

(c) After evaluating any additional evidence submitted by the excluded person (or at the end of the 30-day period described in paragraph (a) of this section, if no documentary evidence or written request is submitted), the initiating agency sends written notice to the excluded person either confirming the denial, or approving the reinstatement in the manner set forth in § 402.304. If the initiating agency elects to uphold its denial decision, the written notice also indicates that a subsequent request for reinstatement will not be considered until at least 1 year after the date of the written denial notice.

(d) The decision to deny reinstatement is not subject to administrative review.

§ 402.308 Waivers of exclusions.

(a) *Basis.* Section 1128(c)(3)(B) of the Act specifies that in the case of an exclusion from participation in the Medicare program based upon section 1128(a)(1), (a)(3), or (a)(4) of the Act, the individual may request that CMS present, on his or her behalf, a request to the OIG for a waiver of the exclusion.

(b) *Definitions.* For purposes of this section:

Excluded person has the same meaning as a “person” as defined in § 402.3 who meets for the purposes of this subpart, the definition of the term “exclusion” in § 402.3.

Hardship for purposes of this section means something that negatively affects Medicare beneficiaries and results from the imposition of an exclusion because the excluded person is the sole community physician or sole source of essential specialized services in the Medicare community.

Sole community physician has the same meaning as that term is defined § 1001.2 of this title.

Sole source of essential specialized services in the community has the same meaning as that term defined by the § 1001.2 of this title.

(c) *General rule.* If CMS determines that a hardship as defined in paragraph (b)(2) of this section results from exclusion of an affected person from the Medicare program, CMS may consider and may make a request to the Inspec-

tor General for waiver of the Medicare exclusion.

(d) *Submission and content of a waiver of exclusion request.* An excluded person must submit a request for waiver of exclusion in writing to CMS that includes the following:

(1) A copy of the exclusion notice from the OIG.

(2) A statement requesting that CMS present a waiver of exclusion request to the OIG on his or her behalf.

(3) A statement that he or she is the sole community physician or sole source of essential specialized services in the community.

(4) Documentation to support the statement in paragraph (d)(3) of this section.

(e) *Processing of waiver of exclusion requests.* CMS processes a request for a waiver of exclusion as follows:

(1) Notifies the submitter that the waiver of exclusion request has been received.

(2) Reviews and validates all submitted documents.

(3) During its analysis, CMS may require additional, specific information, and authorization to obtain information from private health insurers, peer review organizations (including, but not limited to, Quality Improvement Organizations), and others as necessary to determine validity.

(4) Makes a determination regarding whether or not to submit the waiver of exclusion request to the OIG based on review and validation of the submitted documents.

(5) If CMS elects to submit the waiver of exclusion request to the OIG, CMS copies the excluded person on the request.

(6) If CMS denies the request, then CMS notifies the excluded person of the decision and specifies the reason(s) for the decision.

(f) *Administrative or judicial review.* A determination rendered under paragraph (e)(4) of this section is not subject to administrative or judicial review.

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A [Reserved]