

CMS-6019-P-1

**Revised Civil Money Penalties, Assessments, Exclusions, and
Related Appeals Procedures**

Submitter : Mr. bob namba

Date & Time: 08/24/2005

Organization : Mr. bob namba

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

recent headline indicated that santa cruz county had a higher cost of living than san francisco. certainly santa cruz has higher costs for housing. my wife and i are both seniors and recently brought my 90 yr old mother to live with us. we had to ask several doctors before we found one who would take another medicare covered patient. this included new doctors in the area who were taking patients other than those covered by medicare.

it would help if the county was designated urban rather than rural. please make this change.

CMS-6019-P-2 **Revised Civil Money Penalties, Assessments, Exclusions, and
Related Appeals Procedures**

Submitter : Mr. Irv Cohen

Date & Time: 09/29/2005

Organization : Fulbright

Category : Attorney/Law Firm

Issue Areas/Comments

GENERAL

GENERAL

See attachment--comments relating to the Proposed Rule of August 4, 2005 'Revised Civil Money Penalties, Assessments, Exclusions and Related Appeals Procedures,' 70 Fed. Reg. 44879. Please advise us immediately if the attachment cannot be viewed. Thank you. (202-662-4679)

CMS-6019-P-2-Attach-1.DOC

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September 29, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6019-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Comments on Proposed Rule, Revised Civil Money Penalties, Assessments, Exclusions, and Related Appeals Procedures

Dear Gentlemen:

Pursuant to your notice of August 4, 2005, the following comments are being submitted.

The proposed rule ("Proposed Rule") sets forth the general requirements and procedures for requesting waiver of exclusion from the Medicare program because of the hardship such exclusion would cause Medicare beneficiaries. 70 Fed. Reg. 44879 (August 4, 2005). The Proposed Rule would implement section 949 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").

Section 1128A of the Social Security Act (the "Act") authorized the Secretary of Health and Human Services (the "Secretary") to impose upon health care entities civil money penalties, assessments, and/or exclusion from the Medicare program. The Secretary has delegated that authority to the Office of the Inspector General (the "OIG") or the Centers for Medicare and Medicaid Services ("CMS"). Section 949 of the MMA amends the Act to enable the Secretary to waive an exclusion in the case of a provider or health care entity that is the sole community physician or sole source of essential specialized services in the community after consulting with the OIG.

We have been unable to identify a delegation of section 944 waiver authority from the Secretary to the OIG, although the regulation implements the provision as if such delegation of authority has been made. We would oppose such delegation.

Placing the waiver authority in the same organization that determines that the party should be excluded, creates a conflict of interest. The statute specifically states that the Secretary is supposed to consult with the OIG before determining whether to waive the exclusion. Delegating the Secretary's authority to waive to the OIG would ostensibly put the OIG in a position to consult with itself on whether to overturn its own decision to exclude.

The soundness of such an arrangement is questionable at best and could be seen to circumvent the MMA's requirement that an avenue be created to consider waiver to prevent beneficiary hardship. Congress intended to ensure that the exclusion authority granted to the Secretary would not be exercised to the detriment of Medicare beneficiaries; to negate the Congressionally-mandated consultation with the OIG would be to thwart the intent of Congress to create such a protective mechanism on behalf of the Medicare population.

We strongly recommend that the Secretary delegate to another departmental staff, not part of the OIG, to perform this function.

Second, we urge you to issue clear definitions of three of the terms used in the Proposed Rule to describe the entities eligible for the exclusion waiver: (1) sole community physician or source of services; (2) essential specialized services; and (3) Medicare community. Because each of these terms can be broadly or narrowly construed, eligibility for waiver will be unpredictable and not uniformly enforced. Each of these terms is capable of being specifically defined (similar terms are defined in other Medicare regulations for other purposes).

Accordingly, we urge you to reconsider the Proposed Rule and modify the provisions first to create the protective mechanism that Congress intended to prevent hardship on Medicare beneficiaries, and second to make clear the description and definition of entities eligible for waiver so that the waiver could be more easily and predictably applied.

Thank you for this opportunity to comment.

Very truly yours,

Irwin Cohen

IC/ask

cc: Anne Sullivan Kimbel (Firm)