

also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. We estimate that implementation of all the standards will require the expenditure of more than \$110 million by the private sector. Therefore, the rule establishes a Federal private sector mandate and is a significant regulatory action within the meaning of section 202 of UMRA (2 U.S.C. 1532). We have included the statements to address the anticipated effects of these rules under section 202.

These standards also apply to State and local governments in their roles as health plans or health care providers. Because these entities, in their roles as health plans or providers, must implement the requirements in these rules, the rules impose unfunded mandates on them. Further discussion of this issue can be found in the previously published impact analysis for all standards (65 FR 50360 through 50361).

The anticipated benefits and costs of the security standards, and other issues raised in section 202 of the UMRA, are addressed in the analysis below, and in the combined impact analysis. In addition, as required under section 205 of the UMRA (2 U.S.C. 1535), having considered a reasonable number of alternatives as outlined in the preamble to this rule, HHS has concluded that this final rule is the most cost-effective alternative for implementation of HHS's statutory objective of administrative simplification.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The proposed rule was published before the enactment of Executive Order 13132 of August 4, 1999, Federalism (published in the **Federal Register** on August 10, 1999 (64 FR 43255)), which required meaningful and timely input by State and local officials in the development of rules that have Federalism implications). However, we received and considered comments on the proposed rule from State agencies and from entities who conduct transactions with State agencies. Several of the comments referred to the costs that will result from implementation of the HIPAA standards. As we stated in the impact analysis, we are unable to estimate the cost of implementing

security features as implementation needs will vary dependent upon a risk assessment and upon what is already in place. However, the previously referenced impact analysis in the August 17, 2000 final rule (65 FR 50312) showed that Administrative Simplification costs will be offset by future savings.

In complying with the requirements of part C of title XI, the Secretary established interdepartmental implementation teams who consulted with appropriate State and Federal agencies and private organizations. These external groups consisted of the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security, the Workgroup for Electronic Data Interchange (WEDI), the National Uniform Claim Committee (NUCC), the National Uniform Billing Committee (NUBC), and the American Dental Association (ADA). The teams also received comments on the proposed regulation from a variety of organizations, including State Medicaid agencies and other Federal agencies.

B. Anticipated Effects

The analysis in the August 2000, Transaction Rule included the expected costs and benefits of the administrative simplification regulations related to electronic systems for 10 years. Although only the electronic transaction standards were promulgated in the transaction rule, HHS expected affected parties to make systems compliance investments collectively because the regulations are so integrated. Moreover, the data available to us were also based on the collective requirements of this regulation. It is not feasible to identify the incremental technological and computer costs for each regulation. Although HHS is issuing rules under HIPAA sequentially, affected entities and vendors are bundling services, that is, they have been anticipating the various needs and are designing relatively comprehensive systems as they develop hardware and software. For example, a vendor developing a system for electronic billing would also anticipate and include security features, even in the absence of any regulation. Moreover, a draft of the security rule was first published in 1998. Even though the final is different (and less burdensome), vendors had a reasonable indication of the direction policy would go. Thus, in preparing the electronic transaction rule, we recognized and included costs that might theoretically be associated with security or other HIPAA rules. Hence, some of the "costs" of security have already been accounted for in the Standards for Electronic

Transactions cost estimate (45 CFR parts 160 and 162), which was published in the **Federal Register** on August 17, 2000 (65 FR 50312).

This analysis showed that the combined impact of the Administrative Simplification standards is expected to save the industry \$29.9 billion over 10 years. We are including in each subsequent rule an impact analysis that is specific to the standard or standards in that rule, but the impact analysis will assess only the incremental cost of implementing a given standard over another. Thus, the following discussion contains the impact analysis for the marginal costs of the security standards in this final rule.

The following describes the specific impacts that relate to the security standards. The security of electronic protected health information is, and has been for some time, a basic business requirement that health care entities ignore at their peril. Instances of "hacking" and other security violations may be widely publicized, and can seriously damage an institution's community standing. Appropriate security protections are crucial for encouraging the growth and use of electronic data interchange. The synergistic effect of the employment of the security standards will enhance all aspects of HIPAA's Administrative Simplification requirements. In addition, it is important to recognize that security is not a one-time project, but rather an on-going, dynamic process.

C. Changes From the 1998 Impact Analysis

The overall impact analysis for Administrative Simplification was first published on May 7, 1998 (63 FR 25320) in the proposed rule for the National Provider Identifier standard (45 CFR part 142), the first of the proposed Administrative Simplification rules. That impact analysis was based on the industry situation at that time, used statistics which were current at that time, and assumed that all of the HIPAA standards would be implemented at roughly the same time, which would permit software changes to be made less expensively. While the original impact analysis represented our best information at that time, we realize that the state of the industry, and of security technology, has changed since 1998. We discuss several of those changes and how they affect the impact of this regulation.

1. Changes in Technology

The state of technology for health care security has changed since 1998. New