

work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated: _____

/s/ _____

Appropriate officer or official

[66 FR 62991, Dec. 4, 2001]

Subpart D—Waivers and Effect of Exclusion

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from a State health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not sub-

ject to administrative or judicial review.

(g) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in § 1001.2.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(2) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made for items or services furnished, ordered or prescribed,

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including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) CMS will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare, Medicaid or any of the other Federal health care programs warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion,

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of the exclusion, and

(iii) Any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion. (For the period October 2, 1998, to October 4, 1999, payment may be made under Medicare or a State health care program for up to 60 days after the effective date of the exclusion for any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of such exclusion and delivered within 60 days of the effect of the exclusion.)

(4) CMS will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 15 days or more after the notice of the provider's exclusion was mailed to the supplier.

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

[57 FR 3330, Jan. 29, 1992, as amended at 60 FR 32917, June 26, 1995; 63 FR 46690, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

Subpart E—Notice and Appeals

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part, or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.