

(b) In making the reinstatement determination, the OIG will consider—

* * * * *

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid or satisfactory arrangements have been made to fulfill these obligations; and

(4) Whether HCFA has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations.

(c) If the OIG determines that the criteria in paragraphs (a)(1) (ii) and (iii) of this section have been met, an entity excluded in accordance with § 1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity's exclusion—

* * * * *

(d) If the OIG determines that the criteria in paragraphs (a)(1) (ii) and (iii) of this section have been met, an individual excluded in accordance with § 1001.1051 will be reinstated upon a determination with paragraph (a) of this section of § 1001.3005.

(e) Reinstatement will not be effective until the OIG grants the request and provides notice under § 1001.3003(a) of this part. Reinstatement will be effective as provided in the notice.

(f) A determination with respect to reinstatement is not appealable or reviewable except as provided in § 1001.3004.

(g) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

C. Part 1002 would be amended as follows:

PART 1002—[AMENDED]

1. The authority citation for part 1002 would continue to read as follows:

Authority: 42 U.S.C. 1302, 1320a-3, 1320a-5, 1320a-7, 1396(a)(4)(A), 1396(p)(1), 1396a(30), 1396a(39) 1396b(a)(6), 1396b(b)(3), 1396b(i)(2) and 1396b(q).

2. Section 1002.3 would be amended by revising paragraph (b)(2) and by adding a new paragraph (b)(3) to read as follows:

§ 1002.3 Disclosure by providers; information on persons convicted of crimes.

* * * * *

(b) *Notification to Inspector General.*

* * *

(2) The agency must promptly notify the Inspector General of any action it takes on the provider's application for participation in the program.

(3) The agency must also promptly notify the Inspector General of any action it takes to limit the ability of an individual or entity to participate in its program, regardless of what such an action is called. This includes, but is not limited to, suspension actions, settlement agreements and situations where an individual or entity voluntarily withdraws from the program to avoid a formal sanction.

* * * * *

3. Section 1002.203 would be amended by revising paragraph (a) to read as follows:

§ 1002.203 Mandatory exclusion.

(a) The State agency, in order to receive Federal financial participation (FFP), must provide that it will exclude from participation any HMO, or entity furnishing services under a waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Could be excluded under §§ 1001.1001 or 1001.1051 of this chapter, or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under §§ 1001.1001 or 1001.1051 of this chapter.

* * * * *

4. Section 1002.211 would be amended by revising paragraph (a) to read as follows:

§ 1002.211 Effect of exclusion.

(a) *Denial of payment.* Except as provided for in § 1001.1901 (c)(3), (c)(4) and (c)(5)(i) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when a person furnishing such item or service knew, or had reason to know, of the exclusion.

PART 1005—[AMENDED]

D. Part 1005 would be amended as follows:

1. The authority citation for part 1005 would continue to read as follows:

Authority: 42 U.S.C. 405(a), 405(b), 1302, 1320a-7, 1320a-7a and 1320c-5.

2. Section 1005.15 would be amended by revising introductory paragraph (f)(1) to read as follows:

§ 1005.15 The hearing and burden of proof.

* * * * *

(f)(1) A hearing under this part is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Subject to the 15-day requirement under § 1005.8, additional items and information, including aggravating or mitigating circumstances that arose or became known subsequent to the issuance of the notice letter, may be introduced by either party during its case-in-chief unless such information or items are—

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Dated: March 13, 1997.

June Gibbs Brown,

Inspector General, Department of Health and Human Services.

Approved: June 18, 1997.

Donna E. Shalala,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

Negotiated Rulemaking Committee on the Shared Risk Exception; Meetings

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Meeting of Negotiated Rulemaking Committee.

SUMMARY: In accordance with the Federal Advisory Committee Act, this document announces the dates and location for the fourth and fifth set of meetings by the Negotiated Rulemaking Committee on the Shared Risk Exception. The purpose of this committee is to negotiate the development of an interim final rule addressing the shared risk exception to the Federal health care programs' anti-kickback provisions, as statutorily-mandated by section 216 of the Health Insurance Portability and Accountability Act of 1996.

DATES: The fourth series of meetings will be held from 9:00 a.m. to 5:00 p.m. on October 8 and 9, 1997, and from 9:00 a.m. to 2:00 p.m. on October 10, 1997. The fifth series of meetings will be held from 9:00 a.m. to 5:00 p.m. on November 19, 20 and 21, 1997.

ADDRESSES: The October meeting will be held in the OIG Conference Room, Room 5542, Cohen Building, 330 Independence Avenue, S.W.,

Washington, D.C. 20201. The November meeting will be held in Rooms 383 and 385, Hall of States Building of the National Association of Insurance Commissioners, 444 North Capitol Street, N.W., Washington, D.C. 20001.

FOR FURTHER INFORMATION CONTACT: Inquiries regarding these meetings should be addressed to Joel Schaer, OIG Regulations Officer, Office of Counsel to the Inspector General, Room 5518, Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201; or call (202) 619-0089.

SUPPLEMENTARY INFORMATION: The Negotiated Rulemaking Committee on the Shared Risk Exception has been established to provide advice and make recommendations to the Secretary of Health and Human Services with respect to the text or content of an interim final rule that will establish standards relating to the exception to the anti-kickback statute for risk-sharing arrangements, set forth in section

1128B(b)(3)(F) of the Social Security Act. The exception was enacted by section 216 of Public Law 104-191, the Health Insurance Portability and Accountability Act (HIPAA) of 1996. Section 216 of HIPAA provides that the Secretary will promulgate regulations that establish standards for the exception using an expedited negotiated rulemaking process.

The intent to form the negotiated rulemaking committee and the dates for the first two series of meetings held in June and July 1997 were announced in the **Federal Register** on May 23, 1997 (62 FR 28410). The third series of meetings is scheduled for September 9 and 10, 1997 (see 62 FR 39798 for times and location of the September meetings).

During the scheduled October and November meetings, the committee will continue to discuss issues relating to the development of the interim final rule and to generate and discuss options for resolving those issues.

The meetings will be open to the public without advanced registration. Public attendance at the October meeting may be limited to space available. Members of the public wishing to attend the October sessions may want to notify the contact person listed above in advance to expedite access to the Cohen Building. A summary of all proceedings of these meetings and relevant matters and other material will also be available for public inspection at the address listed above from the hours of 8:30 a.m. to 5:00 p.m., or can be accessed through the OIG web site (<http://www.sbaonline.sba.gov/ignet/internal/hhs/hhs.html>).

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2).

Dated: August 27, 1997.

June Gibbs Brown,

Inspector General.

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