

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
*	*	<p>3. Changes in Operating Conditions: GM must notify the EPA in writing if the manufacturing process, the chemicals used in the manufacturing process, the treatment process, or the chemicals used in the treatment process at JTAP significantly change. GM must handle wastes generated at JTAP after the process change as hazardous until it has demonstrated that the waste continues to meet the delisting levels and that no new hazardous constituents listed in appendix VIII of part 261 have been introduced and GM has received written approval from EPA.</p> <p>4. Data Submittals: GM must submit the data obtained through verification testing at JTAP or as required by other conditions of this rule to EPA Region 5, Waste Management Branch (DW-8J), 77 W. Jackson Blvd., Chicago, IL 60604. The quarterly verification data and certification of proper disposal must be submitted annually upon the anniversary of the effective date of this exclusion. GM must compile, summarize, and maintain at JTAP records of operating conditions and analytical data for a minimum of five years. GM must make these records available for inspection. All data must be accompanied by a signed copy of the certification statement in 40 CFR 260.22(i)(12).</p> <p>5. Reopener Language—(a) If, anytime after disposal of the delisted waste, GM possesses or is otherwise made aware of any data (including but not limited to leachate data or groundwater monitoring data) relevant to the delisted waste at JTAP indicating that any constituent is at a level in the leachate higher than the specified delisting level, or is in the groundwater at a concentration higher than the maximum allowable groundwater concentration in paragraph (e), then GM must report such data in writing to the Regional Administrator within 10 days of first possessing or being made aware of that data.</p> <p>(b) Based on the information described in paragraph (a) and any other information received from any source, the Regional Administrator will make a preliminary determination as to whether the reported information requires Agency action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment.</p> <p>(c) If the Regional Administrator determines that the reported information does require Agency action, the Regional Administrator will notify GM in writing of the actions the Regional Administrator believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing GM with an opportunity to present information as to why the proposed Agency action is not necessary or to suggest an alternative action. GM shall have 30 days from the date of the Regional Administrator's notice to present the information.</p> <p>(d) If after 30 days GM presents no further information, the Regional Administrator will issue a final written determination describing the Agency actions that are necessary to protect human health or the environment. Any required action described in the Regional Administrator's determination shall become effective immediately, unless the Regional Administrator provides otherwise.</p> <p>(e) Maximum Allowable Groundwater Concentrations (mg/L):; antimony—0.006; arsenic—0.005; cadmium—0.005; chromium—0.1; lead—0.015; nickel—0.750; selenium—0.050; tin—23; zinc—11; p-Cresol—0.190; and formaldehyde—0.950.</p>
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**42 CFR Part 403**

[CMS-1428-F3]

RIN-0938-AM80

**Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2005 Rates: Fire Safety Requirements for Religious Non-Medical Health Care Institutions: Correction To Reinstate Requirements for Written Fire Control Plans and Maintenance of Documentation**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule; correcting amendment.

**SUMMARY:** In the August 11, 2004 issue of the **Federal Register** (69 FR 48916), we published the Hospital Inpatient Prospective Payment System final rule. This correcting amendment reinstates paragraphs (a)(2) and (a)(3) in 42 CFR 403.744 (Condition of participation: Life safety from fire), which were accidentally deleted by that rule. Those paragraphs relate to requirements for fire control plans and maintenance of documentation in religious non-medical health care institutions. The effective date was October 1, 2004.

**EFFECTIVE DATE:** This correcting amendment is effective November 25, 2005.

**FOR FURTHER INFORMATION CONTACT:** Janice Graham, (410) 786-8020; Danielle

Shearer, (410) 786-6617; or Jeannie Miller, (410) 786-3164.

#### SUPPLEMENTARY INFORMATION:

##### Need for Corrections

On November 30, 1999, we published an interim final rule with comment period titled "Religious Nonmedical Health Care Institutions and Advance Directives" (64 FR 67028) to adopt the 1997 edition of the Life Safety Code (LSC) for religious non-medical health care institutions (RNHCIs). We adopted the 1997 edition of the LSC because we believed that it provided the highest available level of protection for patients, staff, and the public at that time. The regulation also permitted a RNHCI to meet a fire and safety code imposed by State law if we found that the State-imposed code adequately protected patients. This interim final rule also added paragraphs (a)(2) and (a)(3) to the Life Safety from Fire Condition of Participation at 42 CFR 403.744. These paragraphs were added in order to ensure that RNHCIs had adequate fire plans in case of a fire emergency and to ensure that RNHCIs documented the fire safety inspections and approvals related to their State or local fire control agencies.

On January 10, 2003, we issued a final rule titled "Fire Safety Requirements for Certain Health Care Facilities" (68 FR 1374) amending the fire safety standards for RNHCIs that adopted, with certain exceptions, the 2000 edition of the LSC published by the National Fire Protection Association (NFPA). One of the exceptions to the 2000 edition of the LSC concerned the use of roller latches in health care facilities, including RNHCIs. In the 2003 final rule, we prohibited health care facilities, including RNHCIs, from having roller latches. The final rule provided a 3-year phase-in period to allow facilities time to replace their roller latches.

On August 11, 2004, we published the Hospital Inpatient Prospective Payment System (IPPS) final rule (69 FR 48916). In this final rule, we clarified the phase-in date of the roller latch provision, and accidentally deleted paragraphs (a)(2) and (a)(3), which stated:

- (a)(2) The religious non-medical health care institution (RNHCI) must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.
- (a)(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

This correcting amendment re-incorporates paragraphs (a)(2) and (3), which were inadvertently deleted from the regulations by the 2004 IPPS rule.

##### Collection of Information Requirements

This document does contain information collection requirements as summarized below. However, we believe the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 403.744(a)(2) states that the RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff and the public; evacuation; and cooperation with fire fighting authorities.

Section 403.744(a)(3) states that the RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

##### Waiver of Proposed Rulemaking and Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. We also ordinarily provide a 30-day delay in the effective date of the provisions of a rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. We can waive both the notice of proposed rulemaking and the 30-day delay in effective date, however, if the Secretary finds good cause that a notice-and-comment procedure and a 30-day delay in the effective date are impracticable, or contrary to the public interest and incorporates a statement of the finding and the reasons in the rule issued.

We believe that proceeding with notice and comment procedures and delaying the effective date are impracticable, and contrary to the public interest.

The notice and comment procedures and delay in the effective date are impracticable because delaying implementation of these provisions would hinder our ability to provide continuous safety standards for RNHCI patients. These requirements were established in order to protect the patients, facility staff, and the public, and they continue to be necessary in

order to ensure that RNHCIs provide safe care.

Proceeding with notice and comment rulemaking and delaying the effective date would delay the restoration of these two paragraphs. During this delay, fire safety could be compromised because providers would not be required to maintain their written fire control plans or document their inspection and approval by State or local fire control agencies, two requirements that are key to ensuring patient safety. In addition, our ability to ensure compliance with § 403.738 would be impeded if facilities did not maintain documentation of their compliance with State or local inspections and approval processes, as required by applicable State or local laws, regulations, and codes.

Publishing a proposed rule and delaying the effective date are contrary to the public interest because of the imminent danger to life posed by failing to enforce the requirements of § 403.744(a)(2) and (a)(3). One of the major responsibilities of a RNHCI is to provide an environment for their patients, staff, and the public that includes safety measures as outlined in its fire safety plan. These requirements re-enforce the importance of continually providing and maintaining a safe environment for RNHCI patients.

Therefore, we find good cause to waive the notice of proposed rulemaking and delayed effective date and to issue this correcting amendment.

#### Corrections to Regulations Text

##### List of Subjects in 42 CFR Part 403

Grant programs-health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

- Accordingly, 42 CFR chapter IV is corrected by making the following correcting amendments:

#### PART 403—SPECIAL PROGRAMS AND PROJECTS

- 1. The authority citations for part 403 continues to read as follows:

**Authority:** 42 U.S.C. 1395b-3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

- 2. Section 403.744 is corrected by adding paragraphs (a)(2) and (a)(3) to read as follows:

##### § 403.744 Condition of participation: Life safety from fire.

(a) \* \* \*

(2) The RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing

fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.

(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

\* \* \* \* \*

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 21, 2005.

**Ann C. Agnew,**

*Executive Secretary to the Department.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 424

[CMS–0008–F]

RIN 0938–AM22

#### Medicare Program; Electronic Submission of Medicare Claims

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule adopts as final, and makes amendments to, the interim final rule published on August 15, 2003. That interim final rule implemented the statutory requirement that claims for reimbursement under the Medicare Program be submitted electronically as of October 16, 2003, except where waived. These regulations identify those circumstances for which mandatory submission of electronic claims to the Medicare Program is waived.

**DATES:** Effective date: These regulations are effective on December 27, 2005.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Simmons, (410) 786–6157. Stewart Streimer, (410) 786–9318.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 3 of the Administrative Simplification Compliance Act (ASCA), Pub. L. 107–105, was enacted by the Congress to improve the administration of the Medicare Program by facilitating program efficiencies gained through the electronic submission of Medicare claims. Section 3 of ASCA amends

subsection (a) of section 1862 of the Social Security Act (the Act) (42 U.S.C. 1395y(a)) and adds a new subsection (h) to section 1862 (42 U.S.C. 1395y). The amendment to subsection (a) requires the Medicare Program, subject to subsection (h), to deny payment under Part A or Part B for any expenses for items or services “for which a claim is submitted other than in an electronic form specified by the Secretary.”

Subsection (h) provides that the Secretary shall waive such denial in two types of cases and may also waive such denial “in such unusual cases as the Secretary finds appropriate.”

Section 3 of ASCA operates in the context of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191. Those provisions require the Secretary to adopt, among other standards, standards for financial and administrative transactions for the health care industry, including health claims transactions (see section 1173(a) of the Act). In the August 17, 2000 **Federal Register** (65 FR 50311), the Secretary of Health and Human Services (the Secretary) published a final rule (generally known as the Transactions Rule) that adopted standards for eight electronic transactions. The transactions standards adopted by that final rule, as subsequently modified by final rule published on February 20, 2003 (68 FR 8381), are codified at 45 CFR part 162, subparts A and I through R.

The HIPAA standards apply to health plans, health care clearinghouses, and certain health care providers; collectively, these entities are known as “covered entities.” An additional category of covered entities—prescription drug card sponsors—was added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173. Covered entities are required to comply not only with the standards established by the Transactions Rule, but also with those established via other HIPAA Administrative Simplification rules—such as the Privacy Rule, the Employer Identifier Rule, the Security Rule, and the National Provider Identifier Rule—by the respective applicable compliance dates specified in those rules.

Compliance with the standards for the electronic transactions established by the Transactions Rule was required for all covered entities other than small health plans by October 16, 2002; compliance by small health plans was required by October 16, 2003. However, section 2 of ASCA extended the October 16, 2002 compliance deadline to October 16, 2003 for covered entities

that were not small health plans and that submitted a compliance plan by October 15, 2002. In accordance with 45 CFR 162.900(c), covered entities that were not small health plans and that did not timely submit a compliance plan under ASCA were required to comply by October 16, 2002. Thus, all covered entities, regardless of type, were required to be in compliance no later than October 16, 2003.

Since a significant number of covered entities had expressed strong concern over the health care industry’s state of readiness to conduct fully compliant HIPAA transactions and we wanted to promote compliance while ensuring that cash flow and health care operations would not be unnecessarily disrupted, the Department of Health and Human Services (HHS) issued guidance on the approach CMS would take to enforce the HIPAA electronic transactions and code sets provisions. In accordance with the July 24, 2003 guidance, the Secretary explained that we would focus on voluntary compliance, use a complaint-driven approach, and would not impose penalties on covered entities that deployed temporary contingency plans, if they made reasonable and diligent efforts to become compliant and, in the case of health plans, facilitated the compliance of their trading partners.

By statute, the Medicare Program is a health plan under HIPAA (see section 1171(5)(D) of the Act). It is, therefore, a covered entity. In 45 CFR 160.102(a)(3), we specify that, in accordance with section 1172(a)(3) of the Act, health care providers are covered entities if they transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard (covered transaction). In 45 CFR 162.923(a), we specify that if a covered entity electronically conducts a covered transaction with another covered entity, it must conduct it as a standard transaction.

Approximately 86.1 percent of claims submitted to the Medicare Program are submitted electronically, which means that approximately 139 million claims are submitted on paper per year (fiscal year (FY) 2002). Section 3 of ASCA required Medicare providers to submit Medicare claims electronically by October 16, 2003, unless one of the specified grounds for waiver applies. As the October 16, 2003 deadline approached, we made the decision to implement our own contingency plan after reviewing statistics showing that an unacceptably low number of Medicare providers would likely be capable of submitting compliant claims