

§ 1003.1560 Notice to other agencies.

(a) Whenever a penalty, an assessment, or an exclusion becomes final, the following organizations and entities will be notified about such action and the reasons for it: The appropriate State or local medical or professional association; the appropriate quality improvement organization; as appropriate, the State agency that administers each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term-care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

(b) When the OIG proposes to exclude a nursing facility under this part, the OIG will, at the same time the facility is notified, notify the appropriate State licensing authority, the State Office of Aging, the long-term-care ombudsman, and the State Medicaid agency of the OIG's intention to exclude the facility.

§ 1003.1570 Limitations.

No action under this part will be entertained unless commenced, in accordance with § 1003.1500(a), within 6 years from the date on which the violation occurred.

§ 1003.1580 Statistical sampling.

(a) In meeting the burden of proof in § 1005.15 of this chapter, the OIG may introduce the results of a statistical sampling study as evidence of the number and amount of claims, specified claims, and/or requests for payment, as described in this part, that were presented, or caused to be presented, by the respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims, specified claims, or requests for payment, as described in this part.

(b) Once the OIG has made a prima facie case, as described in paragraph (a) of this section, the burden of production shall shift to the respondent to produce evidence reasonably calculated

to rebut the findings of the statistical sampling study. The OIG will then be given the opportunity to rebut this evidence.

[81 FR 88364, Dec. 7, 2016, as amended at 88 FR 42841, July 3, 2023]

§ 1003.1590 Effect of exclusion.

The effect of an exclusion will be as set forth in 42 CFR 1001.1901.

§ 1003.1600 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of 42 CFR 1001.3001 through 1001.3004.

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A QUALITY IMPROVEMENT ORGANIZATION

Subpart A—General Provisions

Sec.

1004.1 Scope and definitions.

Subpart B—Sanctions Under the QIO Program; General Provisions

1004.10 Statutory obligations of practitioners and other persons.

1004.20 Sanctions.

Subpart C—QIO Responsibilities

1004.30 Basic responsibilities.

1004.40 Action on identification of a violation.

1004.50 Meeting with a practitioner or other person.

1004.60 QIO finding of a violation.

1004.70 QIO action on final finding of a violation.

1004.80 QIO report to the OIG.

1004.90 Basis for recommended sanction.

Subpart D—OIG Responsibilities

1004.100 Acknowledgement and review of report.

1004.110 Notice of sanction.

Subpart E—Effect and Duration of Exclusion

1004.120 Effect of an exclusion on program payments and services.

1004.130 Reinstatement after exclusion.

§ 1004.1

42 CFR Ch. V (10–1–23 Edition)

Subpart F—Appeals

1004.140 Appeal rights.

AUTHORITY: 42 U.S.C. 1302 and 1320c–5.

SOURCE: 60 FR 63640, Dec. 12, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 1004.1 Scope and definitions.

(a) *Scope*. This part implements section 1156 of the Act by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from quality improvement organizations (QIOs) when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions*. As used in this part, unless the context indicates otherwise—

Dentist is limited to licensed doctors of dental surgery or dental medicine.

Economically means the services are provided at the least expensive, medically appropriate type of setting or level of care available.

Exclusion means that items and services furnished or ordered (or at the medical direction or on the prescription of a physician) by a specified health care practitioner, provider or other person during a specified period are not reimbursed under titles V, XVIII, XIX, or XX of the Social Security Act and all other Federal non-procurement programs.

Gross and flagrant violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

Health care service or services means services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs.

Health professional shortage area (HPSA) means an area designated by the Secretary and defined in 42 CFR 5.2.

Metropolitan Statistical Area means an area as defined by the Executive Office of Management and Budget.

Obligation means any of the obligations specified at section 1156(a) of the Act.

Other person means a hospital or other health care facility, an organization or an agency that provides health care services or which payment may be made (in whole or in part) under the Medicare or State health care programs.

Pattern or care means that the care under question has been demonstrated in more than three instances, each of which involved different admissions.

Pharmacy professional is a term limited to individuals who are licensed or registered to provide pharmaceutical services.

Podiatric professional is a term limited to licensed doctors of podiatric medicine.

Practice area means the location where over 50 percent of the practitioner's or other person's patients are seen.

Practitioner means a physician or other health care professional licensed under State law to practice his or her profession.

Primary medical care professional is a term limited to:

(i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or

(ii) Those facilities where care and treatment is provided to patients with health problems other than mental disorders.

Pro area means the geographic area subject to review by a particular QIO.

Provider means a hospital or other health care facility, agency, or organization.

Psychiatric professional is a term limited to licensed doctors of medicine who limit their practice to psychiatry

or to those facilities where care and treatment is limited to patients with mental disorders.

Rural means any area outside an urban area.

Rural health professional shortage area means any health professional shortage area located outside a Metropolitan Statistical Area.

Sanction means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a QIO.

Serious risk includes situations that may involve the risk of unnecessary treatment, prolonged treatment, lack of treatment, incorrect treatment, medical complication, premature discharge, physiological or anatomical impairment, disability, or death.

State health care program means a State plan approved under title XIX, any program receiving funds under title V or from an allotment to a State under such title, or any program receiving funds under title XX or from an allotment to a State under such title.

Substantial violation in a substantial number of cases means a pattern of providing care, as defined in this section, that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

Urban means a Metropolitan Statistical Area as defined by the Executive Office of Management and Budget.

Vision care professional is a term limited to licensed doctors of medicine who limit their practice to ophthalmology and to doctors of optometry.

Subpart B—Sanctions Under the QIO Program; General Provisions

§ 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are—

(a) Provided economically and only when, and to the extent, medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of medical necessity and quality in the form and fashion and at such time that the reviewing QIO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements) to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under the law, a practitioner or other person may be—

(a) Excluded from participating in programs under titles V, XVIII, XIX, and XX of the Social Security Act for a period of no less than 1 year; or

(b) In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, and XX of the Act, if the violation involved the provision or ordering of health care services (or services furnished at the medical direction or on the prescription of a physician) that were medically improper or unnecessary, required to pay an amount of up to \$10,000 for each instance in which improper or unnecessary services were furnished or ordered (or prescribed, if appropriate). The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

[62 FR 23143, Apr. 29, 1997]

Subpart C—QIO Responsibilities

§ 1004.30 Basic responsibilities.

(a) The QIO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 1004.10.

(b) When the QIO identifies situations where an obligation specified in

§ 1004.40

§1004.10 is violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§1004.40 and 1004.60.

(c) The QIO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section and, if appropriate, the opportunity to enter into and complete a corrective action plan (CAP) if the QIO finds that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of admissions; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The QIO report to the OIG must comply with the provisions of §1004.80.

(e) If a practitioner or other person relocates to another QIO area prior to a finding of a violation or sanction recommendation, and the originating QIO—

(1) Is able to make a finding, the originating QIO must, as appropriate, close the case or forward a sanction recommendation to the OIG; or

(2) Cannot make a finding, the originating QIO must forward all documentation regarding the case to the QIO with jurisdiction, and notify the practitioner or other person of this action.

(f) The QIO must deny payment for services or items furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by an excluded practitioner or other person when the QIO identifies the services or items. It must report the findings to the Centers for Medicare & Medicaid Services.

§ 1004.40 Action on identification of a violation.

When a QIO identifies a violation, it must—

(a) Indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases; and

(b) Send the practitioner or other person written notice of the identifica-

42 CFR Ch. V (10–1–23 Edition)

tion of a violation containing the following information—

(1) The obligation(s) involved;

(2) The situation, circumstances or activity that resulted in a violation;

(3) The authority and responsibility of the QIO to report violations of any obligation under section 1156(a) of the Act;

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate;

(5) The sanction that the QIO could recommend to the OIG;

(6) The right of the practitioner or other person to submit to the QIO within 30 days of receipt of the notice additional information or a written request for a meeting with the QIO to review and discuss the finding, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary. The notice will also state that if a meeting is requested—

(i) It will be held within 30 days of receipt by the QIO of the request, but may be extended for good cause;

(ii) The practitioner or other person may have an attorney present; and

(iii) The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person's behalf; and

(7) A copy of the material used by the QIO in arriving at its finding except for QIO deliberations, as set forth in §480.139 of this part.

[60 FR 63640, Dec. 12, 1995, as amended at 85 FR 72910, Nov. 16, 2020]

§ 1004.50 Meeting with a practitioner or other person.

If the practitioner or other person requests a meeting with the QIO—

(a) The QIO panel that meets with the practitioner or other person must consist of a minimum of 3 physicians;

(b) No physician member of the QIO panel may be in direct economic competition with the practitioner or other person being considered for sanction;

(c) The QIO must ensure that no physician member of the QIO panel has a substantial bias for or against the

practitioner or other person being considered for sanction;

(d) At least one member of the QIO panel meeting with the practitioner or other person should practice in a similar area, e.g., urban or rural, and at least one member of the panel must be in the same specialty (both requirements could be met by a single individual);

(e) If the practitioner or other person has an attorney present, that attorney will be permitted to make opening and closing remarks, ask clarifying questions and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person behalf;

(f) The physician who recommends to the QIO that a practitioner or other person be sanctioned may not vote on that recommendation at the meeting;

(g) The QIO may allow the practitioner or other person 5 working days after the meeting to provide the QIO additional relevant information that may affect its finding; and

(h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§ 1004.60 QIO finding of a violation.

(a) On the basis of any additional information received, the QIO will affirm or modify its finding. If the QIO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the QIO. If the finding has been resolved to the QIO's satisfaction, the QIO may modify its initial finding or recommendation or close the case.

(b) The QIO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in § 1004.70.

(c) At least one member of the QIO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g. urban or rural,

and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the QIO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or other person being recommended for sanction.

§ 1004.70 QIO action on final finding of a violation.

If the finding is not resolved to the QIO's satisfaction as specified in § 1004.60(a), the QIO must—

(a) Submit its report and recommendation to the OIG;

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to the OIG, advising that—

(1) The QIO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified in § 1004.100(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered; and

(c) Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits a report and recommendations to the OIG with respect to a physician or other person whom the board is responsible for licensing.

§ 1004.80 QIO report to the OIG.

(a) *Manner of reporting.* If the violation(s) identified by the QIO have not been resolved, it must submit a report and recommendation to the OIG at the field office with jurisdiction.

(b) *Content of report.* The QIO report must include the following information—

§ 1004.90

(1) Identification of the practitioner or other person and, when applicable, the name of the director, administrator or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances and other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence, including reports of conversations with the practitioner or other person regarding the violation and, if applicable, a copy of the verbatim transcript of the meeting with the practitioner or other person;

(6) The QIO's finding that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in a substantial number of cases or is gross and flagrant;

(7) A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to the QIO's initial finding;

(8) A copy of the CAP that was developed and documentation of the results of such plan;

(9) The number of admissions by the practitioner or other person reviewed by the QIO during the period in which the violation(s) were identified;

(10) The professional qualifications of the QIO's reviewers; and

(11) The QIO's sanction recommendation.

(c) *QIO recommendation.* The QIO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable;

(4) The availability of alternative sources of services in the community, with supporting information; and

(5) The county or counties in which the practitioner or other person furnishes services.

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

42 CFR Ch. V (10–1–23 Edition)

§ 1004.90 Basis for recommended sanction.

The QIO's specific recommendation must be based on documentation provided to the OIG showing its consideration of—

(a) The type of offense involved;

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioner's or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the QIO considers relevant, such as the duration of the problem.

Subpart D—OIG Responsibilities

§ 1004.100 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the QIO of the date it received the QIO's report and recommendation.

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

(1) The QIO has followed the regulatory requirements of this part; and

(2) A violation has occurred.

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

(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; and

(7) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the QIO 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 QIO 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).

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

§ 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 notice—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. 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 same 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

§ 1004.120

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 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 the OIG in accordance with § 1004.110(d)(1). The date of receipt is presumed to be 5 days after the date of the ALJ's decision, unless there is a reasonable showing to the contrary.

(e) Notice of the sanction is also provided to the following entities as appropriate—

(1) The QIO that originated the sanction report;

(2) QIOs in adjacent areas;

(3) State Medicaid fraud control units and State licensing and accreditation bodies;

(4) Appropriate program contractors and State agencies;

(5) Hospitals, including the hospital where the sanctioned individual's case

42 CFR Ch. V (10–1–23 Edition)

originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations and Federally-funded community health centers where the practitioner or other person works;

(6) Medical societies and other professional organizations; and

(7) Medicare carriers and fiscal intermediaries, health care prepayment plans and other affected agencies and organizations.

(f) If an exclusion sanction is effectuated because a decision was not made within 120 days after receipt of the QIO recommendation, notification is as follows—

(1) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person, in compliance with the requirements of paragraph (c) of this section, affirming the QIO recommendation based on the OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and

(2) Notice of sanction is also provided as specified in paragraph (e) of this section.

[60 FR 63640, Dec. 12, 1995; 61 FR 1841, Jan. 24, 1996, as amended at 62 FR 23143, Apr. 29, 1997]

Subpart E—Effect and Duration of Exclusion

§ 1004.120 Effect of an exclusion on program payments and services.

The effect of an exclusion is set forth in § 1001.1901 of this chapter.

§ 1004.130 Reinstatement after exclusion.

(a) A practitioner or other person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with provisions of §§ 1001.3001 through 1001.3005 of this chapter.

(b) The OIG may also consider a practitioner's or other person's compliance with the certification obligation in § 1004.110(d) at the time of reinstatement.

Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) *Right to preliminary hearing.* (1)(i) A practitioner or other person excluded from participation in Medicare and any State health care programs under section 1156 of the Act may request a preliminary hearing if the location where services are rendered to over 50 percent of the practitioner's or other person's patients at the time of the exclusion notice is in a rural HPSA or in a county with a population of less than 70,000.

(ii) Unless the practitioner's or other person's practice meets the definition for psychiatric professional, vision care professional, dental professional, podiatric professional or pharmacy professional, the HPSA used by the OIG for determination of entitlement to a preliminary hearing will be the HPSA list for primary medical care professional.

(iii) Information on the population size of a county in order to determine entitlement to a preliminary hearing will be obtained by the OIG from the responsible officials of that county.

(2)(i) A request for a preliminary hearing must be made in writing and received by the Departmental Appeals Board (DAB) no later than the 15th day after the notice of exclusion is received by a practitioner or other person. The date of receipt of the notice of exclusion by the practitioner or other person is presumed to be 5 days after the date appearing on the notice, unless there is a reasonable showing to the contrary.

(ii) A request for a preliminary hearing will stay the effective date of the exclusion pending a decision of the ALJ at the preliminary hearing, and all the parties informed by the OIG of the exclusion will be notified of the stay.

(iii) A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ in accordance with paragraph (b) of this section.

(iv) If the practitioner or other person exercises his, her or its right to a preliminary hearing, such a hearing must be held by the ALJ in accordance with paragraph (a)(3)(i) of this section

unless the OIG waives it in accordance with paragraph (a)(6)(i) of this section.

(v) The ALJ cannot consolidate the preliminary hearing with a full hearing without the approval of all parties to the hearing.

(3)(i) The preliminary hearing will be conducted by an ALJ of the DAB in a city that the ALJ deems equitable to all parties. The ALJ will conduct the preliminary hearing and render a decision no later than 45 days after receipt of the request for such a hearing by the DAB. Unless there is a reasonable showing to the contrary, date of receipt by the DAB is presumed to be 5 days after the date on the request for a preliminary hearing or, if undated, the date of receipt will be the date the DAB actually received the request. A reasonable extension to the 45-day period of up to 15 days may be requested by any party to the preliminary hearing and such a request may be granted upon concurrence by all parties to the preliminary hearing. Such request must be received no later than 15 days prior to the scheduled date of the preliminary hearing.

(ii) The only issue to be heard and decided on by the ALJ at the preliminary hearing, based on the preponderance of the evidence, is whether the practitioner's or other person's continued participation in the Medicare and State health care programs during the appeal of the exclusion before an ALJ would place program beneficiaries at serious risk. The ALJ's decision is to be based on the preponderance of the evidence.

(iii) In the interest of time, the ALJ may issue an oral decision to be followed by a written decision.

(iv) In those cases where the ALJ has stayed an exclusion after a preliminary hearing, a full hearing must be held and a decision rendered by the ALJ within 6 months. If, for any reason, the request for a full hearing before the ALJ is withdrawn or dismissed, the practitioner or other person will be excluded effective 5 days after the notice of the withdrawal or dismissal is received in the OIG headquarters.

(4) The preliminary hearing decision is not appealable or subject to further administrative or judicial review.

(5) A practitioner or other person found at the preliminary hearing not to place program beneficiaries at serious risk, but later determined to have been properly excluded from program participation after a full hearing before an ALJ, is not entitled to have the exclusion stayed further during an appeal to the DAB. Exclusions in such instances will be effective 5 days after receipt of the ALJ decision in the OIG headquarters.

(6)(i) After notice of a timely request for a preliminary hearing, the OIG may determine that the practitioner's or other person's continued program participation during the appeal before the ALJ will not place program beneficiaries at serious risk and waive the preliminary hearing. Under these circumstances, the exclusion will be stayed pending the decision of the ALJ after a full hearing. The hearing must be held, and a decision reached, within 6 months.

(ii) If the OIG decides to waive the preliminary hearing, the request for the preliminary hearing will be considered a request for a hearing before the ALJ in accordance with paragraph (b) of this section.

(b) *Right to administrative review.* (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in §1004.100(e), the following limitations apply—

(i) The period of time for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed will not be considered by the ALJ or the DAB.

(3) The OIG's determination continues in effect unless reversed by a hearing.

(c) *Rights to judicial review.* Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

Sec.

- 1005.1 Definitions.
- 1005.2 Hearing before an administrative law judge.
- 1005.3 Rights of parties.
- 1005.4 Authority of the ALJ.
- 1005.5 Ex parte contacts.
- 1005.6 Prehearing conferences.
- 1005.7 Discovery.
- 1005.8 Exchange of witness lists, witness statements and exhibits.
- 1005.9 Subpoenas for attendance at hearing.
- 1005.10 Fees.
- 1005.11 Form, filing and service of papers.
- 1005.12 Computation of time.
- 1005.13 Motions.
- 1005.14 Sanctions.
- 1005.15 The hearing and burden of proof.
- 1005.16 Witnesses.
- 1005.17 Evidence.
- 1005.18 The record.
- 1005.19 Post-hearing briefs.
- 1005.20 Initial decision.
- 1005.21 Appeal to DAB.
- 1005.22 Stay of initial decision.
- 1005.23 Harmless error.

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

SOURCE: 57 FR 3350, Jan. 29, 1992, unless otherwise noted.

§ 1005.1 Definitions.

Civil money penalty cases refers to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose civil money penalties (CMPs).

DAB refers to the Departmental Appeals Board or its delegatee.

Exclusion cases refers to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose exclusions.

Inspector General (IG) means the Inspector General of the Department of Health and Human Services or his or her designees.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000; 88 FR 42841, July 3, 2023]

§ 1005.2 Hearing before an administrative law judge.

(a) A party sanctioned under any criteria specified in parts 1001, 1003 and