

This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden on covered entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this final rule will not have an additional significant impact on a substantial number of small rural hospitals. This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden, particularly on hospitals and other institutional providers, who will no longer be required to adopt the NDC for transactions involving drugs and biologics.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule will have no mandated consequential effect on State, local, or tribal governments, or on the private sector when using the Regulatory Impact Analysis for the Transactions Rule (65 FR 50350 through 50365) as a baseline.

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. We have determined that this final rule will not significantly affect the rights, roles, and responsibilities of States. This final rule makes only minor modifications to the regulatory process already put in place by the Transactions Rule (65 FR 50350 through 50365), which will generally reduce compliance burden on covered entities.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget (OMB).

List of Subjects in 45 CFR Part 162

Administrative practice and procedure, Electronic transactions, Health facilities, Health insurance, Hospitals, Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble of this final rule, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, part 162 as follows:

PART 16—ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 162 continues to read as follows:

Authority: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–8), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

2. Section 162.900 is revised to read as follows:

§ 162.900 Compliance dates for transaction standards and code sets.

(a) *Small health plans.* All small health plans must comply with applicable requirements of subparts I through R of this part no later than October 16, 2003.

(b) *Covered entities that timely submitted a compliance plan.* Any covered entity, other than a small health plan, that timely submitted a compliance plan with the Secretary under the provisions of section 2 of Pub. L. 107–105, 115 Stat. 1003 (ASCA) must comply with the applicable requirements of subparts I through R of this part no later than October 16, 2003.

(c) *Covered entities that did not timely submit a compliance plan.*

Any covered entity, other than a small health plan, that did not timely submit a compliance plan under the provisions of section 2 of Pub. L. 107–105, 115 Stat. 1003 (ASCA) must comply with the applicable requirements of subparts I through R of this part—

(1) Beginning on October 16, 2002, and ending on October 15, 2003—

(i) For the corresponding time period; or

(ii) For the time period beginning on October 16, 2003.

(2) Beginning on and after October 16, 2003, for the corresponding time period.

3. Section 162.920 is revised to read as follows:

§ 162.920 Availability of implementation specifications.

A person or an organization may directly request copies of the

implementation standards described in subparts I through R of this part from the publishers listed in this section. The Director of the Office of the Federal Register approves the implementation specifications described in this section for incorporation by reference in subparts I through R of this part in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The implementation specifications described in this paragraph are also available for inspection by the public at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC; and the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244. Copy requests must be accompanied by the name of the standard, number, if applicable, and version number. Implementation specifications are available for the following transactions:

(a) *ASC X12N specifications.* The implementation specifications for ASC X12N standards may be obtained from the Washington Publishing Company, PMB 161, 5284 Randolph Road, Rockville, MD, 20852–2116; Telephone (301) 949–9740; and FAX: (301) 949–9742. They are also available through the Washington Publishing Company on the Internet at <http://www.wpc-ed.com/>. The transaction implementation specifications are as follows:

(1) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1, as referenced in § 162.1102 and § 162.1802.

(2) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1, as referenced in § 162.1102 and § 162.1802.

(3) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as referenced in § 162.1102 and § 162.1802.

(4) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company,