI), Mark Green (R-WI), Ron Kind (D-WI) and James Sensenbrenner (D-WI) sent a letter to HHS Secretary Thompson stating that "[w]e write to respectfully request that you reexamine the implementation schedule for the administrative simplification provisions – specifically transactions and code sets – ...and urge you to support an additional two-year extension of the October 2002 compliance deadline."

See Exhibit 21.

As early as 1997, NCVHS foresaw that a four year time frame would be required – even if HHS stuck to its original obligation to promulgate all of the rules by February 1999.[8] Thus, on June 25, 1997, based on the assumption that HHS would meet its

[8] Under HIPAA, HHS is required to rely on the advice of NCVHS, and to consult with appropriate state and federal agencies and private groups. See SSA § 1172(f) (42 U.S.C. §

"responsibility for adopting such standards by February 1998," NCVHS recommended a four-year initial compliance framework (*i.e.*, February 1998-February 2002) for at least one of the electronic standards, the ASC X12N 837. NCVHS's rationale was that a shorter deadline would interrupt payments for claims and possibly lead to financial failures. Exhibit 24. Thus, NCVHS recognized at an early stage in the rulemaking proceeding that a four-year compliance period would be necessary.

In sum, the diversity of those calling for an extension of the initial compliance deadline, the legitimacy and numerousness of the circumstances (beyond the control of covered entities) necessitating such an extension, HHS's failure to respond adequately to implementation inquiries, and the good faith compliance efforts already undertaken by those subject to the new rule all mandate that OMB work with HHS, Congress and stakeholders to arrive at a practicable time frame for implementing the new standards.

J. It Will Be Impossible to Comply with the ETS Final Rule Until HHS Identifies State Variations.

1. HHS Should Have Taken State-Law Requirements into Account Before Issuing the ETS Final Rule.

When it enacted HIPAA, Congress recognized that federal information requirements would have to be compatible with state requirements. Accordingly, HIPAA provides that HHS must allow states to seek HHS "determinations" that certain state requirements can remain in place, and effectively be incorporated into the federal

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1320d-1(f); see also 63 Fed. Reg. at 25,273.

requirements. In an attempt to meet the statutory directive, the ETS Final Rule allows states to seek "modifications" from HHS in what could take the form of a petition process that would result in modifications being published in the Code of Federal Regulations.

In light of the above, the August 17, 2000 "final rule" on ETS is not really "final" at all: the final requirements will not exist until HHS determines which specific state data elements will be incorporated into the final federal regulation. This places respondents in a dilemma, because they are being asked to attain initial compliance with a paradigm that they know is going to be significantly changed. Respondents are effectively being told to comply with an ***admittedly incomplete*** information collection requirement.

To illustrate this problem, one could consider the case of a health plan operating in California, Nevada, Oregon and Washington. That plan cannot implement the requirements until such time as the plan knows what "modifications" the state governments of California, Nevada, Oregon and Washington are going to obtain from HHS. It would be unduly burdensome to require the plan to go through all of the steps of overhauling all of its systems at the present time, when it is clear that a new layer of state modifications will ultimately be imposed.

HHS should have obtained input from the states as to what state requirements needed to be incorporated into the HIPAA regulation when it was planning and developing the initial regulations, *i.e.*, ***before*** issuance of a final rule. This problem can be remedied by directing HHS to stay the compliance deadline until it has worked with state officials and determined what modifications will be made to the present proposal.

2. The State Governors and State Medicaid Officials Have Stated That Additional Time to Implement the ETS Final Rule Is Imperative.

Both the National Governors Association and state Medicaid officials from a number of states, including notably California, have issued statements publicly calling upon HHS to provide a complete regulatory regime with one deadline for all of the regulations. According to the National Governors Association:

> Since enactment of HIPAA in 1996, it has become clear that the length and structure of its implementation period is unrealistic and untenable....Unfortunately, it will be impossible for states to comply effectively with any part of HIPAA until all relevant regulations have been finalized and their implications can be assessed as a whole.

See Exhibit 23. Similarly, the Assistant Deputy Director for Medical Services of the California Health Services Department testified before NCVHS that the ETS Final Rule presents problems for state Medicaid programs in terms of both initial deadlines and substantive compliance:

> The proposed code set standards do not adequately support the current business needs of the Medicaid program. Prohibiting Medicaid agencies from using local codes will preclude our ability to respond to providers and consumers as well as hamper our ability to process claims and data efficiently. First, existing services that are being provided and reimbursed would cease to be billable in the absence of appropriate alternative codes. Secondly, states will not be able to adopt new services or program developments if there is no way to acknowledge that service or product in the EDI world. Finally, major changes to the claims processing system will be needed. To implement many of the codes, additional processing steps must be added to accomplish what the local code accomplished in one step. Besides being costly

> in terms of both implementation and operation, these changes could affect the performance of the claims processing system and cause delays in final adjudication of claims.

Exhibit 25.[9]

It is clear that the state governments, as well as "covered entities" in the private sector, have made good faith efforts to comply with the ETS Final Rule in its present form. It is equally clear that both the state governments and the private sector have encountered serious impediments to attaining compliance due to HHS's failure to provide a complete set of regulations as required by Congress. HHS's inflexibility, while it may serve the purpose of administrative convenience, is detrimental to the constituency HHS is supposed to serve in light of the financial waste that is being imposed on the health care industry nationwide, and in light of the threat to the smooth functioning of the Medicaid program in the 50 states. Accordingly, it is imperative that OMB rise to the occasion and exercise its own statutory oversight obligations by working with HHS, state governments and private sector stakeholders to develop a reasonable solution that will allow "covered entities" to attain compliance with a complete set of regulations at the earliest reasonable time.

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[9] As regards local codes, NCVHS acknowledged in a letter to then-HHS Secretary Shalala that "some of the local codes may need to be considered for inclusion in other code sets," yet the ETS Final Rule fails to resolve this key issue. See Exhibit 26.

K. HHS Has Violated Requirements of OMB Circular A-119 Issued Pursuant to the Technology Transfer Act.

The Technology Transfer Act was enacted to ensure that agencies such as HHS give adequate consideration to national and international standards when adopting regulations. OMB Circular A-119 establishes the policies and procedures for federal agencies to follow in implementing the Technology Transfer Act. HHS has failed to comply with key provisions of OMB Circular A-119, including:

(i) § 6(f), which requires HHS to comply with the "Principles of Regulation" and other analytical requirements set forth in Executive Order 12866 (entitled "Regulatory Planning and Review");

(ii) § 6(h), which requires HHS to consider international standards without preference for domestic standards; and,

(iii) §§ 6(f) and 11(b)(1), which require that HHS list, and provide full cost-benefit analyses for, each available alternative standard.

1. Cost-Benefit Analyses for Alternative Standards.

OMB Circular A-119 states that "[i]f your agency is proposing to incorporate a standard into a proposed or final rulemaking, your agency *must comply* with the 'Principles of Regulation'...and with the other analytical requirements of Executive Order 12866." Circular A-119, § 6(f) (emphasis added).

HHS adopted a set of ten principles for guiding the selection of standards to be used in the ETS regulation. See 63 Fed. Reg. at 25,274 (ETS NPRM); 65 Fed. Reg. at

50,351-50,352 (ETS Final Rule). According to HHS, the ten principles were based on: (i) HIPAA; (ii) the regulatory philosophy set forth in Executive Order 12866; and (iii) the PRA. However, the HHS principles do not encompass all of the analytical requirements required by the Executive Order. HHS' statement in the NPRM that its principles were, in part, based on, "principles *that support* the regulatory philosophy set forth in Executive Order 12866..." appears to be a tacit admission that HHS did not carry out *all* of the required analyses. 63 Fed. Reg. at 25,274 (emphasis added).

For example, although one of the principles enumerated in the NPRM is that the standard selected have low additional development and implementation costs relative to benefits, this principle falls far short of the significantly more detailed cost and benefit analysis requirements (including the requirement to analyze the costs and benefits *of alternative options*) that are required under §§ 6(B)(ii) and 6(C)(i)-(iii) of the Executive Order. Accordingly, in order to attain compliance with § 6(f) of Circular A-119, HHS must conduct the various analyses specified in Executive Order 12866, including an analysis of the costs and benefits *of each alternative standard*.

2. Consideration of International Standards.

OMB Circular A-119 states that "in the interests of promoting trade and implementing the provisions of international treaty agreements, your agency should consider international standards in...regulatory applications." Circular A-119, § 6(h). Yet HHS made only passing references to key international standards in the NPRM and Final Rule. In particular, HHS failed to consider the United Nations Standard Messages

("UNSM") developed under the United Nations Rules for Electronic Data Interchange for Administration, Commerce and Transport ("UN/EDIFACT"). Standards developed under UN/EDIFACT are described by Accredited Standards Committee X12 ("ASC X12") as "intended for both national and international EDI applications." Furthermore, ASC X12, an ANSI accredited standards development organization ("SDO"), described the UNSM group of standards as "suitable for implementation." See Exhibit 27.

The UN/EDIFACT standards were developed by the UN Centre for the Facilitation of Procedures and Practices for Administration, Commerce and Transport ("UN/CEFACT"). The United States Head of Delegation to UN/CEFACT has authorized ASC X12 to act as the *de facto* US representative to the UN/EDIFACT Working Group ("EWG"). See Exhibit 27. Thus, an ANSI-accredited SDO has: (i) participated in the development of the UN/EDIFACT standards; and (ii) determined that UNSMs are "suitable for implementation." Accordingly, the UN/EDIFACT UNSMs are consensus standards which need to be considered by HHS since they fall within the HIPAA definition of standards which have been "developed, adopted or modified" by an ANSI-accredited SDO. HIPAA does *not* require *individual standards* to be accredited by ANSI as American National Standards in order to be considered for use in the rulemaking; it suffices if the SDO participating in developing the standard (or adopting the standard) is ANSI-accredited. See 63 Fed. Reg. at 25,273 ("[t]he Secretary may adopt a standard developed, adopted, or modified by a standard setting organization (that is, an organization accredited by the American National Standards Institute..."); see also SSA

§§ 1171(8); 1172(c)(1) (42 U.S.C. §§ 1320d(8); 1320d-1(c)(1)).

In that UN/EDIFACT standards involve both treaty agreements and trade issues, it is essential that OMB and HHS: (i) consult with the Department of State, the United States Trade Representative and NIST to determine relevant treaty obligations regarding UN/EDIFACT standards as well as U.S. trade interests with regard to such standards; and (ii) evaluate the relevant UN/EDIFACT standards in light of both the analysis of treaty obligations and trade interests as well as all other analytic criteria discussed in the NPRM and set out in Executive Order 12866.

3. Identification of Available Alternatives.

OMB Circular A-119 states that when an agency uses a consensus standard, it is required to provide a statement that identifies "any alternative voluntary consensus standards which have been identified." Circular A-119, § 11(b)(1). Although the preamble to the ETS Final Rule does identify the consensus standards used, it does not provide the required list of all *alternative* consensus standards identified. The preamble does, in its response to comments, discuss some but not all alternative standards identified. See, *e.g.*, 65 Fed. Reg. at 50,332.

Similarly, the ETS NPRM references the Inventory of Health Care Information Standards relevant to HIPAA developed by ANSI's Health Care Informatics Standards Board. However, discussion of the Inventory in the NPRM is not a substitute for the required list of all identified alternatives in the Final Rule. See, *e.g.*, 63 Fed. Reg. at 25,281. In order to achieve full compliance with its legal obligations, HHS must, *inter*

alia, publish a complete list of all identified alternative consensus standards.

L. Conclusions and Relief Requested.

1. Conclusions.

This Petition has demonstrated that:

(a) OMB has an obligation to oversee agency compliance with the PRA;

(b) HHS has failed to comply with a number of mandatory, ministerial, nondiscretionary duties under the PRA which must be fulfilled before OMB can have jurisdiction or authority to consider the merits of any clearance package requesting control numbers for information collections in the ETS Final Rule;

(c) HHS has failed to provide the regulated community with a complete set of Administrative Simplification regulations;

(d) "Staggered" or "piecemeal" compliance with incomplete elements of Administrative Simplification violates HIPAA and threatens to double the costs of compliance and lead to significant disruptions of health care transactions;

(e) OMB has both the authority and the obligation to correct HHS's procedural violations before considering the merits of the information collection requests contained in the ETS Final Rule; and,

(f) OMB has the authority to work with HHS, state officials, and private-sector

stakeholders to work out a compliance timetable that will not unduly disrupt health care transactions or cause unjustified financial hardship for covered entities.

2. Considerations OMB Must Take into Account in Determining the Appropriate Relief.

There are four considerations that OMB must take into account in considering how OMB should exercise its broad authority to grant relief under the PRA:

(1) HHS Failed to Apply the HIPAA Methodology for Developing Standards.

HHS's did not follow Congress' instructions for selecting and modifying the transactions standards. Under HIPAA, HHS was required to proceed in two steps: *First*, HHS was supposed to identify available consensus standards. *Second*, to the extent that the identified standards were inadequate, HHS was required to undertake negotiated rulemaking to develop appropriate standards. See SSA § 1172(c)(2)(A) (42 U.S.C. § 1320d-1(c)(2)(A)); see also discussion at "D.2" (at page 15) above.

The existing consensus standards identified by HHS (and now constituting the ETS Final Rule) are clearly inadequate for the smooth day-to-day functioning of health care transactions. Testimony before WEDI amply establishes that the ETS Final Rule would eliminate, without adequate (or any) replacement, existing local codes, as well as codes for state program use, and other codes. In addition, this Petition has shown that the standards adopted by HHS prohibit the use of web-based electronic technologies and will force batch-based electronic technology users to revert to manual, paper transactions.

Given the inadequacy of the consensus standards initially identified by HHS, HHS should have undertaken a negotiated rulemaking pursuant to SSA § 1172(c)(2)(A). This is especially the case as subsection (c)(2)(A) is triggered when a negotiated rulemaking standard would "substantially reduce administrative costs to health care providers and health plans compared to the alternatives." Id. § 1172(c)(2)(A)(i).[10]

Accordingly, OMB should direct HHS to conduct a negotiated rulemaking to modify the present ETS regulation to address all of the substantive problems with the information collections identified by respondents.

(2) Information Collection Requirements in the ETS Final Rule Must Be Conformed to Information Collection Requirements in the DOL Health Claims Procedure Rule Under ERISA. As is discussed at "G.6" (pages 51-52) above, covered entities under the ETS Final Rule will be required to comply with the information collection requirements in the DOL Health Claims Procedure Rule. This latter set of requirements must be incorporated into the ETS regulation to ensure that no duplicative or conflicting information collection requirements will be imposed on respondents.

[10] Although § 1172(c)(2)(A) is couched in discretionary terms ("[t]he Secretary *may* adopt a standard that is different..."), given the gross shortcomings of the standards incorporated into the ETS Final Rule and their deleterious impact on the health care industry, HHS's failure to modify the initial consensus standards pursuant to negotiated rulemaking is clearly "arbitrary and capricious" and an "abuse of discretion."

(3) Staggered Promulgation of Administrative Simplification Regulations Is Not Consonant with HIPAA. The initial compliance deadline in HIPAA is not supposed to begin to run until HHS promulgates a complete set of regulatory requirements; staggered promulgation was not Congress' intent. See discussion at "I.1" (pages 54-58) above.

(4) The ETS Compliance Deadline Must Accord with HIPAA § 1172(b). The HIPAA provision on compliance deadlines must be read in the light of HIPAA § 1172(b) (42 U.S.C. § 1320d-1(b)), which requires that "[a]ny standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care." This Petition has amply demonstrated that rigid adherence to the present ETS deadline would *increase* the "administrative costs of providing and paying for health care," *inter alia*, by requiring covered entities to redo the same software overhauls many times over and by forcing companies that now conduct electronic transactions to revert to manual, paper transactions (due to the elimination without replacement of whole sets of currently used codes, and, more generally, due to the inability of companies to meet the deadline). *Accordingly, SSA § 1172(b) must take precedence over §§ 1174 and 1175(b)(1).*

3. Specific Relief Requested.

For all of the reasons set forth in this Petition, Petitioner The Center for Regulatory

Effectiveness respectfully requests that the Office of Management and Budget take the following actions to remedy the violations set forth above:

(1) With respect to HHS's violations of the *PRA* and *HIPAA*:

(a) Require HHS to submit a complete clearance package for the information collections in the ETS Final Rule, including a complete Supporting Statement, containing all of the required certifications, justifications, and supporting data, as required by PRA sections 3506 and 3507 (as set forth at "D.1" (pages 9-13) and "E" (pages 16-17) above);

(b) Refrain from deciding whether to approve, modify or disapprove the information collections until the clearance package demonstrates that HHS has met all of the substantive standards of the PRA described in this Petition;

(c) Refrain from reviewing the ETS clearance package until HHS has promulgated the remaining Administrative Simplification final rules (except for the unique personal identifier and privacy rules), so that OMB can assess the impact that other Administrative Simplification components will have on whether the ETS requirements will ultimately comply with the PRA;

(d) Require HHS to provide complete and accurate burden estimates in the clearance package; and

(e) Direct HHS to extend the deadline for compliance with the ETS Final Rule, as well as for the other Administrative Simplification final rules (except for the unique personal identifier and privacy regulations), until two years from 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) have been issued as final rules;

(ii) the date on which OMB has granted control numbers for all of 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 has published in the Federal Register a notice of its determinations as to which modifications will be made to the ETS Final Rule to accommodate state-law requirements (as discussed at "J.1" (pages 65-66) above);

(iv) the date on which HHS has modified the ETS regulation to incorporate information collection requirements in the DOL Claims Procedure Final Rule, promulgated pursuant to ERISA; and,

(v) the date on which HHS has completed a negotiated rulemaking proceeding pursuant to SSA § 1172(c)(2)(A) to modify

the ETS regulation to correct practical implementation problems identified by covered entities and other stakeholders.

and,

(2) With respect to *OMB Circular A-119*:

(a) Require HHS to publish in the Federal Register a list of alternative consensus standards that could have been adopted in lieu of those incorporated into the ETS Final Rule; and,

(b) Require HHS to establish that it carefully considered all of the alternative consensus standards and to provide a rationale for its rejection of those alternatives that were not adopted.

Respectfully submitted this 17th day of April, 2001 by,

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Jim J. Tozzi,
Member of the Board,
The Center for Regulatory Effectiveness