

(b) *Review.* The OIG will review the PRO report and recommendation to determine whether—

- (1) The PRO has followed the regulatory requirements of part 1004;
- (2) A violation has occurred; and
- (3) The practitioner or other person has demonstrated an unwillingness or lack of ability substantially to comply with an obligation.

(c) *Rejection of the PRO recommendation.* If the OIG decides that a sanction is not warranted, it will notify the PRO that recommended the sanction, the affected practitioner or other person, and the licensing board informed by the PRO of the sanction recommendation that the recommendation is rejected.

(d) *Decision to sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

- (1) The recommendation of the PRO;
- (2) The type of offense;
- (3) The severity of the offense;
- (4) The previous sanction record of the practitioner or other person;
- (5) The availability of alternative sources of services in the community;
- (6) Any prior problems the Medicare or State health care programs have had with the practitioner or other person;
- (7) Whether the practitioner or other person is unable or unwilling to comply substantially with the obligations, including whether he, she or it entered into a CAP—where such plan was deemed appropriate by the PRO—prior to the PRO's recommendation and, if so, whether he, she or it successfully completed such CAP; and
- (8) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 1004.110(f).

(f) *Monetary penalty.* If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 1004.110 (a)–(e).

§ 1004.110 Notice of sanction.

(a) The OIG must notify the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 20 days from the date of the notice. Receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice must specify—

- (1) The legal and factual basis for the determination;
- (2) The sanction to be imposed;
- (3) The effective date and, if appropriate, the duration of the exclusion;
- (4) The appeal rights of the practitioner or other person;
- (5) The opportunity and the process necessary to provide alternative notification as set forth in paragraphs (d) and (e) of this section; and
- (6) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) *Patient notification.* (1)(i) The OIG will provide a sanctioned practitioner or other person an opportunity to elect to inform each of their patients of the sanction action. In order to elect this option, the sanctioned practitioner or other person must, within 30 calendar days from receipt of the OIG notice, inform both new and existing patients through written notification—based on a suggested (non-mandatory) model provided to the sanctioned individual by the OIG—of the sanction and, in the case of an exclusion, its effective date and duration. Receipt of the OIG notice is presumed to be 5 days after the date of the notice, unless there is a reasonable showing to the contrary. Within this time period, the practitioner or other person must also sign and return the certification that the OIG will provide with the notice. For purposes of this section, the term “all existing patients” includes all patients currently under active treatment with the practitioner or other person, as well as all patients who have been treated by the practitioner or other person within the last 3 years. In addition, the practitioner or other person must notify all prospective patients orally at the time such persons request an appointment. If the sanctioned party is a hospital, it must notify all physicians who have privileges at the hospital, and must post a notice in its emergency room, business office and in all affiliated entities regarding the exclusion. In addition, for purposes of this section, the term “in all affiliated entities” encompasses all entities and properties in which the hospital has a direct or indirect ownership interest of 5 percent or more and any management, partnership or control of the entity.

(ii) The certification will provide that the practitioner or other person—

- (A) Has informed each of his, her or its patients in writing that the practitioner or other person has been sanctioned, or if a hospital, has informed all physicians having

privileges at the hospital that it has been sanctioned;

(B) If excluded from Medicare and the State health care programs, has informed his, her or its existing patients in writing that the programs will not pay for items and services furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by the practitioner or other person until they are reinstated, or if a hospital, has provided this information to all physicians having privileges at that hospital;

(C) If excluded from Medicare and State health care programs, will provide prospective patients—or if a hospital, physicians requesting privileges at that hospital prior to furnishing or ordering (or in the case of an excluded physician, medically directing or prescribing) services—oral information of both the sanction and that the programs will not pay for services provided and written notification of the same at the time of the provision of services;

(D) If excluded from Medicare and State health care programs and is an entity such as a hospital, has posted a notice in its emergency room, business office and in all affiliated entities that the programs will not pay for services provided; and

(E) Certifies to the truthfulness and accuracy of the notification and the statements in the certification.

(2) If the sanctioned practitioner or other person does not inform his, her or its patients *and* does not return the required certification within the 30-day period, or if the sanctioned practitioner or other person returns the certification within the 30-day period but the OIG obtains reliable evidence that such person nevertheless has not adequately informed new and existing patients of the sanction, the OIG—

(i) Will see that the public is notified directly of the identity of the sanctioned practitioner or other person, the finding that the obligation has been violated, and the effective date and duration of any exclusion; and

(ii) May consider this failure to adhere to the certification obligation as an adverse factor at the time the sanctioned practitioner or other person requests reinstatement.

(3) If the sanctioned practitioner or other person is entitled to a preliminary hearing in accordance with § 1004.140(a) and requests such a preliminary hearing, and if the administrative law judge (ALJ) decides that he, she or it poses a risk to program beneficiaries, the sanctioned practitioner or other person would have 30 days from the date of receipt of the ALJ's decision to provide certification to