The Rule Making Process for Administrative Simplification: What Is Taking So Long?

The goal is simplification, but the process is far from simple. It is a deliberate process designed to achieve consensus within HHS and across other Federal departments. Once the proposed rule is approved from within the government, the public is given the opportunity to comment on the proposal, and those comments are analyzed and considered in the development of the final rules. The process is important because the final rules will have the force of Federal law.

During 1998, HHS Implementation Teams drafted Notices of Proposed Rule Making (NPRMs) for the:

1. Administrative and Financial Transaction Standards and Code Sets;
2. National Provider Identifier for health care providers;
3. Identifier for Health Plans;
4. Identifier for Employers;
5. Security Standards to protect health care information.

Before an NPRM can be published in the *Federal Register*, it must be reviewed and approved within the Federal government. Questions and concerns from within the government must be answered and resolved before the NPRMs can be published for public comment. (For example, the NPRM proposing a standard identifier for health plans is still being considered within HHS.)

This within-government review is a 3-stage process. The NPRMs must be approved by:

1. The HHS Data Council's Committee on Health Data Standards. This Committee is responsible for overseeing the entire AS implementation process for the Secretary of HHS. This Committee, composed of members from many Federal agencies, must approve the content of the NPRMs before they go to the next review step.
2. Advisors to the Secretary within HHS. HHS consists of several divisions that may be affected by the proposed standards or that are responsible for particular issues, such as the impact of the standards on the Federal budget. Agency heads also act as formal advisors to the Secretary of HHS in the rule making process. Agreement among the Secretary's advisors must be reached before the NPRMs go to the next review step.
3. The Office of Management and Budget. OMB reviews the NPRMs from a government-wide perspective and circulates the NPRMs for review by Federal departments other than HHS. These departments, which will also be affected by the proposed standards, include the Departments of Defense and Veterans Affairs. In addition, OMB reviews the NPRMs for their potential impacts -- e.g., on the Federal budget, on intergovernmental relations, and on small business -- and for their compliance with the principles of regulation set out in Executive Order 12866.

What happens then?

Publication of a proposed regulation in the *Federal Register* begins the next phase of formal public participation in rule making.

1. Publication of Proposed Rule. A Notice of Proposed Rule Making (NPRM) is published in the *Federal Register* and on the Administrative Simplification Home Page.
2. Comment Period. Each NPRM is followed by a period set aside for public comment. Comments will be accepted through this website and by postal mail for 60 days following publication. The purpose of the comment period is to provide an opportunity for the public and interested and affected parties to influence the outcome by raising issues and questions that can be addressed before the regulation is finalized.
3. Public Inspection of Comments. Comments received are made available for public inspection. Traditionally, comments submitted by mail are available for public viewing in a room at HHS Headquarters in Washington, DC. Comments will be available for public viewing at this website after the comment period has ended.
4. Analysis of Comments. Comments are analyzed and summarized, and responses are prepared by the Implementation Teams responsible for the content.
5. Publication of Final Rule. The Final Rule is published in the Federal Register and on the Administrative Simplification Home Page. The Final Rule includes a summary of the comments and responses to the comments, including any changes that were made to the proposed regulation as a result of the comments.

How do these delays affect the implementation schedule?

Delays in adoption of the standards will not shorten the period for implementation. The standards will become effective 24 months after adoption for most organizations; 36 months after adoption for small health plans.

To keep informed:

NPRMs, the final rules, and information about the status of the process are posted on the Administrative Simplification homepage as they become available. To be notified of developments by e-mail, subscribe to the HIPAA-REGS listserv.