Quality Improvement Organization Manual

Chapter 9 - Sanction and Abuse Issues

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9000 - Citations and Authority

(Rev. 12, 10-03-03)

Section 1156(a) of the Social Security Act (the Act) and regulation at 42 CFR 1004.10 provide that health care 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 preadmission 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 Organization (M+CO), 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+CO. The notifications must include a copy of the initial notice to the M+CO. 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 the Inspector General (OIG), the designee of the Secretary of the Department of Health & Human Services (DHHS).

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:

- 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

- 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: §4095 of the Omnibus Budget Reconciliation Act of 1987 (as amended by §401(c)(1) of PL 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

(Rev. 12, 10-03-03)

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:

- Your examination of a practitioner's or other person's services furnished;
- Your individual case review; or
- Referral from your subcontractor, Medicare intermediary or carrier, licensing and certification agencies, Centers for Medicare & Medicaid Services (CMS), or OIG.

The following are the three statutory obligations of practitioners and other persons that, 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 that may occur related to the obligations:

- 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.

- 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.

- 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 that meets professionally recognized standards.

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

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

- 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.

- 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

(Rev. 12, 10-03-03)

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

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

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

- 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;

- 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);

- 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;

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

- 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

- 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

(Rev. 12, 10-03-03)

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

(Rev. 12, 10-03-03)

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

- Submit a report and your recommendation to OIG;
- 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

- 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.

- 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 the Inspector General (OIG)

(Rev. 12, 10-03-03)

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:

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

- The type of health care services involved;

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

- Pertinent documentary evidence;

- 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;

- 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;

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

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

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

- The professional qualifications of QIO reviewers; and
- Your sanction recommendation.

C. QIO Recommendation -- The report must specify:

- The sanction recommended;
- The amount of monetary penalty recommended, if applicable;
- The period of exclusion recommended, if applicable;
- The availability of alternative sources of services in the community, with supporting information; and
- 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 1004.100(c)).

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

(Rev. 12, 10-03-03)

A. Exclusion Sanction (See 42 CFR 1004.100(e)) -- If a decision is not made within 120 days (from date of receipt) by 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 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 indirect 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:

- The QIO that originated the sanction report;

- QIOs in adjacent areas;

- State Medicaid fraud control units and State licensing and accreditation bodies;

- Appropriate program contractors and State agencies;

- 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+COs, and Federally-funded community health centers where the practitioner or other person works;

- Medical societies and other professional organizations; and

- 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)):

- 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

- Notice of sanction is provided as specified at §9030.C.

9035 - Effect of an Exclusion Sanction on Medicare Payments and Services

(Rev. 12, 10-03-03)

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

- 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;

- 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

- 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:

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

- 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:

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

- 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

(Rev. 12, 10-03-03)

Exclusion will remain in effect until (See 42 CFR 1004.130):

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

- 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

(Rev. 12, 10-03-03)

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)).

9100 - Statutory Background

(Rev.12, 10-03-03)

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), PL 99-272, revised §1866, "Agreements with Providers of Services," of the Social Security Act (the Act), and added §1867, "Examination and Treatment for Emergency Medical Conditions and Women in Active Labor." This section prohibited hospitals with emergency departments from turning away or transferring patients without screening for emergency medical conditions, and stabilizing such conditions or determining that transfer is in the best interest of the patient. The Omnibus Budget Reconciliation Act of 1989 (OBRA 89), PL 101-239, further refined the requirements of §1154, "Functions of Peer Review Organizations," §§1866 and 1867 of the Act, and deleted the word "Active" from the title of §1867.

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90), PL 101-508, added §1867(d)(3). This section, titled "Consultation with Peer Review Organizations," is implemented by 42 CFR 489.24(g). These regulations require that, unless the delay would jeopardize the health or safety of individuals, or when there was no screening examination, CMS will request Quality Improvement Organizations (QIOs) to review cases where a medical opinion is necessary to determine a physician's or hospital's liability under §1867(d)(1) of the Act. The QIO will provide a report on their findings before the OIG may impose a Civil Monetary Penalty (CMP) against a physician or hospital or an exclusion sanction against a physician. The QIO must also offer the involved physician(s) and hospital(s) an opportunity to discuss the case and an opportunity to submit additional information before OIG may impose sanctions (except in cases where the delay would jeopardize the health or safety of individuals or when there was no screening examination).

9110 - Hospital Requirements

(Rev.12, 10-03-03)

Congress enacted the above provisions to prevent hospitals from refusing to treat individuals requiring emergency care or inappropriately transferring or discharging individuals with un-stabilized emergency conditions. An emergency medical condition is defined as a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, psychiatric disturbances, and/or substance abuse, such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual or unborn child in serious jeopardy; serious impairment to any bodily function; or serious dysfunction of any bodily organ or part.

With respect to a pregnant woman who is having contractions, an emergency condition occurs when there is inadequate time to affect a safe transfer to another hospital before delivery or when the transfer may pose a threat to the health or safety of the woman or the unborn child.

In addition, a participating hospital that has specialized capabilities or facilities, including (but not limited to) burn units, shock-trauma units, neonatal intensive care units, or, in rural areas, regional referral centers may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual. Violations of the provisions of §1867 of the Act are commonly called "dumping violations."

§1866 of the Act contains requirements related to §1867. The related provisions require hospitals and rural primary care hospitals to:

- Comply with the requirements of §1867;
- Have and enforce policies and procedures to ensure compliance;
- Maintain medical and other records related to individuals transferred to or from the hospital for 5 years from the date of transfer;
- Maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency condition; and
- Post in the emergency department (ED) a conspicuous sign(s) informing individuals of their rights under §1867 to examination and treatment, and appropriate transfer, as necessary, for emergency medical conditions and women in labor, regardless of ability to pay.

§1867 of the Act, as interpreted at 42 CFR 489.24(b), requires participating hospitals with EDs, as defined in the regulations, to provide an appropriate medical screening examination within the capacity of the hospital's ED, including ancillary services routinely available to the ED, to anyone (whether or not eligible for Medicare benefits and regardless of ability to pay) who comes by him or herself or with another person to the hospital (including the parking lot, ambulance owned or operated by the hospital regardless of location, and other units in the hospital) in order to determine whether or not he/she has an emergency medical condition. Unless the individual or a person acting on the individual's behalf refuses treatment or transfer after being advised by the hospital of the risks and benefits involved, the hospital must provide to an individual who is determined to have an emergency medical condition either:

- Further medical examination and treatment to stabilize the condition, including delivery of the child and placenta, if relevant; or

- Appropriate transfer of the un-stabilized individual or woman in labor to another medical facility after a physician has certified that such transfer is in the individual's best medical interest or after request by the individual or person acting on his or her behalf.

Patients who are not stable must either be treated until stabilized or transferred in accordance with the transfer requirements. The transfer requirements apply only to un-stabilized patients. Appropriate transfers must be affected through qualified persons and transportation equipment (if medically necessary) to a receiving hospital which has available space and qualified personnel to treat the individual and which has agreed to accept the individual. The medical record must accompany the individual. Note that hospitals with specialized capabilities/facilities cannot refuse transfer if they have the capacity to provide treatment.

9120 - Hospital Penalties for Noncompliance

(Rev. 12, 10-03-03)

This law applies regardless of whether or not a hospital will receive payment for services rendered. Participating hospitals may not delay the provision of an appropriate medical screening examination or further medical examination and treatment in order to inquire about the individual's method of payment or insurance status.

Hospitals that fail to meet the requirements of §1867 may have their provider agreements terminated. In addition, a hospital with fewer than 100 beds is subject to a Civil Monetary Penalty (CMP) of up to $25,000 for each negligent violation, while a hospital with 100 or more beds is subject to fines of not more than $50,000 per violation. A physician who is responsible for the examination, treatment, or transfer of an individual in a participating hospital, including a physician on-call for the care of such an individual, and who negligently violates a requirement, is subject to a CMP of not more than $50,000 for each such violation, and if the violation is gross and flagrant, or repeated, to exclusion from participation in Medicare and State health care programs. A participating hospital may not penalize or take adverse action against a physician because the physician refuses to authorize the transfer of an individual with an emergency condition that has not been stabilized. Additionally, individuals suffering personal harm as a direct result of a violation may bring civil action against the hospital for damages for personal injury under the law of the State in which the hospital is located. Medical facilities suffering financial loss as a direct result of a participating hospital's violation may bring a civil action against the hospital for financial loss under the law of the State in which the hospital is located. Filing a civil action is limited to a period of 2 years after the date of the alleged violation.

9130 - Regional Office Responsibilities

(Rev. 12, 10-03-03)

When the Department of Health & Human Services (DHHS) receives a complaint, information, or an allegation regarding inappropriate or lack of emergency medical screening, stabilizing treatment, or appropriate transfer, CMS' appropriate Regional Office is responsible for determining whether the complaint implicates §1867. If the Regional Office determines that the case involves a possible violation of §1867, the Regional Office is responsible for investigating the matter thoroughly. In this situation, the Regional Office may ask you to perform a 5-day review to support a possible termination action against a hospital that violates §1867. The 5-day physician review is done at the Regional Office's discretion and seeks medical expertise on whether the individual was adequately screened, examined, and treated. Your physician reviewer, a Regional Office physician or a State Agency physician with the necessary expertise, may do this review. It is not mandated that your physician reviewer perform the 5-day assessment review or that the hospital and/or physician be given an opportunity to respond to the allegations. The 5-day QIO physician review is a resource for the Regional Office to use in deciding the merits of the complaint.

The Regional Offices are to follow the chronological sequence of events that include:

- Acknowledging the complaint;
- Investigating the complaint;
- Asking for a 5-day physician review, if needed;
- Making a compliance determination; and
- Referring the case to OIG and you for the 60-day review.

Your 5-day review of a potential dumping case is advisory. If the Regional Office has concerns or questions about how your review was conducted or the information considered, it should contact you for clarification. If the Regional Office disagrees with your physician reviewer's medical assessment, it can make a different determination or can ask another physician outside of the QIO to review the case.

When the Regional Office determines that there is a violation, it will simultaneously forward all supporting documentation to you, for a 60-day review, and to OIG, Counsel to Inspector General, U.S. Department of Health & Human Services, Cohen Building - Room 5527, 330 Independence Avenue, S.W., Washington, D.C. 20201. The supporting documentation should include the State Agency report, a copy of the medical record(s), copies of letters to the hospital(s), and a copy of the 5-day advisory medical review, if such a review was requested by the Regional Office. The Regional Office should not delay forwarding the case if all documentation is not available. As a part of the 60-day review, you are required to provide the physician/hospital an opportunity to discuss the

case and an opportunity to submit additional information (See 42 CFR 489.24(g)(2) and §9150.C).

If you performed a 5-day review at the Regional Office's request and the Regional Office finds the allegation to be substantiated, your subsequent 60-day review required for the assessment of CMPs is considered a separate review and has no substantive bearing on the original Regional Office determination. If there is a discrepancy between the 5-day and 60-day review findings, that discrepancy may have an effect on whether OIG pursues the case for CMPs or physician exclusion, but it would not change the Regional Office's original determination of noncompliance. The Regional Office will have already followed its procedures and taken action as appropriate to protect other individuals who seek emergency care at the hospital.

The Regional Office may release your review results to the affected physician and/or hospital, and to the individual or his or her representative. Your physician reviewer's identity is confidential unless he or she consents to release his or her identity in accordance with the disclosure regulations (See 42 CFR 480.132 and 480.133).

9140 - State Agency Surveys

(Rev. 12, 10-03-03)

State Agencies perform Medicare certification surveys of hospitals that offer emergency services, including surveys for compliance with §1867 requirements. Regional Offices have the responsibility for authorizing certification surveys, including initial and re-certification surveys, validation surveys, and complaint investigations specifically focused on possible §1867 violations. The Regional Office initiates an investigation by directing the State Agency to conduct an onsite survey, which includes medical record reviews, policy and procedure reviews, and staff interviews. During the survey, the State Agency will make a copy of reviewed medical records that the State Agency believes may indicate violation(s) of §1867 requirements. The Regional Office will forward the medical records to you when requesting the 5-day advisory review or the 60-day review. However, if you are in a position (i.e., while performing other onsite reviews) to copy the patient's medical record more quickly than the State Agency or the Regional Office, you may do so.

9150 - QIO Review Responsibilities

(Rev. 12, 10-03-03)

A. Peer Review -- Select a physician to review the case who is a specialist (actively practicing in his or her specialty and, whenever possible, board-certified) in either the specialty of the physician who attended the patient or the specialty indicated by the condition of the patient who's care is under review. Whenever possible, the physician reviewer should practice in a similar setting as that of the physician who attended the

patient. Select a physician who agrees in writing to provide medical advice and to testify as an expert witness if necessary to properly adjudicate the case. Under most circumstances, you should be able to locate an acceptable specialist to review the case, but if you are unable to do so, notify the contact person in the referring Regional Office immediately.

NOTE: QIO review is not required in cases where a delay in effecting a sanction would jeopardize the health and safety of individuals or in situations where medical review is inappropriate (e.g., cases where the individual was denied a medical screening examination).

B. QIO Assessment: 5-Day Medical Advisory Review During Possible Termination Phase -- In the violation determination phase, at the Regional Office's option, the Regional Office may require you to provide a medical advisory review of the medical record(s) within 5 working days. In reviewing cases, you should consider the information a physician:

- Had, could have had, and should have had available to him/her at the time of the individual's visit; and

- Could have discovered reasonably and which was necessary to adequately care for the individual (i.e., the physician should have conducted an adequate history interview) at the time of the individual's visit.

As part of the review, you may acquire additional information either through further record reviews or interviews with the involved parties. However, all the information you consider should be limited to information the physician should have or could have considered at the time of the individual's visit.

The required assessment format is contained in Exhibit 9-1, “Physician Review Outline.” The review must contain the name of the physician or the hospital (or both where applicable), the name of the individual, and the dates and times the individual arrived at and was transferred (including discharged) from the hospital. The review must contain your physician reviewer's medical assessment, using statutory definitions, regarding whether:

- The individual had an emergency medical condition;

- The individual's emergency medical condition was stabilized;

- The individual was transferred appropriately;

- The certification that the benefits of transfer outweighed the risks was correct; and

- There were any medical utilization or quality of care issues involved in the case.

Provide a detailed narrative of your assessment of the individual's medical condition and attach this summary to the Physician Review Outline, if necessary.

The Regional Office may also require you to participate in an informal discussion that the Regional Office sets up with the affected physician/hospital to discuss the case. CMS has the authority and responsibility to determine whether the law has been violated. Your review will not state an opinion regarding whether a violation has occurred.

C. 60-day QIO Review: Possible OIG CMP/Exclusion Sanction Phase and Preparation of Report -- The Regional Office will notify you of confirmed dumping cases that it is forwarding to OIG. Before OIG can assess a CMP or exclude a physician from the Medicare program, you must review the case and provide a report of your findings to the originating Regional Office, who is responsible for forwarding the report to OIG. Your review includes offering the involved physician(s) and hospital(s) an opportunity to discuss the case and an opportunity to submit additional information before OIG may impose sanctions.

You must provide the notice of the opportunities to the affected physician/hospital (See 42 CFR 489.24(g)(2)), arrange the meeting, either by telephone or face-to-face, and provide the equipment for recording the meeting. The letter should identify the name of the individual and the date he or she presented to the emergency room.

Notify OIG at the appropriate Regional Office of the time and date the physician and, if appropriate, the hospital are meeting with you, or notify OIG that the physician and, if appropriate, the hospital have waived the opportunity to do so. Your final report to the Regional Office, who will forward a copy to the OIG, includes information the physician/hospital provides during or following the opportunity to discuss the case.

60 Calendar Day Timeframe -- The timeframe is as follows:

- Calendar Day 1: You receive the record from CMS.

- Calendar Day 15: Notify the involved physician and, if appropriate, the hospital by certified letter, return receipt requested, that you are reviewing the case, of your tentative findings based on information available to you at that time, and of the opportunity to discuss the case (in person or on the telephone). Inform the physician/hospital that he/she/it may submit additional information within 30 calendar days of receipt of letter. The letter must also contain the name of each individual who is the subject of the violation, the date on which each violation occurred, a statement that the rights to discuss the case and provide additional information will be waived if the invitation is not accepted, and a copy of 42 CFR 489.24. Notify the Regional Office and OIG of the time and date the physician/hospital wishes to discuss the case.

- Calendar Day 20: The above letter(s) is (are) presumed to have been received by the physician and/or hospital.

- Calendar Day 50: Discussion and physician/hospital submission of data, if desired, is complete. If a meeting occurs, all parties have a right to legal counsel. You may control the scope, extent, and manner of presentation of information. Provide equipment for recording the meeting so that, if requested by CMS or OIG, a verbatim transcript may be generated. If CMS or OIG requests a transcript, the affected physician/hospital may request that CMS provide a copy of the transcript.

- Calendar Day 60: Complete your review. The Regional Office must receive your final medical assessment report, both by telephone and letter (facsimile or mail), by the close of business. Your report must contain the name of the physician or the hospital (or both where applicable), the name of the individual, and the dates and times the individual arrived at, and was transferred (or discharged) from, the hospital.

    - In addition, the report contains your medical assessment regarding whether the individual had an emergency condition, whether the individual's emergency condition was stabilized, whether the individual was transferred appropriately, whether the certification that the benefits of transfer outweighed the risks was correct, and whether there were any medical utilization or quality of care issues involved in the case. Do not state an opinion or conclusion regarding whether a violation has occurred.

D. Issues in QIO Review of Violations of §1867 "Anti-dumping" Provisions -- §1867(d)(3) of the Act requires the Secretary to consult with you prior to imposition of CMPs against hospitals or physicians, or exclusions of physicians, for violations of §1867. You must specifically assess, and provide a report of your findings, as to whether the individual involved had an emergency medical condition that had not been stabilized. Such sanctions may be imposed prior to your review, however, only in cases in which a delay would jeopardize the health or safety of individuals.

There is a need for a clear understanding of the definition of "stabilize" and the relationship of this definition to an "appropriate" transfer. Keep in mind that §1867 requirements do not absolutely prohibit the transfer of an individual who has an emergency medical condition. In fact, the law requires only that certain transfers be protected. In order to transfer an individual with an emergency medical condition that has not been stabilized (as defined by the law), the transfer must meet specific criteria set forth in §1867(c).

Section 1867(e)(4) defines transfer very broadly, to include the movement, including the discharge, outside the hospital's facilities at the direction of any person employed by or associated with the hospital of an individual.

To stabilize, as defined in 42 CFR 489.24(b), means, with respect to an emergency medical condition, to either provide the necessary treatment to assure, within reasonable

medical probability, that no material deterioration of the condition is likely to result from, or occur during, the transfer of the individual from a facility, or, in relevant cases, that the woman has delivered the child and the placenta.

There is no reason for physicians to change their use of the term "to stabilize," and your physician reviewers should understand that there is nothing devious about a transferring physician's description of a patient as stable in situations where a supervised transfer would still be medically required in order to avoid likely material deterioration of the patient's condition.

In order to transfer an individual with an emergency medical condition that has not been stabilized, the following requirements must be met: the transfer must meet the criteria stated in §489.24(d)(2) for an appropriate transfer (See below); the individual, or a legally responsible person acting on their behalf, must request the transfer in writing after being informed of both the risks and benefits of the transfer and of the hospital's obligations under §289.24; and a physician must sign a certification, as specified in §489.24(d), that the benefits of transfer outweigh the risks imposed by the transfer. If a physician is not physically present in the emergency department at the time of transfer, a qualified medical person, as defined by the hospital in its by-laws or rules and regulations, must sign the certification after a physician, in consultation with the qualified medical person, agrees with the certification and subsequently countersigns it.

The criteria for an appropriate transfer include: the transferring hospital provides, within its capability, medical treatment that minimizes the risks to the individual's and/or the unborn child's health; the receiving hospital has available space and qualified personnel to treat the individual and has agreed to accept the individual; the transferring hospital sends to the receiving facility all the pertinent medical records (or copies thereof), including the consent and certification documentation; and the transfer is effected through qualified medical personnel and transportation as indicated by the patient's condition.

A hospital has met its obligations under 42 CFR 489.24 if it offers a transfer in accordance with 489.24(d) and the individual or a person legally acting on the individual's behalf refuses to consent to transfer. The hospital should take all reasonable steps to obtain the individual's written refusal. If the patient refuses the transfer and refuses to sign a statement regarding informed refusal, the hospital may document this refusal as they see fit.

Additional interpretive guidance relating to EMTALA regulations can be found in the State Operations Manual, Appendix V, Section "Interpretive Guidelines-Responsibilities of Medicare Participating Hospitals in Emergency Cases."

E. Review Process -- The Regional Office will provide you with a copy of the patient's medical record(s), the ambulance record, if any, and instructions to use the assessment format entitled, "Physician Review Outline" (See Exhibit 9-1), or an alternative format that contains all the information listed in Exhibit 9-1. The Physician Review Outline

summarizes the law's medical definitions within the text of its questions. The use of this document is highly recommended. If using this format, proceed as follows:

- The referring Regional Office completes Section I of the document, providing identifying information about the patient as well as admission and discharge information, and will notify you whether to use the 60- or 5-day timeframe;

- Your physician reviewer completes Section II with yes/no responses and rationale (or NA if the particular question is not applicable to the case) regarding whether specific requirements of the law were met;

- Your physician reviewer must agree to provide advice, if additional development is necessary to properly adjudicate any issues, and testimony as an expert witness;

NOTE: You are precluded from disclosing information that would identify a QIO reviewer without his or her consent (42 CFR 480.133(a)(2)(iii)). Therefore, you must ensure that each physician reviewer is aware of the potential need to serve as expert witnesses and, prior to review of cases, secure a statement of willingness to serve as an expert witness to certify his or her availability for expert witness testimony. Maintain a file that contains the names of peer reviewers (e.g., physicians). The names of individuals who reviewed specific medical records are provided upon request from the OIG for expert witnesses.

- Your physician reviewer must sign and date the completed document; and

- You fax the completed report by the review date given in Subsection C.

F. Content of Report -- Exhibit 9-1, "Physician Review Outline," is provided as a strongly recommended assessment format for your convenience. If the Regional Office does not provide you with the Physician Review Outline, you may be instructed to use another format. Your report must include the following:

- Whether an emergency medical condition existed and whether it was treated and stabilized within the definitions and requirements contained in §1867 of the Act and the implementing regulations;

- The reviewing physician's(s') written statement of responses and willingness to provide advice on the additional development of the case, and to testify as an expert witness; and

- The basis for your determinations.

If your physician reviewer determines that the patient was stable prior to being discharged, but other quality care concerns were identified, document this information in the report. To review those quality concerns, follow the instructions in Chapter 4 of the QIO Manual.

G. QIO Payment -- All reasonable costs related to §1867 review activities are reimbursable. Submit a request for contract modification to the CMS contracting officer, in accordance with current guidelines to obtain this additional funding.

H. Reporting Results of Review to CMS -- Submit to CMS a report of cases referred to you for review and the required data in accordance with the Users' Guide.

9200 - Scope of QIO Fraud and Abuse Review Activities

(Rev. 12, 10-03-03)

In accordance with your contract, make available the medical expertise necessary to render quality of care and medical necessity decisions in cases referred to you by CMS. The referrals may involve Medicare services in settings other than those normally covered by your reviews.

If you identify possible practice or performance patterns of fraud or abuse situations during your regular review activity, regardless of whether these situations/issues are within your area of responsibility, notify the Federal or State fraud and abuse enforcement agency that has jurisdiction, or in the case of a provider, the appropriate intermediary component. You may notify such Federal or State fraud and abuse enforcement agencies of incidents of suspected fraud or abuse that do not reflect a practice or performance pattern.

9210 - Review Responsibility

(Rev. 12, 10-03-03)

When you receive a fraud or abuse review referral from any source other than CMS, you must obtain approval in advance from your Regional Office Project Officer. All requests for your review from outside agencies, including OIG and the Department of Justice (DOJ), must be approved by CMS Central Office. Every request must be in writing, must offer clear and cogent rationale, and must be submitted through your Project Officer in the CMS Regional Office. Upon receipt of such a request, you must:

- Analyze the request to determine the appropriate staff hours and associated budget you will require; and

- Submit both the request and your cost analysis to your Project Officer.

NOTE: DO NOT BEGIN TO PERFORM THE WORK.

Your Project Officer will notify you if the review is to be performed under your QIO contract. For these cases, investigate the issues and decide on any matters involving

medical necessity or quality of care. Provide written evaluations of all cases to CMS or the outside agency, as appropriate, within 45 calendar days of receipt of the referral. Physician reviewers should be board-certified (although it is not required) and actively practicing in the same specialty or specialties as the physician who treated the patient whose case resulted in the review. In addition, whenever possible, the physician reviewer should practice in a setting similar to that of the physician who attended the patient. CMS or the outside agency will ensure that all relevant case materials are available to you on the day the case is referred for investigation. Therefore, the entire 45 days is available to complete your review.

9220 - Evaluation Report

(Rev. 12, 10-03-03)

Your written report must contain:

- Your findings as to the medical appropriateness, necessity, and quality of the services provided;
- The basis for your determination; and
- If necessary, your advice on additional development needed to properly adjudicate any remaining issues.

The report must be signed by your authorized representative (e.g., the Executive Director or Medical Director) and include the titles and qualifications of the physician reviewer(s). When you forward your report, include with it all material provided to you by CMS or the outside agency. After your evaluation is reviewed, you may be directed to initiate a sanction recommendation if the issues found are within your area of responsibility. Otherwise, your involvement with the particular case usually ends with the evaluation report.

9230 - Availability of Expert Witness

(Rev. 12, 10-03-03)

Physicians reviewing medical records must be available for expert witness testimony regarding the medical findings contained in your evaluation report. The role of an expert witness in each case is given in instruction(s) from the referring component. Expert witnesses should be board-certified (although it is not required) and actively practicing in the same specialty or specialties as the physician or physicians who treated the patient whose case result is under review. In addition, whenever possible, the expert witness should practice in a setting similar to that of the physician who attended the patient. Ensure that physician reviewers are aware of the potential need to serve as expert witnesses.

Prior to review of cases, secure a statement of willingness to serve as an expert witness from the physician reviewers to certify their availability for expert witness testimony.

Maintain a file that contains the names of peer reviewers (e.g., physicians). Upon request from the OIG, DOJ, or other outside agency for expert witnesses, provide the names of individuals who reviewed specific medical records.

9240 - Reopening of Cases

(Rev. 12, 10-03-03)

Cases previously reviewed by you may be reopened at any time under the following circumstances:

- Whenever there is a finding that a claim for service involves fraud or a similar abusive practice that does not support a finding of fraud, review and deny payment (42 CFR 476.96(c)(1)).

- Whenever there is a finding that an initial denial determination or a change in Diagnosis Related Groups (DRG) determination was obtained through fraud or a similar abusive practice that does not support a finding of fraud, reopen and revise the denial or DRG change (42 CFR 476.96(c)(2)).

- Whenever there is a finding that a reconsidered determination review or a re-review determination of a DRG change was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud, reopen and revise at any time the reconsidered determination or the DRG change, or notify the appropriate ALJ or Appeals Council so that they may reopen a decision of theirs (42 CFR 478.48(c)).

Exhibit 9-1 - List of OIG Field Offices

(Rev. 12, 10-03-03)

REGION I - BOSTON Field Office Regional Inspector General for QI P.O. Box 8767 Government Center Station Boston, MA 02114 617-565-2660 (Fax) 617-835-3750	REGION V - CHICAGO Field Office Regional Inspector General for QI P.O. Box 2197 Chicago, IL 60690 312-353-2740 (Fax) 312-353-0147
REGION II - NEW YORK Field Office	REGION VI - DALLAS Field Office

Regional Inspector General for QI P.O. Box 3209 Church Street Station New York, NY 10008 212-264-1690 (Fax) 212-264-6307	Regional Inspector General for QI 1100 Commerce Street, Room 4E1-B Dallas, TX 75242 214-767-8406 (Fax) 214-767-2039
REGION III - PHILADELPHIA Field Office Regional Inspector General for QI P.O. Box 8049 Philadelphia, PA 19101 215-596-6796 (Fax) 215-596-4050	REGION VII-VIII - DENVER Field Office Regional Inspector General for QI P.O. Box 299 Denver, CO 80201 303-844-5621 (Fax) 303-844-2529
REGION IV - ATLANTA Field Office Regional Inspector General for QI P.O. Box 2288 Atlanta, GA 30301 404-331-2131 (Fax) 404-730-2308	REGION IX-X - SAN FRANCISCO Field Office Regional Inspector General for QI P.O. Box 42516 San Francisco, CA 94101 415-556-8880 (Fax) 415-556-4161 or 415-556-9513

Exhibit 9-2 - Initial Sanction Notice of Substantial Violation in a Substantial Number of Cases

(Rev. 12, 10-03-03)

QIO LETTERHEAD

(Name and Address of Practitioner or Provider)

(Dear Dr. _____:) or (Dear Mr./Mrs./Ms. _____:)

The purpose of this notice is to inform you that (Name of QIO), the Quality Improvement Organization for the State of (Name of State), has concluded that there is a reasonable basis for determining that (you have) (your hospital has) violated (your) (its) obligation(s) under §1156 of the Social Security Act (the Act) to assure that the services provided to program beneficiaries are:

SELECT OBLIGATION(S) VIOLATED

Choose (1), (2), and/or (3) from below:

(1) Provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care;

and/or (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion and at such time as may be required.

(Name of QIO) has concluded that there is a reasonable basis for determining that (you have) (your hospital has) failed to comply substantially with your statutory obligations in a substantial number of cases.

- If the QIO determines finally that such a violation has occurred and recommends a sanction to the Secretary of the Department of Health & Human Services (DHHS), and if a final determination is made by the Secretary through the Office of the Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE EXCLUDED FROM PARTICIPATING IN THE MEDICARE PROGRAM AND ANY STATE HEALTH CARE PROGRAM AS DEFINED IN SECTION 1128(h) OF THE ACT EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME OR, ALTERNATIVELY, REQUIRED TO PAY THE UNITED STATES GOVERNMENT A MONETARY PENALTY AS A CONDITION FOR (YOUR) (YOUR HOSPITAL'S) CONTINUED PARTICIPATION IN THE MEDICARE AND STATE HEALTH CARE PROGRAMS. Therefore, you are strongly encouraged to contact the (Name of QIO) to provide additional information and/or meet with (Name of QIO).

- An in-depth discussion of the cases involved is included below in the case summary section.

- You will be given an opportunity to provide additional information and/or request a meeting with (Name of QIO). Although no sanction recommendation will be made to OIG after this meeting, it is nevertheless an important first step in the sanction process. The section entitled: "additional information" explains how to submit the additional information and/or request a meeting.

- Enclosure 1 provides a brief overview of the sanction process.

OBLIGATIONS

Section 1156 of the Act and 42 U.S.C. 1320c-5 impose certain obligations upon health care practitioners and other persons who furnish or order services under Medicare or State health care programs. These obligations are to assure that the services are: (l) provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care; and (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion and at such time as may be required. See also 42 CFR Part 1004.

QIO RESPONSIBILITIES

The Secretary of DHHS has a contract with the (Name of QIO) to review Medicare services. Section 1156(b) of the Act provides that if (Name of QIO) determines that a

practitioner or other person has failed to comply substantially with any of these obligations in a substantial number of cases or has grossly and flagrantly violated such obligation in one or more instances, (Name of QIO) must report such determinations to the Department of Health & Human Services' OIG, along with a recommendation for appropriate sanction actions. If OIG agrees with the QIO's recommendation and finds that the practitioner or other person is unable or unwilling substantially to comply with his/her statutory obligations, OIG may impose a sanction. These sanctions may include exclusion from eligibility to provide services to patients of the Medicare and State health care programs on a payable basis either permanently or for a specified period of time. Alternatively, payment of a monetary penalty in the amount of the actual or estimated cost of medically improper or unnecessary services may be required as a condition for continued eligibility to receive payment under the programs.

VIOLATION OF OBLIGATION - CASE SUMMARY

The (Name of QIO) has reviewed medical records pertaining (to your medical practice), or (to the health care services and items furnished in your hospital). As a result of this review, the (Name of QIO) is concerned that (your medical practice) (your hospital's health care services and items furnished to program beneficiaries), as documented in these medical records, does not appear to comply substantially with the obligations imposed on (you) (your hospital) under the Act in the following respects:

(Include an in-depth discussion of each situation, circumstance, or activity that resulted in a violation as well as the obligation involved.)

EXAMPLES:

Providing Services Not Medically Necessary and/or Not Provided in the Most Economical Setting

1. Chart No. _____ Admission Date _____

    - Hospitalization was totally unnecessary for this active, 72-year-old male who was not acutely ill and did not receive intensive medical services. All he required was a protective environment and assistance with activities of daily living. His dementia, which resulted in his not taking medications properly, was caused by Alzheimer's disease.

2. Chart No. _____ Admission Date _____

    - Although this patient had lowered hemoglobin, it was not so low that the 65-year-old female required transfusing. The diagnostic studies needed to ascertain the cause of her anemia could have been performed safely and effectively on an outpatient basis.

Providing Services Which Do Not Meet Professionally Recognized Standards of Care

1. Chart No. _____ Admission Date _____

    - Several glaring omissions exist in the initial evaluation and management of this non-surgical patient. For example, recent hematemesis is mentioned in the history, but no nasal gastric tube was passed and no rectal exam was performed.

    - In addition, no additional Hemoglobin or Hematocrits were obtained. A marked deficiency of management occurred on the 2nd day of hospitalization when the patient spiked a temperature to 104°F, accompanied by shaking chills and was given Aspirin. The temperature remained elevated in the range of 102.6°-103°F for the next two days. No evaluation or treatment of the elevated temperature was undertaken until the fifth day of the stay.

2. Chart No. _____ Admission Date _____

    - This insulin-dependent diabetic was admitted for a cholecystectomy. Her preoperative blood sugar was 103, but this was drawn one week prior to admission. Her post-operative course was eventful in that she had an elevated temperature of 103-104 degrees on the 3rd and 4th postoperative days, for which the physician ordered the administration of IV antibiotics. A fasting blood sugar drawn on the third post-operative day was 300. No other laboratory studies were performed. On the fifth post-operative day, the day before her discharge, she complained of lower abdominal pain and was noted on that date, as well as the day of discharge, to be lethargic. Her fasting blood sugar on the day of discharge was 380. Since there were no studies to determine the source of her fever, the evaluation of her febrile state was not adequate. In addition, the evaluation of her diabetic condition was not adequate to determine the possible presence of impending diabetic ketoacidosis.

-ETC.-

A summary of the information considered by (Name of QIO) in arriving at the above findings is enclosed.

CORRECTIVE ACTION PLAN (if applicable)

Describe the method and timeframe for correcting the identified violation(s).

ADDITIONAL INFORMATION

If you do not believe that the care rendered in the above cases is in violation of (your) (your hospital's) obligations under Section 1156, you may, within 20 days of the date of

receipt of this notice, submit additional information to, and/or request a meeting with (Name of QIO). The date of receipt is presumed to be 5 days after the date on this letter. The additional information and/or request for a meeting should be submitted to:

(Contact Person)
(Name of QIO)
(Address)

IF YOU REQUEST A MEETING

The purpose of the meeting is to allow (you) (your hospital) to present (your) (hospital's) views regarding the care rendered to program beneficiaries in the above cited cases, to discuss those views with the (Name of QIO), and to assist (Name of QIO) in making its determination as to whether such care failed to comply with the statutory obligations of Section 1156 of the Act.

- The meeting will be held within 30 calendar days of your request. The (Name of QIO) will contact you regarding date, time, and place for the meeting. The meeting date may be extended, but only if you can demonstrate good cause.

- You may have an attorney represent (you) (your hospital) at the meeting. The attorney may make opening and closing statements, assist you in presenting expert testimony, and ask clarifying questions.

- You may bring professional (expert) witnesses to testify on (your) (your hospital's) behalf. The purpose of the witnesses is to discuss relevant medical views pertaining to the above-cited cases.

You should bring to the meeting all-relevant documentation (including office records) regarding the cases in question to fully support your views.

Sincerely yours,

QIO Medical Director

Enclosures:
(1) Overview of the Sanction Process
(2) Summary of Information Used in Determining Findings

Enclosure 1: Overview of Sanction Process for Substantial Violations

INITIAL SANCTION NOTICE*

Twenty days to submit additional information and/or request a meeting and consideration of corrective action (if appropriate)

QIO DECISION

Not substantial violation
Second sanction notice
Thirty days to submit additional information and/or request a meeting and consideration of corrective action (if appropriate).

QIO DECISION

Not substantial violation
Final sanction notice recommendation to OIG
Thirty days to submit additional information to OIG

OIG DECISION

Do not sanction
Sanction
Right to Appeal to an administrative law judge (including a pre-exclusion hearing, if applicable)

*The enclosed letter is an initial sanction notice.

(Note: the above text to be converted to flowchart form - SME.)

Exhibit 9-3 - Second Sanction Notice of Substantial Violation in a Substantial Number of Cases

(Rev. 12, 10-03-03)

QIO LETTERHEAD

(Name and Address of Practitioner or Provider)

(Dear Dr. _____:) or (Dear Mr./Mrs./Ms. _____:)

[The purpose of this notice is to inform you that (Name of QIO) has reviewed the additional information you submitted in response to our letter of _____. It has been determined that this material does not modify the original determination of (Name of QIO) that there was a reasonable basis for determining that (your medical practice does) (the health care services and items furnished in your hospital do) not comply with the obligations imposed on you under Section 1156 of the Social Security Act (the Act) and that, in fact, specific violations of (your) obligations do exist.]

AND/OR

[The purpose of this letter is to advise you that, based on its most recent review, the (Name of QIO) has concluded that there is a reasonable basis for determining that (you have) (your hospital has) failed to substantially comply with the corrective action plan you submitted to the (Name of QIO) on (Date) and which was approved on (Date). The (Name of QIO) has determined that previously identified problems persist.]

(Name of QIO) has concluded that there is a reasonable basis for determining that (you have) (your hospital has) violated your obligation to assure that the services provided to program beneficiaries are:

SELECT OBLIGATION(S) VIOLATED

Choose (1), (2), and/or (3) from below:

(1) Provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care; and/or (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion and at such time as may be required.

- If the QIO determines finally that such a violation has occurred and recommends a sanction to the Secretary of the Department of Health & Human Services (DHHS), and if a final determination is made by the Secretary through the Office of the Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE EXCLUDED FROM PARTICIPATING IN THE MEDICARE PROGRAM AND ANY STATE HEALTH CARE PROGRAM AS DEFINED IN SECTION 1128(h) OF THE ACT EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME OR, ALTERNATIVELY, REQUIRED TO PAY THE UNITED STATES GOVERNMENT A MONETARY PENALTY AS A CONDITION OF (YOUR) (YOUR HOSPITAL'S) CONTINUED PARTICIPATION IN THE MEDICARE AND STATE HEALTH CARE PROGRAMS.

- Because of the serious nature of a final determination by the QIO to recommend a sanction to OIG, you are strongly encouraged to contact (Name of QIO) to provide additional information to assist you in responding to the initial determination of a violation and/or to set up a meeting with the (Name of QIO). THE MEETING WITH THE QIO WILL BE YOUR ONLY OPPORTUNITY TO DISCUSS YOUR SITUATION WITH THE QIO BEFORE IT MAKES A FINAL DECISION WHETHER TO RECOMMEND TO OIG THAT (YOU) (YOUR HOSPITAL) BE SANCTIONED.

- An in-depth discussion of the cases involved is included below in the case summary section. A detailed synopsis of cases is also enclosed.

- The section entitled: "additional information" explains how to submit the additional information and/or request a meeting.

- Enclosure 1 provides a brief overview of the sanction process.

VIOLATION OF OBLIGATION - CASE SUMMARY

The (Name of QIO) has reviewed medical records pertaining to (your medical practice) or (to the health care services and items furnished in your hospital) (if applicable: and the additional information you submitted to (Name of QIO)). As a result of this review, the (Name of QIO) has a reasonable basis for determining that (you have) (your hospital has) failed to comply substantially with the obligations imposed on you under the Act in the following respects:

1. Chart No. _____ Admission Date _____

    - Conclusion:

2. Chart No. _____ Admission Date _____

    - Conclusion:

-ETC.-

A copy of the material used by the (Name of QIO) in arriving at this initial determination is enclosed. Also enclosed is a detailed case synopsis identifying each case reviewed by the (Name of QIO), the issues raised by the (Name of QIO), your response to the issues raised, and a final determination by the (Name of QIO). (See Exhibit 9-4 for Synopsis of Cases.)

It has also been determined that the violations of (your obligations) (your hospital's obligations) under Section 1156 of the Act are serious enough to warrant recommending to the Department of Health & Human Services' OIG that sanctions be imposed upon (you) (your hospital) pursuant to Federal statute and regulations. The sanction to be recommended is [exclusion from participation in the Medicare and State health care programs for a period of _____ years] OR [a monetary penalty in the amount of _____ to be paid to the Government of the United States as a prerequisite for (your) (your hospital's) continued participation in the Medicare and State health care programs]. If OIG agrees with the QIO's recommendation and finds that (you are) (your hospital is) unable or unwilling substantially to comply with your statutory obligations, OIG may impose a sanction.

NOTE: If a corrective action plan was offered, include information here.

ADDITIONAL INFORMATION

By this letter you are hereby formally notified that you may submit to the (Name of QIO) within 30 days of the date of receipt of this letter additional information which you feel

might modify our position and/or a written request to meet with us to review and discuss case specifics. The date of receipt is presumed to be 5 days after the date on this letter.

The additional information and/or request for a meeting should be submitted to:

(Contact Person)
(Name of QIO)
(Address)

IF YOU REQUEST A MEETING

The purpose of the meeting is to allow (you) (your hospital) to present (your) (your hospital's) views regarding the care rendered to program beneficiaries in the above-cited cases, to discuss these views with the (Name of QIO), and to respond to the initial determination of a violation before (Name of QIO) makes a final decision whether to recommend a sanction to OIG.

- The meeting will be held within 30 calendar days of your request. The (Name of QIO) will contact you regarding date, time, and place for the meeting. The meeting date may be extended, but only if you can demonstrate good cause.

- You may have an attorney represent (you) (your hospital) at the meeting. The attorney may make opening and closing statements, assist (you) (your hospital) in presenting expert testimony, and ask clarifying questions.

- (You) (Your hospital) may bring professional (expert) witnesses to testify on (your) (your hospital) behalf. The purpose of the witnesses is to discuss relevant medical views pertaining to the above-cited cases.

- The (Name of QIO) will make a verbatim record of the meeting and provide this record to you as soon as is practicable, but no later than the time a sanction recommendation (if any) is forwarded to OIG.

- You should bring all relevant documentation (including office records) regarding the cases cited above to the meeting to fully support your views.

- You may request that the physician at the QIO who determined that there is a reasonable basis for concluding that (you have) (your hospital has) violated one or more obligations under the Act appear at the meeting to discuss the basis for his/her determination, although the QIO does not have to grant that request.

- You may object to any member of the QIO being permitted to participate in the decision of (your) (your hospital's) case if you believe that he/she has a personal bias against or is in direct economic competition with (you) (your hospital).

- If, prior to the end of the meeting with (Name of QIO), you believe that additional documentation exists which relates to the cases or issues discussed at the meeting, you may request an additional period of time (not to exceed 5 days) to submit the relevant information to (Name of QIO). If the (Name of QIO) concurs, it may grant an additional period of time (not to exceed 5 days) for the submission of this information).

Sincerely yours,

QIO Medical Director

Enclosures:
(1) Overview of Sanction Process
(2) Summary of Information Used in Determining Findings
(3) Case Synopsis
(4) Current QIO Instruction

Enclosure 1: Overview of Sanction Process for Substantial Violations

INITIAL SANCTION NOTICE

Twenty days to submit additional information and/or request a meeting and consideration of a corrective action (if applicable)

QIO DECISION

Not substantial Second sanction notice*
Violation
Thirty days to submit additional information and/or request a meeting and consideration of corrective action (if appropriate)

QIO DECISION

Not substantial Final sanction notice
Violation recommendation to OIG
Thirty days to submit additional information to OIG

OIG DECISION

Do not sanction
Sanction
Right to appeal to an administrative law judge (including a pre-exclusion hearing, if applicable)

*The enclosed letter is a second sanction notice.

[Note: the above text to be converted to flowchart form - SME.]

Exhibit 9-4 - Synopsis of Cases for Use With 30-Day Letter

(Rev. 12, 10-03-03)

(Substantial Number of Cases Only)

Case # _____	Physician: _____
Admitted: _____	Discharged: _____

Principal Diagnosis:	Diverticulosis
Secondary Diagnosis:	Hemorrhoids and Arteriosclerotic heart disease
Procedures Performed:	Sigmoidoscopy Barium Enema Colonoscopy

An 80-year-old male admitted in stable condition with history of constipation, pain in lower left abdominal quadrant, and occasional rectal bleeding. The admitting/working diagnosis was possible sigmoid tumor. No outpatient evaluation was performed prior to admission. The hospital course was unremarkable and pain due to constipation was attributable to poor dietary habits.

Issues Raised and Discussed With Practitioner:

1. Why wasn't there some outpatient workup to determine cause of rectal bleeding and extent of bleeding?

2. A colonoscopy was performed in the presence of a normal barium enema. The validity of performing this study is in question, particularly since a sigmoidoscopy was performed a few days before the colonoscopy and revealed the presence of large internal hemorrhoids.

3. There was no evidence of instructions about importance of diet, exercise, and adequate fluid intake on prevention of constipation.

Oral Arguments or Written Information Provided by Practitioner:

1. A rectal examination performed in the office prior to admission was positive for occult blood. Complete blood count not performed because frank bleeding just started; therefore, Hgb and Crit would not yet be deviant.

2. He complained of weakness; therefore, the preparation for a barium enema would have made him weaker. Since he was not bleeding at the time of the

sigmoidoscopy, the decision was made to perform a more extensive examination. I believed that the colonoscopy was more reliable than a barium enema.

3. This man is 80 years old and has not followed my instructions in the past.

QIO Evaluation of Arguments or Written Information Presented:

1. A rectal examination is not an adequate workup for a patient who was not acutely ill (i.e., complained of occasional bleeding). The CBC performed upon admission and on the day following admission indicated an Hgb of 12 and a Crit of 36, certainly well within normal range.

2. The admission history and physical examination states that the patient was "in no acute distress." No measures were taken (either prophylactically or therapeutically) to indicate that the patient was in any acute distress. The prep for the colonoscopy is not any less stringent than the prep for the barium enema.

3. Since ongoing treatment of his condition is so dependent upon such items as dietary habits, it is most important that this be emphasized and reinforced multiple times with an aged individual.

CONCLUSION OF QIO:

The physician violated his statutory obligations as follows:

1. Substantially violated his obligation to order or furnish only care that is medically necessary by:

    a. Unnecessarily admitting patient to the hospital in that the diagnostic studies performed could have been performed on an outpatient basis.

    b. Inappropriately performing a colonoscopy in the presence of normal barium enema results.

2. Substantially violated his obligation to provide such evidence of medical necessity and quality of health care services provided as a QIO may reasonably require by failing to adequately document the reasons for admission and performance of procedures.

3. Substantially violated his obligation to furnish care which meets professionally recognized standards of quality by failing to provide adequate instructions to prevent readmission of this patient in the future.

Case # _____ Physician: _____
Admitted: _____ Discharged: _____

Principal Diagnosis:	Peripheral vascular disease
Secondary Diagnosis:	Hypokalemia, History of Cancer of Uterus
Procedures Performed:	Venogram
	Arteriogram

A 73-year-old female admitted to hospital because of crampy leg pain. Admitting/working diagnosis was thrombophlebitis.

Issues Raised and Discussed With Practitioner:

1. Admission history and physical examination failed to support the diagnosis of thrombophlebitis; however, the patient received parenteral Heparin therapy for four days without sufficient documentation to support its use.

2. Progress notes for four days were illegible, and the progress notes written on two days do not permit assessment of need for hospital level of care.

3. Physical examination documents the presence of an abdominal fistula. There is no further reference made to this significant abnormality.

4. Why was there no review of old records in this patient who could not give an adequate history of past illnesses?

5. No documentation of pelvic examination in this patient with previous total abdominal hysterectomy with radiation for uterine cancer.

Oral Arguments or Written Information Provided by Practitioner:

1. There was marked edema of the leg, and she responded to touch as if her leg was painful; therefore, I believed that this patient had a thrombophlebitis. (Since this patient was confused and uncooperative, I was unable to elicit correct responses to questions asked about symptomatology.) I did not see the necessity of performing a venogram before beginning intravenous Heparin therapy since this is the treatment of choice for acute thrombophlebitis.

2. All physicians have illegible handwriting. All that is important is that I can read what I wrote. If the patient got better, why should the QIO nitpick about the quality of my handwriting?

3. I saw no need to investigate the abdominal fistula since it was evident to me that she had it for a number of years, it was not draining, and she did not exhibit any signs of an infection in this area.

4. She was admitted in the evening, and the medical records department was closed.

5. There was no need to subject this patient to a pelvic examination even if she had cancer in the past.

QIO Evaluation of Arguments or Written Information Presented:

1. The edema and redness of the legs were bilateral, not just contralateral. There also was not contralateral redness. Given the fact that the signs and symptoms do not lend themselves to an appropriate conclusion that the patient had an acute thrombophlebitis, treatment with intravenous Heparin was not medically indicated without additional diagnostic findings to confirm the diagnosis.

2. The fact that some physicians have poor handwriting is no excuse to have practically no progress notes for the stay. It is imperative that all people rendering care (as well as internal and external review entities) be able to read the progress notes so that they can understand what the physician perceives is happening to the patient (for example, if a particular treatment modality is improving the patient's condition).

3. There was an inadequate description of the abdominal fistula in the chart. Given the information submitted, we agree that non-treatment of the fistula is not an issue.

4. The medical records could have been obtained the next morning. It is essential to have the past records to adequately care for the patient.

5. We continue to believe that a pelvic examination should have been performed. Also, given the history of radiation for uterine cancer, the edema of the legs could have been related to metastatic disease, and there was no workup for this.

CONCLUSION OF QIO:

The physician violated his statutory obligations as follows:

1. Substantially violated his obligation to order or furnish care which meets professionally recognized standards of quality by:

    a. Failing to understand the appropriate diagnosing of thrombophlebitis.

    b. Failing to document a pelvic examination in a patient with previous total hysterectomy with radiation for uterine cancer.

2. Substantially violated his obligation to provide such evidence of medical necessity and quality of health care services provided as a QIO may reasonably require by:

a. Failing to write a progress note on two days and failure to write legible progress notes on four days.

b. Failing to obtain the previous medical records and include vital information from those records in the medical records for the stay.

Case # _____ Physician: _____
Admitted: _____ Discharged: _____

Principal Diagnosis: Chronic Obstructive Pulmonary Disease
Secondary Diagnosis: Myocardial Ischemia
Arteriosclerotic Heart Disease
Diabetes Mellitus, Adult Onset
Urinary Tract Infection

A 78-year-old male with past history of myocardial ischemia admitted with acute crushing chest pain, radiating down his left arm. He also complained of shortness of breath.

Issues Raised and Discussed With Practitioner:

1. Inappropriate admission to a hospital without active coronary care unit.

2. Inadequate evaluation of this patient's complaints of chest pain and shortness of breath. Although a LDH and CPK were performed as part of the SMA-21, no cardiac enzymes were drawn, and no additional cardiac evaluation was performed, other than an EKG.

3. The initial ABGs were abnormal; yet, no follow-up ABGs or other studies were performed. In addition, there were no changes to the treatment plan based upon the abnormal ABGs.

4. Why wasn't a medical consultation ordered?

Oral Arguments or Written Information Provided by Practitioner:

1. The patient's family phoned and stated that the patient had acute chest pain. Since I happened to be at XYZ Hospital, where I only occasionally practice, I told them I would meet them there.

2. Since his initial enzymes were normal, I saw no need to have them repeated. This hospital was unable to perform many of the sophisticated tests one would perform in other hospitals.

3. Given he had a history of underlying lung disease and I had seen him with ABGs that abnormal before, I did not believe that I needed to intervene. I also believed

that the abnormal ABGs were as a result of his hyperventilating due to his apprehension.

4. I had cared for this gentleman for a number of years, and I felt that if I called in a consultant, it would frighten him. I have more than adequately cared for people with the same problems in my 52 years of medical practice.

QIO Evaluation of Arguments or Written Information Presented:

1. The XXX Hospital, which is less than half a block away from the XYZ Hospital, has a Coronary care unit. Since the physician has privileges at that hospital also, he should have instructed the patient's family to take him there, as the admission history and physical examination indicates that he complained of crushing chest pain, unlike any he had ever experienced.

2. The initial enzymes many times will not be indicative of the presence of an acute infarct. Since the admission history states that he arrived at the hospital within 30 minutes of the onset of the pain, the blood work was performed early in relation to the onset of symptoms.

3. The ABGs, at a minimum, should have been repeated to ascertain if there was something that needed to be addressed, either prophylactically or therapeutically. The fact that the ABGs had been that abnormal in the past is not relevant. The acute exacerbation of a chronic lung disease can cause havoc with the treatment of a patient.

4. A surgeon, faced with an acute medical crisis, particularly in one of his non-surgical patients, should obtain a medical consultation. The gentleman's fears could have been assuaged by reassuring him that he was being cared for by a "team" of health care professionals.

CONCLUSION OF QIO:

The physician violated his statutory obligations as follows:

1. Substantially violated his obligation to furnish care which meets professionally recognized standards of quality by:

    a. Failing to investigate adequately the chest pain, which was the presenting complaint.

    b. Failing to repeat blood gases on a patient admitted with abnormal blood gases.

    c. Failing to adequately treat a patient with abnormal blood gases.

d. Failure to transfer patient to medical service in the absence of a surgical problem.

Case # _____ Physician: _____
Admitted: _____ Discharged: _____

Principal Diagnosis: Noninfectious gastroenteritis
Secondary Diagnosis: Arteriosclerotic Heart Disease
Diabetes Mellitus, Adult Onset

A 75-year-old female with history of nausea, vomiting, and diarrhea of three days duration. Although patient complained of weakness, admission electrolytes were normal, and no additional diagnostic studies were obtained other than a chest X-ray, EKG, and SMA-21. She received intravenous fluids; however, the rate of administration was ordered as KVO.

Issues Raised and Discussed With Practitioner:

1. Inappropriate admission to a hospital for a clinically stable patient.

2. If patient wasn't stable, why weren't additional diagnostic studies performed or fluid replacement more aggressive?

Oral Arguments or Written Information Provided by Practitioner:

1. The patient's family phoned and reported that she had nausea, vomiting, and diarrhea of 3-days duration. Knowing that the aged dehydrate quickly, I feared that this was the case and, thus, admitted her. I had no way of knowing that her electrolytes would be normal.

2. Once it was determined that her electrolytes were normal, I saw no need to do anything other than to treat her symptoms (i.e., medication for diarrhea). I saw no need to administer intravenous fluids and set her up for a round of congestive heart failure.

QIO Evaluation of Arguments or Written Information Presented:

1. An evaluation of her condition could have been performed on an outpatient basis (e.g., a physical examination for signs of dehydration, electrolytes, etc.).

2. The QIO is not alleging that the physician should have put the patient in a fluid overload. Rather, the QIO is merely pointing out that the physician, upon admission, must not have believed that the patient wasn't stable in that intravenous fluid replacement was limited to a KVO order.

CONCLUSION OF QIO:

The physician violated his statutory obligations as follows:

1. Substantially violated his obligation to order or furnish only care that is medically necessary by unnecessarily admitting patient to the hospital.

Exhibit 9-5 - Initial Sanction Notice of Gross and Flagrant Violation

(Rev. 12, 10-03-03)

QIO LETTERHEAD

(Name and Address of Practitioner or Provider)

(Dear Dr. _____:) or (Dear Mr./Mrs./Ms. _____:)

The purpose of this notice is to inform you that (Name of QIO), the Quality Improvement Organization for the State of (Name of State), has concluded that there is a reasonable basis for determining that (you have) (your hospital has) violated (your) (its) obligation under Section 1156 of the Social Security Act (the Act) to assure that the services provided to program beneficiaries are:

SELECT OBLIGATION(S) VIOLATED

Choose (1), (2), and/or (3) from below:

(1) Provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care; and/or (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion and at such time as may be required.

(Name of QIO) has concluded that there is a reasonable basis for determining that (you have) (your hospital has) grossly and flagrantly violated (your) (its) statutory obligations.

- If the QIO determines finally that such a violation has occurred and recommends a sanction to the Secretary of the Department of Health & Human Services (DHHS), and if a final determination is made by the Secretary through the Office of the Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE EXCLUDED FROM PARTICIPATING IN THE MEDICARE PROGRAM AND ANY STATE HEALTH CARE PROGRAM AS DEFINED IN SECTION 1128(h) OF THE ACT EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME OR, ALTERNATIVELY, REQUIRED TO PAY THE UNITED STATES GOVERNMENT A MONETARY PENALTY AS A CONDITION FOR (YOUR) (YOUR HOSPITAL'S) CONTINUED PARTICIPATION IN THE MEDICARE AND STATE HEALTH CARE PROGRAMS.

- Because of the serious nature of a final determination by the QIO to recommend a sanction to OIG, you are strongly encouraged to contact (Name of QIO) to provide additional information to assist you in responding to the initial determination of a violation and/or to set up a meeting with the (Name of QIO). THE MEETING WITH THE QIO WILL BE YOUR ONLY OPPORTUNITY TO DISCUSS (YOUR) (YOUR HOSPITAL'S) SITUATION WITH THE QIO BEFORE IT MAKES A FINAL DECISION WHETHER TO RECOMMEND TO OIG THAT (YOU) (YOUR HOSPITAL) BE SANCTIONED. IF AS A RESULT OF THE MEETING A CORRECTIVE ACTION PLAN (CAP) IS IMPLEMENTED, NO FINAL DECISION WILL BE MADE UNTIL THE END OF THE CAP PERIOD.

- An in-depth discussion of the cases involved is included below in the case summary section. A detailed synopsis of cases is also enclosed.

- The section entitled: "additional information" explains how to submit the additional information to, and/or request a meeting with, the QIO.

- Enclosure 1 provides a brief overview of the sanction process.

OBLIGATIONS

Section 1156 of the Act and 42 U.S.C. 1320c-5 impose certain obligations upon health care practitioners and other persons who furnish or order services under Medicare or State health care programs. These obligations are to assure that the services are: (1) provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care; and (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion and at such time as may be required. See also 42 CFR Part 1004.

QIO RESPONSIBILITIES

The Secretary of DHHS has a contract with the (Name of QIO) to review Medicare services. Section 1156(b) of the Act provides that if (Name of QIO) determines that a practitioner or other person either has failed to comply substantially with any of these obligations in a substantial number of cases, or has grossly and flagrantly violated any such obligation in one or more instances, (Name of QIO) must report such determination(s) to the Department of Health & Human Services' OIG, along with a recommendation for appropriate sanction actions. If OIG agrees with the QIO's recommendation and finds that the practitioner or other person is unable or unwilling substantially to comply with his/her statutory obligations, OIG may impose a sanction. These sanctions may include exclusion from eligibility to provide services to patients of the Medicare and State health care programs on a payable basis either permanently or for a specified period of time. Alternatively, payment of a monetary penalty in the amount

of the actual or estimated cost of medically improper or unnecessary services may be required as a condition for continued eligibility to receive payment under the programs.

VIOLATION OF OBLIGATION - CASE SUMMARY

The (Name of QIO) has reviewed medical records pertaining (to your medical practice), or (to the health care services and items furnished in your hospital). As a result of this review, the (Name of QIO) has a reasonable basis for determining that (you have) (your hospital has) grossly and flagrantly violated (your) (its) obligations under Section 1156 of the Act in the following respects:

1. Chart No. _____ Admission Date _____
    - Conclusion:
2. Chart No. _____ Admission Date _____
    - Conclusion:

-ETC.-

A copy of the material used by the (Name of QIO) in arriving at this initial determination is enclosed. Also enclosed is a detailed case synopsis identifying each case reviewed by the (Name of QIO), the issues raised by the (Name of QIO), your response to the issues raised, and a final determination by the (Name of QIO). (See Exhibit 9-6 for Sample Synopsis of a Case.)

It has also been initially determined that the violations of (your) (your hospital's) obligations under Section 1156 of the Act are serious enough to warrant recommending to DHHS that sanctions be imposed upon you pursuant to Federal statute and regulations. The sanction to be recommended is (exclusion from participation in the Medicare and State health care programs [for a period of _____ years]) or (that [you] [your hospital] pay to the Government of the United States a monetary penalty in the amount of _____ as a condition for your continued participation in the Medicare and State health care programs).

CORRECTIVE ACTION PLAN (If applicable)

Describe the method and timeframe for correcting the identified violation(s).

ADDITIONAL INFORMATION

By this letter you are hereby formally notified that you may submit to the (Name of QIO) within 30 days of the date of receipt of this letter, additional information which you feel might modify our position and/or a written request to meet with us to review and discuss case specifics. The date of receipt is presumed to be 5 days after the date on this letter.

The additional information and/or request for a meeting should be submitted to:

(Contact Person)
(Name of QIO)
(Address)

IF YOU REQUEST A MEETING

The purpose of the meeting is to allow (you) (your hospital) to present (your) (your hospital's) views regarding the care rendered to program beneficiaries in the above-cited cases, to discuss these views with the (Name of QIO), and to respond to the initial determination of a violation before (Name of QIO) makes a final decision whether to recommend a sanction to OIG.

- The meeting will be held within 30 calendar days of your request. The (Name of QIO) will contact you regarding date, time, and place for the meeting. The meeting date may be extended, but only if you can demonstrate good cause.

- You may have an attorney represent (you) (your hospital) at the meeting. The attorney may make opening and closing statements, assist (you) (your hospital) in presenting expert testimony, and ask clarifying questions.

- (You) (Your hospital) may bring professional (expert) witnesses to testify on (your hospital's) behalf. The purpose of the witnesses is to discuss relevant medical views pertaining to the above-cited cases.

- The (Name of QIO) will make a verbatim record of the meeting and provide this record to you as soon as is practicable, but no later than the time a sanction recommendation (if any) is forwarded to OIG.

- You should bring all relevant documentation (including office records) regarding the cases cited above to the meeting to fully support your views.

- You may request that the physician at the QIO who determined that there is a reasonable basis for concluding that (you have) (hospital has) violated one or more obligations under the Act appear at the meeting to discuss the basis for the determination, although the QIO does not have to grant that request.

- You may object to any member of the QIO being permitted to participate in the decision of (your) (your hospital's) case if you believe that he/she has a personal bias against or is in direct economic competition with (you) (your hospital).

- If, prior to the end of the meeting with (Name of QIO), you believe that additional documentation exists which relates to the cases or issues discussed at the meeting, you may request an additional period of time (not to exceed 5 days) to submit the

relevant information to (Name of QIO). If the (Name of QIO) concurs, it may grant an additional period of time (not to exceed 5 days) for the submission of this information).

Sincerely yours,

QIO Medical Director

Enclosures:
(1) Overview of Sanction Process
(2) Summary of Information Used in Determining Findings
(3) Case Synopsis
(4) Current QIO Instructions

Enclosure 1: Overview of Sanction Process for Gross and Flagrant Violations

INITIAL SANCTION NOTICE*

Thirty days to submit additional information and/or request a meeting and consideration of corrective action (if appropriate)

QIO DECISION

Not a gross and flagrant violation
Final sanction recommendation notice to OIG
Thirty days to submit additional information to OIG

OIG DECISION

Do not sanction
Sanction
Right to an administrative law judge (including a pre-exclusion hearing, if applicable)

*The enclosed letter is an initial sanction notice.

Exhibit 9-6 - Synopsis of Cases for Use With 30-Day Letter (Gross and Flagrant Violations Only)

(Rev. 12, 10-03-03)

Case # _____ Physician: _____
Admitted: _____ Discharged: _____

Principal Diagnosis:	Diabetes with Hyperosmolar Coma
Diagnoses:	Pneumonia Arteriosclerotic Heart Disease Status Post Cerebral Thrombosis
Procedures Performed:	N/A

REVIEW SUMMARY

This 72-year-old female was admitted in a comatose state from a nursing home with the diagnosis of diabetes mellitus with hyperosmolar coma. Her initial blood sugar was 926, and she did not have ketoacidosis. A portable chest X-ray was obtained shortly after admission; however, the radiologist stated on the report that a second X-ray should be obtained to rule out the presence of pneumonia. The patient's temperature was 102 degrees upon admission, but on the following day it spiked to 104 degrees. No serum osmolality levels were obtained (or calculated), the chest X-ray was not repeated timely, and no blood or sputum cultures were ordered. She was given 5% dextrose in water and large amount of insulin; however, she expired on the second day of the stay.

SPECIFIC FINDINGS

The physician violated his statutory obligation as follows:

- GROSSLY AND FLAGRANTLY failed to furnish proper medical care which meets professionally recognized standards of care.
    - Failed to order the appropriate diagnostic tests for a diabetic hyperglycemic patient with no ketoacidosis.
    - Failed to use isotonic salt solution to re-hydrate the patient.
    - Failed to repeat a questionable chest X-ray for a diabetic patient in hyperosmolar coma.
    - Failed to order diagnostic studies to ascertain the cause of the fever.

Exhibit 9-7 - Final QIO Sanction Notice

(Rev. 12, 10-03-03)

(Name and Address of Practitioner or Provider)

(Dear Dr. _____:) or (Dear Mr./Mrs./Ms. _____:)

As you are aware, on (Date), (Name of QIO) informed (you) (your hospital) of an initial identification of a possible (substantial) (gross and flagrant) violation of obligations in the care of (a) program patient(s). Subsequently, (Name of QIO) informed (you) (your

hospital) by letter dated (Date), of its conclusion that there was a reasonable basis for determining that (you) (your hospital) had, in fact, (substantially) (grossly and flagrantly) violated the obligations under Section 1156 of the Social Security Act (the Act).

Section 1156 of the Act and 42 U.S.C. 1320c-5 impose certain obligations upon health care practitioners and other persons who furnish or order services under Medicare or State health care programs. These obligations are to assure that the services are: (1) provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care; and (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion as may be required.

On the basis of additional information provided in response to the above letters and the results of corrective action measures, if applicable, (Name of QIO) has determined that (you have) (your hospital has) failed to comply with the obligation(s) (CHOOSE (1), (2), and/or (3) from paragraph above) imposed on you by Section 1156 of the Act. Therefore, the (Name of QIO) has submitted a recommendation to the Secretary of the Department of Health & Human Services, Office of the Inspector General (OIG), that (you) (your hospital) be:

(excluded from participating (as a provider) in the Medicare program and any State health care program as defined in Section 1128(h) of the Act for a period of years.)

OR

(required to pay to the United States Government a monetary penalty in the amount of _____ as a condition for [your] [your hospital's] continued participation in the Medicare and State health care programs.)

The (Name of QIO) has determined that (you have) (your hospital has) (substantially) (grossly and flagrantly) violated the obligations under Section 1156 of the Act in the following respects:

1. Chart No. _____ Admission Date _____
    - Conclusion:
2. Chart No. _____ Admission Date _____
    - Conclusion:

-ETC.-

A copy of the material used by (Name of QIO) in arriving at this determination is enclosed. Also enclosed is a detailed case synopsis identifying each case reviewed by (Name of QIO), the issues raised by (Name of QIO) and responded to by you, and a clear

statement of the factual bases for the determination by (Name of QIO) in each case that (you) (your hospital) violated (your) (its) obligations under the Program. This information is the same material that is being sent to OIG.

(You) (Your hospital) may submit, within 30 days from the date of receipt of this letter, any additional material that affects the recommendation (to exclude (you) (your hospital) from Medicare and State health care programs) (to impose a monetary penalty). The date of receipt is presumed to be 5 days after the date on this letter. Such material should be sent to:

Office of the Inspector General
Health Care Administrative Sanctions Staff
Room 1-D-13, Oak Meadows Building
6325 Security Boulevard
Baltimore, Maryland 2l207

If OIG agrees with our recommendation and determines that (you are) (your hospital is) either unwilling or unable to comply with your obligations under Section 1156, it may impose a sanction. OIG may accept, reject, or modify our sanction recommendation. OIG is required by law to determine, within 120 days after receipt of an exclusion recommendation from the QIO, whether a sanction action is warranted. Therefore, where an exclusion has been recommended, the time period for submitting additional material to OIG will not be extended, and any material received by OIG after the 30-day period will not be considered.

Sincerely yours,

QIO Medical Director

Enclosures

Exhibit 9-8 - Combined Initial Sanction Notice of Substantial Violation in a Substantial Number of Cases and in a Gross and Flagrant Violation(s)

(Rev. 12, 10-03-03)

QIO LETTERHEAD

(Name and Address of Practitioner or Provider)

(Dear Dr. _____:) or (Dear Mr./Mrs./Ms. _____:)

The purpose of this notice is to inform you that (Name of QIO), the Quality Improvement Organization for the State of (Name of State), has concluded that there is a reasonable

basis for determining that (you have) (your hospital has) violated (your) (its) obligation(s) under Section 1156 of the Social Security Act (the Act) to assure that the services provided to program beneficiaries are:

SELECT OBLIGATION(S) VIOLATED

Choose (1), (2), and/or (3) from below:

(1) Provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care; and/or (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion and at such time as may be required.

(Name of QIO) has concluded that there is a reasonable basis for determining that (you have) (your hospital has) failed to comply substantially with your statutory obligations in a substantial number of cases and grossly and flagrantly violated your statutory obligations.

- If the QIO determines finally that such violations have occurred and recommends a sanction to the Secretary of the Department of Health & Human Services (DHHS), and if a final determination is made by the Secretary through the Office of the Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE EXCLUDED FROM PARTICIPATING IN THE MEDICARE PROGRAM AND ANY STATE HEALTH CARE PROGRAM AS DEFINED IN SECTION 1128(h) OF THE ACT EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME OR, ALTERNATIVELY, REQUIRED TO PAY THE UNITED STATES GOVERNMENT A MONETARY PENALTY AS A CONDITION FOR (YOUR) (YOUR HOSPITAL'S) CONTINUED PARTICIPATION IN THE MEDICARE AND STATE HEALTH CARE PROGRAMS. Therefore, you are strongly encouraged to contact the (Name of QIO) to provide additional information and/or meet with (Name of QIO).

- An in-depth discussion of the cases involved is included below in the case summary sections for both types of violations.

- You will be given an opportunity to provide additional information and/or request a meeting with (Name of QIO) to discuss both types of violations. The section entitled: "Additional Information" explains how to submit additional information and/or request a meeting that covers/includes these violations. Although no sanction recommendation based on the substantial violations in a substantial number of cases will be made to OIG after this initial meeting, it is nevertheless an important first step in the sanction process. With respect to substantial violations in a substantial number of cases, you are entitled (after this initial meeting) to another opportunity to provide additional information and/or request a meeting with (Name of QIO). With respect to gross and flagrant violations, you

are not entitled to this additional opportunity before a sanction recommendation can be made to OIG.

- THE INITIAL MEETING WITH THE QIO MAY BE (YOUR) (YOUR HOSPITAL'S) ONLY OPPORTUNITY TO (WITH RESPECT TO GROSS AND FLAGRANT VIOLATIONS) DISCUSS (YOUR) (YOUR HOSPITAL'S) SITUATION WITH THE QIO BEFORE IT MAKES A FINAL DECISION WHETHER TO RECOMMEND TO OIG THAT (YOU) (YOUR HOSPITAL) BE SANCTIONED BASED ON A GROSS AND FLAGRANT VIOLATION(S). Therefore, because of the serious nature of a final determination by the QIO to recommend a sanction to OIG based on the gross and flagrant violation(s), you are strongly encouraged to contact (Name of QIO) to provide additional information to assist you in responding to the initial determination of a violation and/or to set up a meeting with the (Name of QIO).

- IF, AS A RESULT OF THE INITIAL MEETING WITH (Name of QIO) PROVIDED AS A RESULT OF THE NOTIFICATION YOU HAVE JUST RECEIVED, A CORRECTIVE ACTION PLAN (CAP) IS IMPLEMENTED, NO FINAL DECISION WILL BE MADE UNTIL THE END OF THE CAP PERIOD. DEPENDING ON WHETHER THE VIOLATION(S) INVOLVES A GROSS AND FLAGRANT OR SUBSTANTIAL VIOLATION, YOU MAY BE ENTITLED TO AN ADDITIONAL OPPORTUNITY TO MEET WITH (Name of QIO). YOU ALSO ARE NOTIFIED THAT ANY VIOLATIONS THAT HAVE BEEN INITIALLY FOUND TO BE GROSS AND FLAGRANT ARE ALSO CONSIDERED TO BE SUBSTANTIAL VIOLATIONS. THEREFORE, THESE CASES ARE ALSO LISTED UNDER SUBSTANTIAL VIOLATIONS IN A SUBSTANTIAL NUMBER OF CASES.

- Enclosure 1 provides a brief overview of the sanction process for concurrent identification of gross and flagrant and substantial violations in a substantial number of cases.

OBLIGATIONS

Section 1156 of the Act and 42 U.S.C. 1320c-5 impose certain obligations upon health care practitioners and other persons who furnish or order services under Medicare or State health care programs. These obligations are to assure that the services are: (1) provided economically and only when, and to the extent, they are medically necessary; (2) of a quality that meets professionally recognized standards of health care; and (3) supported by the appropriate evidence of medical necessity and quality of the services in a form and fashion and at such time as may be required. See also 42 CFR Part 1004.

QIO RESPONSIBILITIES

The Secretary of DHHS has a contract with the (Name of QIO) to review Medicare services. Section 1156(b) of the Act provides that if (Name of QIO) determines that a

practitioner or other person either has failed to comply substantially with any of these obligations in a substantial number of cases, or has grossly and flagrantly violated any such obligation in one or more instances, (Name of QIO) must report such determination(s) to the Department of Health & Human Services' OIG, along with a recommendation for appropriate sanction actions. If OIG agrees with the QIO's recommendation and finds that the practitioner or other person is unable or unwilling substantially to comply with his/her statutory obligations, OIG may impose a sanction. These sanctions may include exclusion from eligibility to provide services to patients of the Medicare and State health care programs on a payable basis either permanently or for a specified period of time. Alternatively, payment of a monetary penalty in the amount of the actual or estimated cost of medically improper or unnecessary services may be required as a condition for continued eligibility to receive payment under the programs.

- The section below entitled "GROSS AND FLAGRANT VIOLATION(S)" identifies the case(s) in which the (Name of QIO) has initially determined that (you have) (your hospital has) grossly and flagrantly violated (your) (its) statutory obligations. The section below entitled "SUBSTANTIAL VIOLATIONS" identifies the cases in which the (Name of QIO) has initially determined that (you have) (your hospital has) substantially violated (your) (its) statutory obligations. An in-depth discussion of each case is included in the enclosed case synopsis.

GROSS AND FLAGRANT VIOLATION(S) OF OBLIGATION - CASE SUMMARY

The (Name of QIO) has reviewed medical records pertaining (to your medical practice) (to the health care services and items furnished in your hospital). As a result of this review, the (Name of QIO) has a reasonable basis for determining that (you have) (your hospital has) grossly and flagrantly violated (your) (its) obligations under Section 1156 of the Act in the following respects:

1. Chart No. _____ Admission Date _____
    - Conclusion:
2. Chart No. _____ Admission Date _____
    - Conclusion:

-ETC.-

A copy of the material used by the (Name of QIO) in arriving at this initial determination is enclosed. Also enclosed is a detailed case synopsis identifying each case reviewed by the (Name of QIO), the issues raised by the (Name of QIO), your response to the issues raised, and a final determination by the (Name of QIO). (See Exhibit 9-6 for Sample Synopsis of a Case).

You are also notified that any violations that have been initially found to be gross and flagrant are also considered to be substantial violations.

CORRECTIVE ACTION PLAN FOR GROSS AND FLAGRANT VIOLATION(S) (If applicable)

Describe the method and timeframe for correcting the identified violation(s).

SUBSTANTIAL VIOLATION OF OBLIGATION IN A SUBSTANTIAL NUMBER OF CASES - CASE SUMMARY

The (Name of QIO) has reviewed medical records pertaining (to your medical practice) (to the health care services and items furnished in your hospital). As a result of this review, the (Name of QIO) is concerned that (your medical practice) (your hospital's health care services and items furnished to program beneficiaries) as documented in these medical records, does not appear to comply substantially with the obligations imposed on you under the Act in the following respects:

(Include an in-depth discussion of each situation, circumstance, or activity that resulted in a violation as well as the obligation involved.)

EXAMPLE:

Providing Services Not Medically Necessary and/or Not Provided in the Most Economical Setting:

1. Chart No. _____ Admission Date _____
    - Conclusion:
2. Chart No. _____ Admission Date _____
    - Conclusion:

Providing Services Which Do Not Meet Professionally Recognized Standards of Care:

1. Chart No. _____ Admission Date _____
    - Conclusion:
2. Chart No. _____ Admission Date _____
    - Conclusion:

-ETC.-

A summary of the information considered by (Name of QIO) in arriving at the above findings is enclosed.

CORRECTIVE ACTION PLAN FOR SUBSTANTIAL VIOLATIONS (If applicable)

Describe the method and timeframe for correcting the identified violation(s).

ADDITIONAL INFORMATION

By this letter you are hereby formally notified that you may submit to the (Name of QIO) within 30 days of the date of receipt of this letter, additional information for both gross and flagrant violation(s) and substantial violations which you feel might modify our position and/or a written request to meet with us to review and discuss case specifics. You may request, if you wish, to meet and discuss both types of violations at a combined meeting or you may opt for separate meetings to discuss each type. The date of receipt is presumed to be 5 days after the date on this letter.

The additional information and/or request for a meeting should be submitted to:

(Contact Person)
(Name of QIO)
(Address)

IF YOU REQUEST A MEETING

The purpose of the meeting with (Name of QIO) is to allow you to present (your) (your hospital's) views regarding the care rendered to program beneficiaries in the above-cited cases, to discuss these views with the (Name of QIO), and to respond to the initial determination of a violation before (Name of QIO) makes a final decision whether to recommend a sanction to OIG. As stated above, you are entitled to an additional opportunity to meet with the (Name of QIO) with regard to substantial violations in a substantial number of cases before (Name of QIO) makes a final decision to recommend sanction to OIG for this type of violation.

- The meeting will be held within 30 calendar days of your request. The (Name of QIO) will contact you regarding date, time, and place for the meeting. The meeting date may be extended, but only if you can demonstrate good cause.

- You may have an attorney represent (you) (your hospital) at the meeting. The attorney may make opening and closing statements, assist you in presenting expert testimony, and ask clarifying questions.

- You may bring professional (expert) witnesses to testify on (your) (your hospital's) behalf. The purpose of the witnesses is to discuss relevant medical views pertaining to the above-cited cases.

- The (Name of QIO) will make a verbatim record of the meeting and provide this record to you, as soon as is practicable, but no later than the time a sanction recommendation for a gross and flagrant violation (if any) is forwarded to OIG.

- You should bring all relevant documentation (including office records) regarding the cases cited above to the meeting to fully support your views.

- You may request that the physician at the QIO who determined that there is a reasonable basis for concluding that you have violated one or more obligations under §1156 of the Social Security Act appear at the meeting to discuss the basis for the determination, although the QIO does not have to grant that request.

- You may object to any member of the QIO being permitted to participate in the decision of (your) (your hospital's) case if you believe that he/she has a personal bias against or is in direct economic competition with (you) (your hospital).

- If, prior to the end of the meeting with (Name of QIO), you believe that additional documentation exists (with respect to the gross and flagrant violations) which relates to the cases or issues discussed at the meeting, you may request an additional period of time (not to exceed 5 days) to submit the relevant information to (Name of QIO). If the (Name of QIO) concurs, it may grant an additional period of time (not to exceed 5 days) for the submission of this information).

Sincerely yours,

QIO Medical Director

Enclosures:
(1) Overview of Sanction Process
(2) Summary of Information Used in Determining Findings
(3) Case Synopsis
(4) Current QIO Instructions

Enclosure 1: Overview of Sanction Process for a Combined Initial Sanction Notification for Gross and Flagrant Violations and Substantial Violations

INITIAL SANCTION NOTICE*

Thirty days to submit additional information and/or request a meeting and consideration of corrective action (if appropriate)

(You may opt to discuss the different types of violations at separate initial meetings.)

QIO DECISION

Not a gross violation	Final sanction recommendation and flagrant notice	Not a substantial violation	Second sanction notice to OIG
	Thirty days to submit additional information and/or request a meeting		Thirty days to submit additional information to OIG and consideration of corrective action (if appropriate)

OIG DECISION		QIO DECISION	
Do not sanction	Sanction	Not substantial violation	Final sanction notice recommendation to QIG
	Right to an administrative law judge (including a pre-exclusion hearing, if applicable)		Thirty days to submit additional information to OIG

OIG DECISION

Do not Sanction	Sanction
	Right to appeal to an administrative law judge (including a pre-exclusion hearing, if applicable

*The enclosed letter is a combined initial sanction notice.

Exhibit 9-15 - Physician Review Outline

(Rev. 12, 10-03-03)

SECTION I

(Regional Office completes in most cases. If State Agency physician performs review, State Agency Physician may complete.)

COMPLAINT CONTROL NUMBER: _____

NAME OF PATIENT: _____

AGE: _____

NAME OF ALLEGED VIOLATING HOSPITAL and/or PHYSICIAN: _____

CITY, STATE: _____ PROVIDER NUMBER: _____

DATE AND TIME OF ADMISSION TO
EMERGENCY SERVICES: _____

DATE AND TIME OF DISCHARGE FROM
EMERGENCY SERVICES: _____

NAME OF RECEIVING HOSPITAL (if applicable): _____

CITY, STATE: _____ PROVIDER NUMBER: _____

DATE AND TIME OF ADMISSION TO
2ND HOSPITAL (if applicable): _____

MANNER OF TRANSPORT: _____

LOCATION AND DISTANCE FROM SENDING HOSPITAL: _____

RURAL OR PRIMARY CARE HOSPITAL: _____

SECTION II

(Completed by reviewing physician.)

MEDICAL SCREENING EXAMINATION

1. Did the hospital provide, within its capability, including ancillary services routinely available and on-call physicians, for a medical screening examination that was:

1.a. Appropriate to the individual's medical complaint, and

YES_____ NO _____

Remarks/Rationale:

1.b. Within reasonable clinical confidence, sufficient to determine whether or not an EMERGENCY MEDICAL CONDITION (as defined below) existed?

YES _____ NO _____

Remarks/Rationale:

NOTE: A medical screening examination may fail to meet the requirements of an appropriate examination under §1867 of the Social Security Act. In addition, it may also constitute negligence under State malpractice law.

Depending upon a patient's presenting symptoms, an appropriate medical screening examination represents a spectrum ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures such as (but not limited to) lumbar puncture, clinical laboratory tests, CT scans and other diagnostic tests and procedures.

The clinical outcome of an individual's condition is not a proper basis for determining whether a person transferred was stabilized. However, it may be a red flag indicating that a more thorough analysis of the individual's condition at the time of transfer is needed.

EMERGENCY CONDITION

2. Did this individual have an EMERGENCY MEDICAL CONDITION?

2.a. A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances, and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in placing the patient's health, and with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

YES _____ NO _____

Remarks/Rationale:

2.b. Was this individual a pregnant woman who was having contractions?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

2.b.1. If YES, at the time of transfer, could it be determined with reasonable medical certainty that there would be adequate time to effect a safe transfer to another hospital before delivery?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

2.b.2. At the time of transfer, could it be determined, with reasonable medical certainty that the transfer might have posed a threat to the health and safety of the patient or her unborn child?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

2.b.3. If the answer to 2.b.2. is YES, did the transfer pose a threat to the health and safety of the patient or her unborn child?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

Note to Physician Reviewer: If the answer to 2.a. above is NO, or if under 2.b. it is determined that (1) there was adequate time for the transfer, and (2) the transfer would not have posed a threat to the health and safety of the patient or her unborn child, then the individual did not have an "emergency medical condition" as defined in Section 1867(e) of the Social Security Act and the requirements of an appropriate transfer, as defined in Section 1867(c) of the Social Security Act, do not apply. When this is the case, the Physician Reviewer should skip to Questions #9 and #10, and sign this form.

STABILIZING TREATMENT

3.a. At the time of transfer, was the individual's emergency medical condition stabilized (meaning that no material deterioration of the condition was likely, within reasonable medical probability, to result from or occur during the transfer of the individual from the facility, or that the woman had delivered the child and placenta)?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

NOTE: If you are unable to assess whether the emergency medical condition was stabilized, you must notify the Regional Office and request from the Regional Office or

the hospital, if appropriate, any additional information you may require to make the necessary assessments.

3.b. Was the individual's medical condition evaluated immediately prior to transfer?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

3.c. A medical screening examination is not an isolated event; it is an ongoing process. Did the record reflect continued monitoring according to the patient's need?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

3.d. Did the monitoring continue until the patient was stabilized or appropriately transferred?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

4. In your medical judgment, did the individual require a supervised transfer because material deterioration of the individual's medical condition was likely to result from or occur during a transfer or if the individual was discharged?

YES _____ NO _____

Remarks/Rationale:

5. If the hospital discharged the patient to his or her home, did it provide the patient with a plan for appropriate follow-up care?

YES _____ NO _____

Remarks/Rationale:

APPROPRIATE TRANSFERS

6. Did the transferring hospital provide further examination and treatment, within its capability, to minimize the risks to the individual's health and, where relevant, the health of the unborn child?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

Note to QIO Reviewer: If the answer to 4 is YES, then the individual was not "stabilized" as defined at §1867(e)(3)(B) of the Social Security Act, and he/she requires an "APPROPRIATE" transfer.

7.a. At the time of transfer, was the individual's emergency condition stabilized (meaning that no material deterioration of the condition was likely, within reasonable medical probability, to result from or occur during the transfer of the individual from the facility, or, where relevant, that the woman had delivered the child and placenta)?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

7.b. Did the transfer of the individual require the use of qualified personnel and transportation equipment, including life support measures if medically appropriate?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

7.c. Were the transportation equipment and personnel provided appropriate to the transferred individual's needs?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

7.d. Did the hospital use staff, services, or equipment, within its capabilities, to substantially minimize the risk of this particular transfer?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

8.a. At the time of transfer, did a physician, or if a physician was not physically present, another qualified medical personnel (in consultation with a physician, who subsequently has countersigned) sign a certification that, based upon the reasonable risks and benefits to the individual and based upon the information available at the time of transfer, the medical benefits reasonably expected from medical treatment at another facility outweighed the increased risks to the patient from effecting the transfer?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

8.b. If YES, do you agree that at the time of transfer, based upon the reasonable risks and benefits to the individual and based upon information available at the time, the medical benefits reasonably expected from medical treatment at another facility outweighed the increased risk to the patient from effecting the transfer and that the certification was therefore appropriate?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

8.c. If NO, did the individual (or legally responsible person acting on the individual's behalf, if the individual was incompetent) request the transfer in writing, after being informed of the hospital's obligations and of the medical risks of transfer?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

RESPONSIBILITY OF RECEIVING HOSPITALS

9. Was there any evidence that a participating hospital that has specialized capabilities or facilities refused an appropriate transfer of an individual who required such specialized capabilities or facilities if the hospital had the capacity to treat an individual?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

DELAY IN TREATMENT

10. Is there any evidence that the hospital delayed the provision of an appropriate medical screening examination or further medical examination and treatment in order to inquire about the individual's method of payment or insurance status?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

QUALITY

11. Aside from the transfer issue, do you have any specific concerns about the quality of care rendered to this patient?

YES _____ NO _____ NOT APPLICABLE _____

Remarks/Rationale:

SUMMARY OF FINDINGS

I agree to provide medical advice on any necessary additional development of this case to properly adjudicate any issues and to testify as an expert witness if necessary.

PHYSICIAN SIGNATURE: _____ DATE: _____

Exhibit 9-16 - 60-Day QIO Review - Opportunity for Discussion (Sample Letter to Physician/Hospital)

(Rev. 12,10-03-03)

(Date)

(Name and Address of Hospital Administrator/Physician)

RE: (Hospital Provider Number)

Dear (Name of Hospital Administrator/Physician):

This letter is to inform you that the (Name of QIO), the Quality Improvement Organization for the State of (Name of State), has received notification from the Centers for Medicare & Medicaid Services (CMS) that your hospital has violated the requirements of 42 CFR 489.20 and 42 CFR 489.24 (commonly referred to as "EMTALA" or "dumping" violations) and that CMS is referring your case for possible sanctions as a result of this(these) violation(s). A list of the deficiencies were provided in separate correspondence sent to you on (Date) by the Division of Medicaid and State Operations (DMSO), Region, in (State Regional Office is located).

In this matter, it is the responsibility of the (Name of QIO) to provide the hospital and/or physician(s) a reasonable opportunity for discussion and for submission of additional information related to the violations prior to (Name of QIO) issuing a report of the findings to CMS.

You may request a meeting, either by phone or in person, to discuss the case(s) and to submit additional information. (Name of QIO) must receive the additional information within 30 days of your receipt of this notice. A meeting, should you request one, must occur within that 30-day time period. The date of receipt of this notice is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

The meeting is intended to afford the hospital and/or physician(s) a full and fair opportunity to present their views regarding the cases with the following provisions:

- The hospital and/or physician has(have) the right to have legal counsel present during the meeting. (Name of QIO) may also have legal counsel present and will control the scope, as well as the extent and manner, of any questioning or any other presentation by the attorney representing the hospital and/or physician.

- (Name of QIO) will make arrangements for a verbatim transcript of the meeting to be recorded in the event that CMS or the Office of the Inspector General (OIG) requests a transcript. If CMS or OIG requests a transcript, the hospital and/or physician may request that CMS provide a copy of the transcript.

- The hospital and/or physician(s) will be afforded the opportunity to present, with the assistance of legal counsel, expert testimony in either oral or written form on

the medical issues presented. (Name of QIO) may limit the number of witnesses and the length of the testimony if such testimony is unrelated to the case or provides information that has already been presented. The physician and/or hospital may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in Title 42, Part 480 of the Code of Federal Regulations.

- (Name of QIO) is not obligated to consider any additional information provided by the hospital and/or physician after the meeting unless, before the end of the meeting, it is requested by (Name of QIO). If additional information is requested, the hospital and/or physician will have 5 calendar days from the date of the meeting to provide the requested information.

A report of (Name of QIO) findings in this case will be submitted directly to the Regional Office who will forward a copy to OIG. Upon request, the (referring Regional Office) will provide copies of (Name of QIO) medical assessment report to (name of hospital administrator and/or affected physician(s)).

Copies of the regulations in 42 CFR 489.20 and 42 CFR 489.24 are enclosed. The name(s) of the individuals who were the subject of the violations and dates of occurrence are as follows:

PATIENT LISTING & DATE OF SERVICE
(Name of Hospital)

Patient	Date of Violation
(Patient's name)	(Date)

If you have any questions related to this letter or wish to schedule a meeting, please contact (QIO's contact person) at (QIO's phone number).

Sincerely,

QIO Medical Director (or designated person)

Enclosure