

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The information collection requirements and associated burdens in §§ 162.1002, 162.1102, 162.1202, 162.1302, 162.1402, 162.1502, 162.1602, 162.1702, and 162.1802 are subject to the PRA. The burden of these standards is addressed under OMB approval number 0938-0866.

We are submitting a copy of these revisions to the regulation sections to OMB for its review of the information collection requirements. We will also submit the all of the revisions for review and reapproval under 0938-0866. These revisions are not effective until OMB has approved them. If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Office of Strategic Operations and Regulatory Affairs, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, MD 21244, Attn: Julie Brown, CMS-0003-F/0005-F; and
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer, CMS-0003-F/0005-F.

VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258 which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules. The analysis in the Transactions Rule assumed that the adopted standards will be able to be implemented successfully by the industry. The changes adopted in this final rule are a result of industry analyses that showed certain minor modifications to the adopted standards would be necessary to permit full industry compliance with the standards.

These modifications make limited adjustments and corrections to the overall standards and would facilitate the congressional intent of implementation of national electronic standards. Thus, the impact analysis previously published, 65 FR 50350 through 50365, would reflect industry experience in implementing the changes adopted in this rule.

In relation to the prior impact analysis, this final rule imposes no additional burdens and creates no additional costs. All of the modifications adopted in this final rule and proposed in CMS-0003-P (67 FR 38044) and CMS-0005-P (67 FR 38050) are required to facilitate successful implementation of the standards. Their implementation will, in fact, avoid costs that were not anticipated in the impact analysis of the Transactions Rule.

The 115 approved modifications to the standards included 48 maintenance changes (minor error corrections or clarifications), and 67 modifications to the standards. Details of these 67 modifications include—

- Changing the usage of data elements from “required” to “situational” (about 20 percent of changes);
- Removal of certain data elements (about 20 percent of changes);
- Allowing certain data elements to be reported via external code sets rather than data elements in the transaction (about 20 percent of changes); and
- Adding additional functionality to some transactions (about 40 percent of changes).

In particular, institutional and professional providers that have submitted ASCA compliance plans will not be required to retool systems and restructure current operations to accommodate the adopted NDC for reporting drugs and biologics on non-retail pharmacy standard transactions. Estimates reported to the NCVHS indicated that the cost of transitioning to NDCs on institutional claims could easily exceed an institution's cost for adopting all other transaction standards combined. While costs could vary depending on the size of the facility, hospitals estimate the minimum cost at \$200,000 per facility to switch from HCPCS codes to NDCs. The industry also estimates that typical physician practices may spend \$800 to as much as \$100,000 for practice management systems.² Although included for purposes of illustration, documentation to substantiate these estimates of the true costs for institutional providers of adopting the NDC as the code set

standard for transactions involving drugs and biologics was not provided. Consequently, we do not consider these to be reliable estimates of the true costs for institutional providers of adopting the NDC as the code set standard for transactions involving drugs and biologics. This final rule retracts the adoption of the NDC and does not adopt any standard medical code set for reporting drugs and biologics on nonretail pharmacy transactions. Institutional and professional providers can continue their current practices for reporting drugs and biologics on institutional and professional standard transactions.

The RFA requires agencies to determine whether a rule will have a significant economic impact on a substantial number of small entities. On November 17, 2000, the Small Business Administration (SBA) published a final rule (65 FR 69432) changing the small business size standards for the health care industry. This SBA rule became effective December 18, 2000. The size standards that the SBA now uses are those defined by the North American Industry Classification System. Before that, the SBA used size standards as defined by the Standard Industrial Codes. The size standard is no longer a uniform \$5 million in annual revenues for all components in the health care sector. Rather, the size standard now ranges from \$6 million to \$29 million. The RFA for this final rule is linked to the aggregate RFA for all the Administrative Simplification standards that appeared in the Transactions Rule, which predated the SBA change. It is appropriate, for purposes of this final rule, to continue to use the \$5 million small business size standard that was in effect at the time of publication of the Transactions Rule. Maintaining this consistent definition for small business size minimizes confusion in the industry and does not adversely impact entities that were not considered small businesses according to the Transaction Rule definition. Nonprofit organizations are considered small entities. Small government jurisdictions with a population of less than 50,000 are considered small entities. Individuals and States are not considered small entities. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less in any one year. For purposes of the RFA, all retail pharmacies are considered to be small entities. We have determined that this final rule will not have a significant economic impact on a substantial number of small entities.

² Testimony from health care providers to the NCVHS on February 1, 2001.