Medicare
Peer Review Organization Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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NEW/REVISED MATERIAL--*EFFECTIVE DATE: December 29, 2002*

References throughout this chapter of the Health Care Financing Administration (HCFA) have been replaced with the Centers for Medicare and Medicaid Services (CMS); and the Peer Review Organization (PRO) has been replaced with the Quality Improvement Organization (QIO).

Section 9000, Citations and Authority, specifies the statutory obligations of health care practitioners and other persons (e.g., hospitals or other health care facilities, organizations, or agencies) who furnish services under the Medicare or State health care programs. In addition, the regulatory citation has been added.

Section 9005, Identification of Potential Violations, explains the actions you must initiate upon identification of potential violation(s) of any of the statutory obligations.

Section 9010, Meeting With a Practitioner or Other Person, delineates the conditions to conduct the mandatory meeting with the QIO and a practitioner or other person as a result of a potential violation notification.

Section 9015, QIO Finding of a Violation, explains your responsibilities found at 42 CFR 1004.60 related to affirming or modifying findings of a statutory violation.

Section 9020, QIO Action on Final Finding of a Violation, delineates the actions you must take after affirming that a violation of a statutory obligation has occurred.

Section 9025, QIO Report to the Office of Inspector General (OIG), specifies the format and content of the sanction report sent by you to the OIG upon determining that a substantial violation has occurred in a substantial number of cases or is gross and flagrant.

Section 9030, Imposition and Notification of Sanctions, specifies the OIG's actions after it determines that a violation has occurred.

Section 9035, Effect of an Exclusion Sanction on Medicare Payments and Services, explains the conditions for payment under the Medicare program after the effectuation of an exclusion sanction.

Section 9040, Reinstatement After Exclusion, specifies the two conditions for termination of an exclusion sanction.

Section 9045, Appeal Rights of the Excluded Practitioner or Other Person, specifies the rights to a pre-exclusion hearing (when applicable), an administrative review, and a judicial review.

Section 9050, Imposition of Sanctions, has been **deleted.**

Section 9055, Notification of Sanction to be Imposed, has been **deleted.**

Section 9060, Effect of an Exclusion Sanction on Medicare Payments and Services, has been **deleted.**

Section 9065, Reinstatement After Exclusion, has been **deleted.**

Section 9070, Appeal Rights of the Practitioner or Other Person Under §1156, has been **deleted.**

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

PART 9

SANCTION AND ABUSE ISSUES

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Section

Sanctions

Anti-Dumping

Fraud and Abuse

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Sanctions

9000. CITATIONS AND AUTHORITY

Section 1156(a) of the Social Security Act (the Act), and regulation at 42 CFR 1004.10, provide that healthcare practitioners and other persons (e.g., hospitals or other health care facilities, organizations or agencies) who furnish or order health care services that may be paid for under the Medicare or State health care programs, are obligated to assure to the extent of his or her or its authority, that the services or items are:

- Provided economically and only when, and to the extent, they are medically necessary (42 CFR 1004.10(a));
- Of a quality that meets professionally recognized standards of health care (42 CFR 1004.10(b)); and
- Supported by appropriate 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) (42 CFR 1004.10(c)) to ensure that the practitioner or other person is meeting these statutory obligations.

If you find that these obligations are not being met, give notice to the practitioner or other person and provide an opportunity for them to discuss and submit additional information to you. This notice initiates the sanction process (42 CFR 1004.30 and 1004.40.)

NOTE: Any time you activate the sanction process against a Medicare+Choice (M+C) organization, notify your project officer (PO) and the respective regional office's (RO's) Division of Health Plans and Providers at the same time you notify the M+C organization. The notifications must include a copy of the initial notice to the M+C organization. Continue to notify your PO and the RO's Division of Health Plans and Providers through each progressive step in the sanction process through the final sanction notice and recommendation to the Office of Inspector General (OIG), the designee of the Secretary of the Department of Health and Human Services.

Also, §1156(b)(1) of the Act, requires that you provide the practitioner or other person with an opportunity to establish and complete a corrective action plan (CAP), if appropriate. A CAP would always be appropriate except in the most egregious situations where beneficiaries could be placed in imminent danger or unnecessarily high-risk situations. If, after reviewing all additional information (including the results of corrective action measures, if applicable), you determine that a substantial violation in a substantial number of cases or a gross and flagrant violation in one or more instances has occurred and you recommend that the practitioner or other person is unable or unwilling to comply with statutory obligations that were violated, send your report and recommendations stating the specific sanction to be imposed to the OIG.

NOTE: Include with any sanction recommendation you forward to OIG a copy of the CAP and the results of the CAP, or your rationale for deciding that a CAP was inappropriate. (See 42 CFR 1004.80.)

After considering your recommendation, OIG decides whether the criteria for sanctions have been met and whether a sanction should be imposed. The sanctions that OIG may impose on a practitioner or other person as a result of your recommendation are:

o Exclusion from participation in programs under titles V, XVIII, XIX, XX, and XXI of the Act, for a period of no less than one year. (See 42 CFR 1004.20(a).) When you make your recommendation for exclusion to OIG, OIG must make its decision by the 120th day after receipt on your recommendation or the exclusion becomes effective and OIG will provide notice in accordance with 42 CFR 1004.110(f); (42 CFR 1004.100(e)); or

o In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, XX, and XXI 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, the practitioner or other person may be 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 the notice or have it deducted from any sums the Federal government owes the practitioner or other person. (42 CFR 1004.20(b).)

NOTE: Section 4095 of OBRA 1987 (as amended by §401(c)(1) of P.L. No. 101-597) established certain pre-exclusion appeal rights for practitioners or other persons located in rural health professional shortage areas or in counties with a population of less than 70,000. (See §1156(b)(5) of the Act and 42 CFR §1004.140.)

You may ask the OIG for assistance in all aspects of sanction procedures. Consult with the OIG staff as early as possible to avoid unforeseen problems and to expedite the sanction process.

9005. IDENTIFICATION OF POTENTIAL VIOLATIONS

Use your 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 §9000.

Identification of violations may occur through:

o Your examination of a practitioner's or other person's services furnished;

o Your individual case review; or

o Referral from your subcontractor, Medicare intermediary or carrier, licensing and certification agencies, CMS, or OIG.

The following are the three statutory obligations of practitioners and other persons which, if not met, may form the basis for the initiation of a sanction action. Also, included are examples of your responsibilities, and violations of practitioners and other persons which may occur related to the obligations:

o Services or items ordered or furnished to Medicare patients are to be provided economically and only when, and to the extent, medically necessary.

Example: Reduce admissions for health care services that could be performed effectively and with adequate assurance of patient safety in a skilled nursing facility setting. For example, practitioners who frequently admit to acute care hospitals patients who clearly need skilled care services may be in violation of their obligation to provide service economically.

Example: Reduce inappropriate or unnecessary invasive procedures. For example, practitioners who implant permanent cardiac pacemakers without clear and appropriate indications may be in violation of their obligation to provide only services that are medically necessary.

o Services or items ordered or furnished are supported by evidence of medical necessity and quality in the form and fashion (and at such time) that you may reasonably require for review (including copies) in exercising your duties and responsibilities.

Example: When reviewing to make decisions about the medical necessity of services, you consistently find that a certain provider has insufficient documentation to support the medical necessity of the services furnished.

o Items or services ordered or furnished are to be of a quality which meets professionally recognized standards of care.

Example: Reduce hospital readmissions resulting from premature discharges. Practitioners and other persons who discharge patients prematurely may be in violation of their obligation to provide services of a quality which meets professionally recognized standards.

When identifying a violation, you must (see 42 CFR 1004.40):

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

o Send the practitioner or other person written notice of the identification of the violation making sure the notice contains:

- The obligation(s) involved;

- The situation, circumstances or activity that resulted in the violation;

- The authority and responsibility you have to report violations of any obligation under §1156(a) of the Act;

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

- The sanction you could recommend to OIG;

- The right of the practitioner or other person to submit to you within 30 days of receipt of the notice (the date of receipt is 5 days after the date on the notice, unless there is reasonable showing to the contrary), additional information and/or a written request for a meeting with you to review and discuss the finding; and

- A copy of the material you used in arriving at your findings, except your deliberations, as set forth in 42 CFR §480.139.

o Conduct the first meeting following the conditions specified at 42 CFR 1004.40(6)(i)-(iii).

- The meeting must be held within 30 days of receipt of the request by you, but may be extended for good cause;

- The practitioner or other person may have an attorney present; and

- The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions, and assist the practitioner or other person in presenting testimony of expert witnesses, who may appear on behalf of the practitioner or other person.

9010. MEETING WITH A PRACTITIONER OR OTHER PERSON

If the practitioner or other person requests a meeting with you (see 42 CFR 1004.50):

o The QIO panel that meets with the practitioner or other person must consist of a minimum of three physicians;

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

o You 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;

o 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);

o 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's behalf;

o The physician who recommends to you that a practitioner or other person be sanctioned may not vote on that recommendation at the meeting;

o You may allow the practitioner or other person 5 working days after the meeting to provide you with additional relevant information that may affect your finding; and

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

9015. QIO FINDING OF A VIOLATION

If you receive additional information, it is your responsibility to affirm or modify your findings. If you affirm the findings, you may suggest that a written method of correction is in order for the situation. (See 42 CFR 1004.60.) You have the flexibility and may use your discretion in working with the practitioner or other person when a CAP is appropriate. When providing the written CAP, allot a time period when you expect the situation to be corrected. This CAP may be in conjunction with or a continuation of a prior CAP, or may be a new proposal based on additional information you received. If you determine, after careful consideration, that implementation of a CAP would not be appropriate, carefully document your rationale for the decision. (Include this documentation in your report to OIG.) However, if the findings are resolved to your satisfaction, you may modify the initial finding or recommend that the case be closed.

Give written notice to the practitioner or other person of any action you take as a result of additional information received. (See 42 CFR 1004.60(b) and 1004.70.)

At least one member of the QIO participating in the process which resulted in a recommendation to OIG that a practitioner or other person be sanctioned, must 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 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.

9020. QIO ACTION ON FINAL FINDING OF A VIOLATION

If the findings are not resolved to your satisfaction as specified in §9015, you must (see 42 CFR 1004.70):

- o Submit a report and your recommendation to OIG;
- o Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to OIG, advising that:
  - You have submitted your recommendation to OIG;
  - The practitioner or other person has 30 days from receipt of the final notice to submit any additional written material or documentary evidence to 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
- o Due to the 120-day statutory requirement specified in 42 CFR 1004.100(e), the period for submitting additional information will not be extended and any material received by OIG after the 30-day period will not be considered; and;
- o You must provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when you submit your report and recommendations to OIG with respect to a physician or other person whom the board is responsible for licensing.

9025. QIO REPORT TO OFFICE OF INSPECTOR GENERAL (OIG)

A. Manner of Reporting.--If the violation(s) identified by you have not been resolved, you must submit a report and your recommendation to OIG at the field office with jurisdiction. (See 42 CFR 1004.80.)

B. Content of Report.--The report must include the following information:

- o Identification of the practitioner or other person and, when applicable, the name of the director, administrator, or owner of the entity involved;
- o The type of health care services involved;

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

o Pertinent documentary evidence;

o 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;

o Your finding that an obligation under §1156(a) of the Act has been violated, that the violation is substantial, and has occurred in a substantial number of cases or is gross and flagrant;

o A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to your initial finding;

o A copy of the CAP that you developed, and documentation of the results of the plan;

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

o The professional qualifications of QIO reviewers; and

o Your sanction recommendation.

C. QIO Recommendation.--The report must specify:

o The sanction recommended;

o The amount of monetary penalty recommended, if applicable;

o The period of exclusion recommended, if applicable;

o The availability of alternative sources of services in the community, with supporting information; and

o The county or counties in which the practitioner or other person furnishes services.

NOTE: Your recommendation to OIG must be based on documentation of the type of offense involved; the severity of the offense; the deterrent value; a consideration of the practitioner's or other person's previous sanction record; the availability of alternative sources of services in the community; and any other factors that you consider relevant, such as the duration of the problem. (See 42 CFR 1004.90.)

D. Rejection of QIO Recommendation.--OIG will inform you of the date it received your report and recommendation, will review the report to determine whether you have followed the regulatory requirements, and will determine if a violation has occurred (42 CFR 1004.100.) If OIG decides that a sanction is not warranted, it notifies you and the affected practitioner or other person and the licensing board that the recommendation to sanction is rejected (see 42 CFR 1004.100c.)

E. Decision to Sanction.--If OIG decides that a violation of an obligation has occurred, it determines the appropriate sanction by considering (see 42 CFR 1004.100(d)):

- Your recommendation;
- The type of offense;
- The severity of the offense;
- The practitioner's or other person's previous sanction record;
- The availability of alternative sources of services in the community;
- Any prior problems the Medicare or State health care programs have had with the practitioner or other person; and
- Any other matters relevant to the particular case.

9030. IMPOSITION AND NOTIFICATION OF SANCTIONS

A. Exclusion Sanction (see 42 CFR 1004.100.(e)).--If a decision is not made within 120 days (from date of receipt) by the OIG, the exclusion sanction recommended by the QIO will become effective and the OIG will provide notice in accordance with 42 CFR 1004.110(f).

B. Monetary Penalty (see 42 CFR 1004.100(f)).--If your recommendation to OIG is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with 42 CFR 1004.110 (a)-(e).

C. Notification to Practitioner or Other Person of OIG Sanction.--OIG notifies the practitioner or other person of the adverse determination and of the sanction to be imposed. The sanction is effective 20 days from the date of the notice. The 20 days begins when the practitioner or person received the notice, with a presumed date of receipt that is 5 days after the date on the notice unless there is a reasonable showing to the contrary.

D. Content of Notice.--The notice must specify (see 42 CFR 1004.110(c)):

- The legal and factual basis for the determination;
- The sanction to be imposed (e.g., exclusion or monetary penalty);
- The effective date and, if appropriate, the duration of the exclusion;
- The appeal rights of the practitioner or other person;
- The opportunity and process necessary for the practitioner or other person to use alternative notification of patients and others (see 42 CFR 1004.110(d) and (e).); and
- In the case of exclusion, the earliest date OIG will accept a request for reinstatement.

E. Patient Notice.--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's notice, inform both new patients and existing patients through written notice based on a suggested (non-mandatory) model provided to the sanctioned individual by OIG, of the sanction and, in the case of an exclusion, its effective date. Receipt of OIG's 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 sign and return the certification that OIG will provide with the notice. For purposes of this section, the term "all existing

patients," includes 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 person requests 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. The term "in all affiliated entities" encompasses all entities and properties in which the hospital has a direct or indirected ownership interest of 5 percent or more, and any management, partnership or control of the entity.

The certification will provide that the practitioner or other person:

- 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;

- 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;

- 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.

- 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

- Certifies to the truthfulness and accuracy of the notification and the statement in the certification.

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 OIG obtains reliable evidence that such person nevertheless has not adequately informed new and existing patients of the sanction, OIG:

- 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;

- 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; and

- If the sanctioned practitioner or other person is entitled to a preliminary hearing in accordance with 42 CFR 1004.140(a) and requests such a preliminary hearing, 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 OIG in accordance with 42 CFR 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.

F. Notification to Entities.—Notice of the sanction is also provided to the following entities as appropriate:

- o The QIO that originated the sanction report;
- o QIOs in adjacent areas;
- o State Medicaid fraud control units and State licensing and accreditation bodies;
- o Appropriate program contractors and State agencies;
- o Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known, skilled nursing facilities; home health agencies; M+C organizations, and Federally-funded community health centers where the practitioner or other person works;
- o Medical societies and other professional organizations; and
- o Medicare carriers and intermediaries; health care prepayment plans; and other affected agencies and organizations.

G. Effectuation of an Exclusion Sanction.--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 (see 42 CFR 1004.110(f)):

- o As soon as possible after the 120th day, OIG will issue a notice to the practitioner or other person, affirming the QIO recommendation based on OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and
- o Notice of sanction is provided as specified at 9030C.

9035. EFFECT OF AN EXCLUSION SANCTION ON MEDICARE PAYMENTS AND SERVICES

A. Payment to an Excluded Practitioner or Other Person (see 42 CFR 1001.1901).--

- o Payment will not be made under the Medicare, Medicaid or any other Federal health care programs as defined in §1128(h) of the Act to an excluded practitioner or other person for items or services furnished, ordered or prescribed during the period of exclusion;
- o Payment will not be made under Medicare, Medicaid or any other Federal health care programs to any provider for items or services ordered by an excluded practitioner or other person when the order was a necessary precondition for payment under Medicare when the person furnishing the item or service knew or had reason to know of the exclusion; and
- o Assignment of a beneficiary's claim for items or services furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion will not be valid.

B. Exceptions to Denial of Medicare Payment (Exclusion) (see 42 CFR 1001.1901(c)(3)).--Unless the Secretary determines that the health and safety of beneficiaries warrants the exclusion taking effect earlier, payment may be made for services or items provided up to 30 days after the effective date of exclusion for:

- o Inpatient hospital or skilled nursing services or items furnished to a beneficiary who was admitted before the effective date of the exclusion; and

o Home health services and hospice care items furnished under a plan established before the effective date of the exclusion.

C. Payment to Beneficiaries (see 42 CFR 1001.1901(c)(1) and (2)).--If a beneficiary submits claims for items or services furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion, CMS will make payments as follows:

o The first claim submitted by the beneficiary will be paid and the beneficiary will be immediately notified of the exclusion; and

o The beneficiary's right to payment will extend to items or services furnished or ordered by the excluded practitioner or other person up to 15 days after the date on the exclusion notice; or after the effective date of the exclusion notice, whichever is later.

9040. REINSTATEMENT AFTER EXCLUSION

Exclusion will remain in effect until (see 42 CFR1004.130):

o OIG's decision to exclude is reversed on appeal; or

o OIG determines, pursuant to a properly filed request for reinstatement (i.e., at the end of the minimum period of exclusion). That the basis for the exclusion no longer exists and there is reasonable assurance that the problems will not reoccur. (See 42 CFR 1001.3001-3005 for OIG's reinstatement procedures.

9045. APPEAL RIGHTS OF THE EXCLUDED PRACTITIONER OR OTHER PERSON

The OIG's determination will continue in effect unless reversed on appeal. (See 42 CFR 1004.140(b)(3).)

A. Right to Pre-exclusion Hearing(s) (see 42 CFR 1004.140(a).--A practitioner or other person excluded from participation in Medicare and any State health care programs under §1156 of the Act, may request a preliminary hearing if the location where the 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 Health Professional Shortage Area (HPSA) or in a county with a population of less than 70,000.

B. Right to an Administrative Review (see 42 CFR 1004.140(b).--A practitioner or other person dissatisfied with an OIG determination or an exclusion that resulted from a determination not being made within 120 days, is entitled to a hearing before an ALJ in accordance with §205(b) of the Act. If the practitioner or other person is dissatisfied with the decision of the ALJ, he or she may appeal that decision and obtain a final determination from the Department Appeals Board (DAB). (See 42 CFR §1005.21.)

C. Right to Judicial Review (see 42 CFR 1004.140(c).--Any practitioner or other person dissatisfied with the final decision of the DAB may file a civil action in accordance with the provision of 205(g) of the Act. (See 42 CFR 1005.21(k).)