Quality Improvement Organization Manual

Chapter 9 – Sanction, *Emergency Medical Treatment and Labor Act (EMTALA), Fraud* and Abuse

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(Rev. 24, Issued: 02-12-16)

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***NOTE**: This chapter is not a substitute for the underlying law. The QIO is responsible for complying with applicable statutes and regulations.*

9 – Section 1 – Sanction
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9000 – Introduction and Organization of Sections
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

This section provides a comprehensive description of the Sanction Review process and procedures to be followed by a Beneficiary and Family-Centered Care – Medicare Quality Improvement Organization (QIO). In addition, the chapter provides a clear understanding of the process the Office of Inspector General (OIG) must follow if a violation of an obligation is confirmed. The process involves a coordinated effort between the QIO, Centers for Medicare & Medicaid Services (CMS), Office of Inspector General (OIG), and the practitioner or other persons involved.

Sanction *means an exclusion or monetary penalty that the Secretary of the Department of Health & Human Services (HHS) may impose on a practitioner or other person as a result of a recommendation from a QIO.*

In accordance with §1156(a) of the *Social Security* Act *(Act)*, it is the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act to assure, to the extent of his/her authority, that services or items ordered or provided by such practitioner or person to beneficiaries and recipients meet certain criteria. The following three statutory obligations of practitioners and other persons, if not met, may form the basis for the initiation of a sanction action:

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

2. 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 the QIO may reasonably require for review (including copies) in exercising QIO duties and responsibilities; and

3. Services or items ordered or furnished are to be of a quality that meets professionally recognized standards of care.

In addition:

- When identifying a violation (see 42 CFR §1004.40), the QIO must indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases (three or more instances involving a separate admission). (*See §9010 – Definitions Related to Sanctions.*)

- When considering the sanction process, the QIO must consider the degree that the practitioner's actions were inconsistent with the professional knowledge at the time care was provided and the degree of harm that occurred to the patient.

The QIO plays a key role in identifying quality of care issues that warrant a referral for sanction activity, preparing the case for CMS and OIG, and coordinating and communicating with the practitioner or other persons of concern. Best practices for QIO operations in this area are that the QIO Sanction Committee and QIO Sanction Panel should oversee and monitor the process to ensure that timelines are met, processes are followed, and regulatory requirements are met. Upon a finding of a violation and failure of the health care provider to resolve the matter, the QIO initiates the sanction process by notifying the practitioner or other persons and submitting a detailed report to OIG for review and consideration for sanction.

*The remainder of this section is organized in accordance **with** the review process flow from the QIO's identification, notification, and reporting of a violation through the detailed process that OIG follows in the imposition of a sanction through the appeal process.*

9005 – Authority

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Unless otherwise noted, statutory cites are to the Act). This section is based on, and interprets the following authority:

***§1156(a)** identifies the* obligations of health care practitioners and other persons (e.g., hospitals or other health care facilities, organizations, or agencies) who provide or order healthcare services for which payment may be made under the Medicare or State health care programs.

***§1156(b) (1)** requires that the* QIO provide the practitioner or other person with notice, an opportunity for discussion, and *if appropriate, the* opportunity to *enter into* and complete a Corrective Action Plan.

***§1156(b)** provides the sanctions for a violation of the obligations in §1156(a), including exclusion for a period of no less than 1 year or payment of an amount of up to$10,000 for each instance in which improper or unnecessary services were furnished, ordered, or prescribed, if appropriate).*

§1156 (b)(5) (added by §4095 of the Omnibus Budget Reconciliation Act of 1987 (as amended by §401(c)(1) of PL No. 101-597) establishes 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 *people*.

***42 CFR §480.139** governs disclosure of QIO deliberations.*

42 CFR §1001.1901 *provides the scope and effect of exclusions from Federal health care programs of individuals and entities under Title 42 of the Code of Federal Regulations, including certain exceptions to exclusions.*

42 CFR §1001.3001-3005 *describes the reinstatement process for excluded individuals who request reinstatement to OIG.*

42 CFR §1004.10 *describes the statutory obligations of practitioners and other persons who furnish services or order services.*

42 CFR §1004.20 *explains sanction actions that may be taken upon a finding by a QIO of a violation of the obligations of §1156(a) and 42 CFR §1004.10.*

42 CFR §1004.30 *explains the basic responsibilities of a QIO in connection with compliance by a practitioner or other person with §1156(a) and 42 CFR §1004.10.*

42 CFR §1004.40 *describes the actions a QIO must take when a violation of 42 CFR §1004.10 is identified, including identifying the type of violation, obligations involved, the situation or circumstances involved, suggested method for correcting the situation (if appropriate), and rights of practitioners or other persons.*

42 CFR §1004.40(b)(6) *identifies the right of the practitioner or other person to request a meeting with the QIO and the parameters of such a meeting.*

42 CFR §1004.50 *describes the QIO's responsibilities when meeting with a practitioner or other person who has been notified of a violation pursuant to §1004.4.*

42 CFR §1004.60 *describes the actions a QIO must take and certain requirements it must meet when it affirms, modifies, or resolves its findings about a violation.*

42 CFR §1004.70 *describes the action a QIO must take on final finding of a violation if the finding is not resolved to the QIO's satisfaction as specified in 42 CFR §1004.60(a), including submission of a report to OIG and providing notice to the practitioner or other person.*

42 CFR §1004.80 *governs the QIO report to OIG for any violations identified by the QIO that have not been resolved.*

42 CFR §1004.90 *requires the QIO to provide specific recommendations based on documentation provided to OIG for consideration.*

42 CFR §1004.100 *describes OIG responsibilities upon receipt of the QIO report and provides for an exclusion, as recommended by the QIO, to take effect after 120 days if OIG does not make a determination.*

42 CFR §1004.110 *specifies the requirements for the issuance of the Notice of Sanction,*

including an opportunity for the practitioner or other person to elect to notify patients.

42 CFR §§1004.120 – 1004.130 *address the exclusion and reinstatement.*

42 CFR §1004.140 *provides for the limited appeal rights.*

9010 – Definitions Related to Sanctions

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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

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

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

Federal Health Care Program *means any plan or program that provides health benefits, whether directly or indirectly, through insurance, or otherwise, which is funded directly or in whole part by the United States Government or any State health care program in accordance with 1128B(f)and (h) of the Act*

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

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

Health professional shortage area (HPSA) *refers to an area designated by the HHS Secretary and defined in 42 CFR 5.2.*

Medicare Health Plan(s)(MHP)*: For the purpose of this chapter, this is a collective reference to Medicare Part C Health Plans (Medicare Health Plans), Medicare Part D Drug Plans, Cost Plans, and Health Care Prepayment Plans (HCPPs).*

Metropolitan Statistical Area *refers to an area defined by the Executive Office of Management and Budget.*

Obligation *means any of the obligations specified in §1156(a) of the Act and 42 CFR §1004.10.*

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

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

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

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

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

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

Primary medical care professional *is a term limited to:*

> *(i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or*
>
> *(ii) Facilities where care and treatment is provided to patients with health problems other than mental disorders.*

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

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

Psychiatric professional *is a term limited to licensed doctors of medicine who limit their practice to psychiatry or to those facilities where care and treatment is limited to patients with mental disorders.*

Reporting Threshold *means a practitioner or other person has either (a) failed substantially to comply with any obligation in a substantial number (three or more) of admissions, or (b) grossly and flagrantly violated any obligation in one or more instances.*

Rural *means any area outside an urban area.*

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

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

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

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

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

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

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

9015 – Roles and Responsibilities

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9015.1 – QIO Role and Responsibilities

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO may identify a potential violation for peer review through individual case reviews, including beneficiary complaints and other general quality of care reviews (see 42 CFR 476 and the QIO Manual Chapters that address quality of care reviews.). Quality of care issues may also be referred from other QIOs and other agencies for review by a QIO physician peer reviewer. (See Chapter 5.)

This includes Medicare Administrative Contractors (MACs), Medicare health plans(MHPs), State survey and certification agencies (SSA), other CMS contractors, CMS, as well as other Federal Government organizations outside of CMS (e.g. the Office of Inspector General, Department of Justice [DOJ], or Office for Civil Rights),

The QIO is responsible for ensuring that the sanction process and plan is followed in accordance with applicable law, including 42 CFR 480, which addresses confidentiality and disclosure requirements. (See also QIO Manual Chapter 10.)

The QIO has the following responsibilities:

(1) Use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in §1156(a) and 42 CFR §1004.10.

(2) Based on case reviews the QIO conducted (see 42 CFR part 476) and referrals from other entities, preliminarily identify situations where an obligation specified in 42 CFR §1004.10 is violated and identify whether the violation meets the standard for reporting to OIG.

(3) Provide notice to the practitioner or other person of the preliminary finding and an opportunity for discussion.

(4) If appropriate, provide an opportunity (and a suggested method) for correcting the situation and a time period for a corrective action. (See 42 CFR §1004.40.)

(5) Make a final finding:

- *To close the case where no violation has been found to be a gross and flagrant violation or where no substantial violation is identified in a substantial number of cases;*
- *That the violation has been resolved based on satisfactory compliance with the corrective action plan; or*
- *To affirm or modify the initial finding that a violation is gross and flagrant or a substantial violation in a substantial number of cases, which must be reported to OIG.*

(6) After making a final finding, report to OIG, in the form and manner required by 42 CFR §1004.80, if the QIO finds that the practitioner or other person has:

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

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

(7) Issue denial of payment for services or items furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by an excluded practitioner or other person when the QIO identifies such services or items.

***NOTE**: The QIO must report the findings to CMS.*

***NOTE**: The "reporting threshold" is when the practitioner or other person has either:*

(a) failed substantially to comply with any obligation in a substantial number (three or more) of admissions; or

(b) grossly and flagrantly violated any obligation in one or more instances.

9015.1.1 – QIO Sanction Committee

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

To properly identify a violation and determine whether a practitioner or other person has committed a gross and flagrant violation in one or more instances, or a substantial violation in a substantial number of cases, the QIO should convene a Sanction Committee to receive and review all cases initially identified as a violation meeting one of those standards by a QIO peer reviewer. Use of a Sanction Committee ensures that consistent standards and judgment are applied when the QIO identifies a gross and flagrant violation in one or more instances, or a substantial violation in a substantial number of cases.

The QIO Sanction Committee should comprise at least three QIO staff and/or board members and include the Review Manager and Medical Director.

NOTE: *No person who is part of the initial identification of a violation and indicated whether the practitioner or other person has committed a gross and flagrant violation in one or more instances, or a substantial violation in a substantial number of cases—except for the QIO Review Manager and QIO Medical Director - should be a member of the QIO Sanction Panel that attends a requested meeting with the practitioner or other person. Neither shall any individual who was part of the Sanction Committee nor the peer reviewer that identifies a potential violation participate in the final recommendation for the final QIO finding and report to OIG. (See 42 CFR §1004.50.)*

The QIO Sanction Committee should complete the following:

1. *Receive the case upon initial referral from the peer reviewer;*

2. *Make its recommendation based on all three Physician Reviewers' determinations. In most cases, this means basing a recommendation on the majority of the determinations; and*

3. *Complete its review and finding within two (2) business days after the two additional reviews have been completed.*

    - *If the QIO Sanction Committee does not identify a violation that meets the reporting threshold, then the original case review process (e.g., beneficiary complaint review, general quality of care review) proceeds in its normal course.*

    - *If the QIO Sanction Committee identifies a violation that meets the reporting threshold, then the QIO must notify the CMS Regional Office Contracting*

Officer's Representative (COR) within 1 business day after the sanction recommendation is made. (See §9025.2.)

9015.1.2 – QIO Sanction Panel

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

For each violation, the QIO must convene a QIO Sanction Panel to attend a meeting with a practitioner or other person regarding the violation and to make the final QIO finding.

The QIO Medical Director and appropriate review department staff should designate the members of the QIO Sanction Panel. The QIO Sanction Panel must consist of a minimum of three physician peer reviewers in addition to the QIO Medical Director and Review Staff (42 CFR §1004.50).

The QIO Sanction Panel:

- *Ensures that violations are reviewed and findings made in accordance with 42 CFR Part 1004, including maintaining proper documentation.*
- *Ensures that the appropriate members participate in the sanction meeting (either in person or via teleconference) with the practitioner or other person.*
- *Oversees the monitoring of the physicians and/or other persons who are under Corrective Action Plans (CAPs).*
- *Reviews the case(s) and prepares the final QIO finding for the report to the Office of Inspector General (OIG), if required.*
- *Communicates with and responds to OIG regarding QIO reports when required.*

9015.1.3 – Use of CMS-Designated Case Review System

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Pursuant to the contract between the QIO and CMS, QIOs are required to use the CMS-designated case review system to record all data/information collected at the time a determination for sanction activity is obtained, using the designated Sanction Activity Module. Data entry should be completed as each step in the sanction process occurs. The QIOs will refer to the appropriate Case Review System User's Guide for instructions as directed by CMS.

9015.2 – CMS Responsibilities

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The designated CMS COR serves as the point of contact between the QIO and CMS during the sanction review process. CMS may issue guidance to QIOs about the Sanction process.

9015.3 – OIG Responsibilities
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

OIG receives and reviews the QIO report of a final finding. OIG has the authority to determine if a violation of an obligation has occurred and, if so, the appropriate sanction to be imposed.

OIG is responsible for all ongoing communications with the practitioner or other persons and the QIO, including:

- *The outcome of its decision about whether a violation occurred;*
- *The decision to sanction and type of sanction to be imposed;*
- *Notification of other entities as appropriate; and*
- *Reinstatement when appropriate after exclusion.*

9020 – Identification of Potential Violations
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 (see §1856(a) of the Act and 42 CFR §1004.10):

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

2. 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 the QIO may reasonably require for review (including copies) in exercising the QIO's duties and responsibilities.

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

After its final finding identifying a violation that is gross and flagrant or is a substantial violation in three or more instances, the QIO must submit a report to OIG. (*The "reporting threshold" is when the practitioner or other person has either:*

(a) failed substantially to comply with any obligation in a substantial number (three or more) of admissions; or

(b) grossly and flagrantly violated any obligation in one or more instances.

See 42 CFR §1004.30 and §9010 of this Chapter 9 for the definition of Gross and Flagrant

and Substantial Violation in three or more instances.) When considering the sanction to recommend as part of its report, the QIO must consider the degree that the practitioner's actions were inconsistent with the professional knowledge at the time care was provided and the degree of harm that occurred to the patient.

9020.1 – How Violations Are Initially Identified

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Potential violations can only be identified through a QIO physician reviewer's review of a practitioner's or other person's statutory obligations. This review may occur in a number of ways, including:

- *The QIO's examination of a practitioner's or other person's services furnished, in the conduct of multiple case reviews by multiple physician reviewers;*
- *An individual case review completed by one physician reviewer; or*
- *A referral from another entity, such as the QIO's Physician Reviewer, a subcontractor providing physician peer review services, another QIO, the MAC, licensing and certification agencies, CMS, or OIG.*

Potential violations of the obligations listed in §9020 above are initially identified and referred to the QIO for a sanction review as described in §9025 below.

9020.2 – Statutory Obligations – Practitioner's or Others Person's Services

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The following are examples of potential violations that may form the basis for the initiation of a sanction action:

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

   ***EXAMPLE**: Ordering or furnishing inappropriate or unnecessary invasive procedures. 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.*

2. *Standard: 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 the QIO conducts reviews to make decisions about the medical necessity of services, a certain provider consistently has insufficient documentation to support the medical necessity of the services furnished.*

3. *Standard: Items or services ordered or furnished are to be of a quality that meets professionally recognized standards of care.*

   ***EXAMPLE**: 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.*

9025 – QIO s – Development of a Sanction Case

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9025.1 – Sanction Committee Initial Review

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Only violations that the original peer reviewer determines meet the gross and flagrant/substantial violation or is a substantial violation in a substantial number of cases are sent to the Sanction Committee for sanction review. (See §9020.1.) The QIO must identify a violation and indicate whether the violation is a gross and flagrant violation or a substantial violation in a substantial number of cases. The referral should include at least the following information and documentation:

- *All physician reviewer Quality Review Determination (QRD) forms;*
- *All medical information and documentation used in the review process;*
- *All determination letter/correspondence with practitioners/providers;*
- *Information received related to the offer of the Opportunity for Discussion Stage, if applicable; and*
- *Any new evidence submitted in requesting the Reconsideration, if applicable.*

To properly identify a violation and determine whether a violation is gross and flagrant or a substantial violation in a substantial number of cases (the "reporting threshold"), the QIO should convene a Sanction Committee to receive and review all cases that have been initially identified as a violation meeting the reporting threshold. In addition to the initial review and identification of a violation that meets the reporting threshold that triggers referral for a sanction review, at least two additional physician reviewers with similar training as the practitioner or other person of concern should complete an additional review of the case(s), and complete a written summary of their review findings.

These two additional case reviews should be completed within Five (5) business days and submitted to the QIO Sanction Committee. The Committee should make its initial finding within two (2) business days after these two additional reviews are completed.

The Sanction Committee makes an initial finding based on all three reviews (i.e., the determinations of the original Physician Reviewer and two additional Peer Reviewers). This initial finding determines how 42 CFR §1004.40 is applied:

- *If the initial finding of the QIO Sanction Committee is that either (1) a violation did not occur or (2) the violation did not meet the reporting threshold, the QIO returns the case for continued processing of the case review that initiated the review of the QIO Sanction Committee. Case reviews are described in 42 CFR Part 476, and guidance on the case review process is provided in Chapter 5 of the QIO Manual.*

- *If the QIO Sanction Committee finds that a violation that meets the reporting threshold occurred, the QIO proceeds with notification to the practitioner or other person. In addition, the QIO notifies the CMS COR of the initial finding and that the QIO is initiating action under 42 CFR §1004.40.*

***NOTE**: Any time the QIO makes an initial finding of a violation meeting the reporting threshold that involves a MHP as defined in Section 9010, the QIO must notify the COR and the respective Regional Office's (RO) Division of Health Plans and Providers. The QIO must continue to notify the COR and the RO's Division of Health Plans and Providers through each progressive step in the sanction review process and through the final QIO finding and report to OIG. Medicare Health Plans include Medicare Part C Plans (Medicare Health Plans), Medicare Part D Drug Plans, and cost plans under §1876 of the Act.*

9025.2 – Written Notification to Practitioner or Other Person

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Under 42 CFR §1004.40, the QIO must send the practitioner or other person written notice of the initial finding and other information. The QIO Sanction Panel should issue this notice within two (2) business days of making the initial finding and notifying the COR. (See Appendices 9.2, 9-5, and 9.8 for Initial Notification Model Letters.)

The written notification must include at least:

- *Obligation(s) involved;*

- *Situation, circumstances, or activity that resulted in the violation;*

- *Authority and responsibility of the QIO to report violations of any obligation under §1156(a) of the Act;*

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

- *Sanction the QIO could recommend to OIG (see 42 CFR §1004.40);*

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

- *Copy of the material the QIO used in arriving at its findings, except for the QIO deliberations, as set forth in 42 CFR §480.139.*

***NOTE**: Any time the QIO activates the sanction process against a Medicare Health Plan, the QIO must notify the COR, the respective Regional Office's (RO) Division for Medicare Health Plan Operations, and Providers and include with that notice a copy of the initial notice to the Health Plan.*

9030 – Initial Meeting with Practitioner or Other Person – Requirements
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If the practitioner or other person requests a meeting with the QIO *within 30 days of receiving notice of the initial QIO finding, the meeting will be with the QIO Sanction* Panel. (See 42 CFR §§1004.40(b)(6) and 1004.50.)

9030.1 - Composition of the QIO Sanction Panel
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The panel selection must meet the following requirements:

- *The QIO Sanction Panel must consist of a minimum of three physicians.*

- *The QIO peer reviewer who was responsible for the medical judgment and development of the initial finding of a potential violation that triggers a referral of a practitioner or other person to the QIO for sanction (i.e., the peer reviewer responsible for the referral to the QIO Sanction Committee) may not vote on the recommendation at a QIO Sanction Panel meeting. The reviewers who complete additional reviews and provide input to the Sanction Committee (see §9025.1) may also not vote on the recommendation at a QIO Sanction Panel meeting.*

- *No physician member of the QIO Sanction Panel may be in direct economic competition with the practitioner or other person being considered for sanction review.*

- *No physician member of the QIO Sanction Panel may have a substantial bias for or against the practitioner or other person being considered for sanction.*

- *At least one member of the QIO Sanction Panel meeting with the practitioner or other person 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 specialty. One individual*

could meet both requirements.

A dentist, optometrist, podiatrist, etc. should be included on the Sanction Panel as necessary to accomplish equitable peer/provider review. An osteopath should be included on the QIO Sanction panel when the physician under review is a Doctor of Osteopathy.

- *When appropriate, the QIO Sanction Panel should include rural hospital representation.*

- *When appropriate, the QIO Sanction Panel should include representation from across the State.*

- *When the sanction involves a provider of services (as defined in §1861 of the Social Security Act) or a facility, health care practitioners other than physicians may be added to the QIO Sanction Panel as necessary—e.g., administrators, directors of nursing, directors of laboratory services. These professionals should be from a provider/facility similar in size as the involved provider/facility and from the appropriate rural versus urban area. See 42 CFR §§1004.50, 1004.60.*

9030.2 - Requirements for the Meeting

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The meeting must be held within 30 days of when the QIO received the request, but this time period may be extended for good cause. The QIO may allow the practitioner or other person five (5) business days after the meeting to provide additional relevant information that may affect their finding.

The practitioner or other person has the following rights at the meeting:

- *The practitioner or other person may have an attorney present. The attorney, if present, must 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.*

- *Three physicians from the QIO Sanction Panel must attend the meeting, in person or by conference call.*

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

The QIO may also have an attorney present at the sanction meeting, but this is not required and often is not necessary. The meeting is not a legal hearing but instead a chance for the involved practitioner to present additional information and seek clarification.

9035 – QIO Sanction Panel – Initial Sanction Recommendation
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9035.1 – QIO Review of Additional Information
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO Sanction Panel must review any additional information received, at the meeting or in writing after the meeting, as part of its consideration of the initial finding and decision on its final finding.

9035.2 – QIO Sanction Panel Determination/Action
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

A majority vote of the peer reviewers who are members of the QIO Sanction Panel makes the determination.

The QIO peer reviewer who was responsible for the medical judgment and development of the initial finding of a potential violation that triggers a referral of a practitioner or other person to the QIO for sanction (i.e., the peer reviewer responsible for the referral to the QIO Sanction Committee) may not vote on the recommendation at a meeting of the QIO Sanction Panel.

The reviewers who complete additional reviews and provide input to the Sanction Committee (see §9025.1) may also not vote on the recommendation at a meeting of the QIO Sanction Panel. Such individuals may be present at the meeting.

The actions the QIO Sanction Panel may take as a result of the additional information are as follows:

a. ***Deferment of Finding**: The Sanction Panel may accept or suggest a proposed method of corrective action and timeframe for completion. (See §9035.3 below.) Should this occur, a final QIO finding (of violation and recommended sanction) is not made until the appropriate amount of time has elapsed for re-evaluation of the physician or provider.*

   - *If the corrective action is not taken within the specified timeframe, if a timeframe and/or corrective action cannot be agreed upon, or if previous corrective action plan(s) have been unsuccessful, and a gross and flagrant violation or a substantial violation in three or more instances is confirmed, deferment is not an option.*

   - *If the finding is resolved to the QIO's satisfaction, the QIO may either (a) modify the initial finding and recommendation or (b) close the case as resolved.*

b. ***Reversal of Initial Finding**: If the Sanction Panel members believe the additional*

information presented is sufficient and that the reporting threshold has not been met, one of the following actions can be taken:

1. *The initial finding is reversed/resolved; or*

2. *The Panel may determine an alternate method of corrective action and follow-up should problems remain evident that does not meet the definitions of "gross and flagrant" or "substantial." The Panel will forward these confirmed quality of care concerns to the QIO's Quality Improvement Committee/Department for monitoring or other action.*

c. ***Affirmation of Initial Finding**: The Sanction Panel may decide to uphold (in whole or in part) the initial finding of a violation and take one of the following actions:*

1. *Refer to OIG immediately. See §9040 below; or*

2. *Recommend a written Corrective Action Plan. See §9035.3 below.*

If the QIO determines, after careful consideration, that implementation of a CAP would not be appropriate, the QIO should carefully document the rationale for the decision and include this documentation in the report to OIG.

Written notice of the QIO action taken must be provided to the practitioner or individual under review. (See 43 CFR §1004.60(b).)

9035.3 – QIO Corrective Action Plan (CAP) Process and Procedures
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If the QIO Sanction Panel defers a final finding or affirms the initial findings, the Panel may suggest a written method of correction be initiated for the situation. (See 42 CFR §1004.60.) The QIO Sanction Panel should monitor the practitioner's or other person's compliance with the corrective action plan.

The QIO has the flexibility and may use its discretion in working with the practitioner or other person when a CAP is appropriate. When providing the written CAP, the QIO should allot a time period when the QIO expects 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 received. If the initial findings are resolved to the QIO's satisfaction, the QIO may modify the initial finding or recommend that the case be closed. See §9035.2 above.

9035.3.1 – Corrective Action Plan (CAP) Request
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO Sanction Panel may suggest that the provider/practitioner submit a written CAP

as appropriate. If requested from the practitioner or other person, the written CAP should be submitted to the QIO Sanction Panel within 30 days of request. The QIO Sanction Panel must review a written CAP that the practitioner or other person submits and the panel must approve or request modifications to it.

Regardless of whether submitted by the practitioner or other person or developed by the QIO Sanction Panel, the CAP should include timeframes and a method of follow-up evaluation and provide clear instructions on what constitutes successful completion of the CAP.

The QIO must communicate the CAP to the practitioner or other person in writing and should document acceptance of the CAP by having the practitioner or other person sign and return a copy of the CAP to the QIO.

9035.3.2 – Monitoring a Corrective Action Plan (CAP)

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO Sanction Panel should monitor and review the outcome of a CAP and determine if the actions a practitioner takes are acceptable. The practitioner or other person must demonstrate improvement using quantifiable measures; CMS recommends that CAPs be monitored over a twelve (12) month period.

The QIO Sanction Panel should, at minimum, evaluate the practitioner's results on a quarterly basis.

- *If at any time the QIO Sanction Panel identifies additional gross and flagrant violations or a substantial violation in three or more instances, the Sanction Panel should initiate the sanction review process by making a referral for an initial finding as described in Sections 9020.1 and 9025 above.*

- *The QIO Sanction Panel may end the CAP before its planned end to pursue a sanction recommendation to OIG if the Sanction Panel determines patients to be in imminent danger.*

- *After the CAP ends, if the QIO Sanction Panel determines that the CAP resulted in measureable improvement and that the finding has been resolved to the QIO's satisfaction, the case should be closed as resolved.*

- *If after the CAP ends, the QIO Sanction Panel determines the results not to be acceptable, the QIO refers the matter to OIG. (See §9040.1.) The QIO Sanction Panel's finding shall be based on majority vote.*

9040 – QIO Action on Final Finding of a Violation

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9040.1 – Unresolved and Affirmed Findings
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If the final finding affirms the initial finding(s) or the initial finding is not otherwise resolved (See §9035 above), the QIO must:

A. *Submit a report of its final finding and sanction recommendation to OIG.*

B. *Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to OIG, advising that:*

   1. *The QIO has submitted its report and recommendation to OIG.*

   2. *The practitioner or other person has 30 days after receiving the final notice to submit any additional written material or documentary evidence to OIG at its headquarters location, including that 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.*

   3. *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 that OIG receives after the 30-day period will not be considered.*

C. *Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits the report and recommendations to OIG with respect to a physician or other person whom the board is responsible for licensing. (See 42 CFR §1004.70.)*

9040.2 – Extenuating Circumstances – Practitioner or Other Person Involved in Sanction Proceeding – Relocation
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9040.2.1 – Practitioner or Other Person – Relocation to Another QIO State
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

In a case where a practitioner or other person involved in sanction proceedings relocates to another QIO area before a final determination of a violation has occurred or a final sanction recommendation has been made to OIG, the QIO in the first location will follow these procedures:

1. *If the QIO is able to make a final finding, after complying with 42 CFR §§1004.40, 1004.50, and 1004.60, the QIO will notify the practitioner (or other person) and either close the case or forward a report of its final finding and recommended sanction to OIG. In addition, the QIO will notify the QIO in the State of the practitioner's new residence or where he/she is now practicing of the action taken.*

2. *If a final determination cannot be made, the original QIO will send a written notification to the QIO in the State of the practitioner's new residence or where he/she is now practicing and to the practitioner (or other person) that a final determination cannot be made and that the documentation is being provided to the QIO in the new jurisdiction. The notice to the QIO in the new jurisdiction must include all documentation regarding the case and should also include the following:*

    - *The results/findings of the QIO's review activity and the action that could be taken based on these results/findings;*

    - *A statement that action cannot be taken because the practitioner has relocated or is practicing outside our review area;*

    - *A notice that the case is being referred to the QIO in the State where he/she is now practicing for further action as deemed appropriate; and*

    - *A statement that if the practitioner again practices in the original QIO's review area, the original QIO will re-evaluate the case and may reopen it depending upon the action the receiving QIO takes.*

9040.2.2 – Practitioner or Other Person – Relocation and Referral from Another QIO

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

After receiving a referral from another QIO, the QIO that accepts the referral should:

1. *Notify the practitioner in writing of the receipt of the referral from the originating QIO;*

2. *Specify the action to be taken;*

***NOTE**: The receiving QIO may or may not adhere to the recommendations of the originating QIO. However, if the originating QIO's recommendation is not followed, the receiving QIO should document the rationale for why another course of action was chosen. The QIO COR will concurrently be notified of such decisions (including rationale).*

3. *Monitor/evaluate in accordance with the receiving QIO's plan of action;*

4. *Issue an initial finding notice (including the right to a meeting) based on the receiving QIO's finding for the violation and in compliance with 42 CFR §§1004.40 and 1004.5; and;*

5. *Render a final finding, with appropriate notification(s)/ report(s) as would be performed for any other sanction action.*

9045 – QIO Report to Office of Inspector General (OIG)
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9045.1 – Manner of Reporting
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If the violation(s) identified have not been resolved, the QIO must submit a report and its recommendation to the OIG Office of Counsel per the contact list in Appendix 9-1. (See 42 CFR §1004.80.)

9045.1.1 – Content of Report
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO report must include at least the following information:

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

2. *The type of health care services involved;*

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

4. *Pertinent documentary evidence;*

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

6. *The QIO's finding that an obligation under §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;*

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

8. *A copy of the CAP that the QIO developed and documentation of the results of the plan;*

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

10. *The professional qualifications of QIO reviewers; and*

11. *The QIO sanction recommendation.*

9045.1.2 – QIO Recommendation Report Requirements
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO report must specify:

1. *Sanction recommended;*
2. *Amount of monetary penalty recommended, if applicable;*
3. *Period of exclusion recommended, if applicable;*
4. *Availability of alternative sources of services in the community, with supporting information; and*
5. *County or counties in which the practitioner or other person furnishes services.*

NOTE: *The QIO's recommendation to OIG must be based on documentation of the type of offense involved, the severity of the offense, the deterrent value of the recommended sanction, 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 it considers relevant such as the duration of the problem. (See 42 CFR §1004.90.)*

9045.2 – OIG Rejection of QIO Recommendations
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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

9045.3 – OIG Process –Decision to Sanction
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If OIG decides that a violation of an obligation has occurred, it determines the appropriate sanction by considering the:

- *QIO's recommendation;*
- *Type of offense;*
- *Severity of the offense;*

- *Practitioner's or other person's previous sanction record;*
- *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.*

(See 42 CFR §1004.100(d).)

9050 – OIG Imposition and Notification of Sanction
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9050.1 – Exclusion Sanction
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If the QIO recommends exclusion and OIG does not make a decision within 120 days from the date of receipt, the exclusion sanction the QIO recommends will become effective, and OIG will provide notice in accordance with 42 CFR§1004.110(f).

9050.2 – Monetary Penalty
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If the QIO's recommendation to OIG is to assess a monetary penalty, the 120-day provision does not apply, and OIG will provide notice in accordance with 42 CFR §1004.110(a)-(e).

9050.3 – Notification to Practitioner or Other Person of OIG Sanction
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 five (5) days after the date on the notice unless there is a reasonable showing to the contrary.

9050.3.1 – Written Notice Contents – Specifications
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The notice must specify: (See 42 CFR §1004.110(c))

1. *Legal and factual basis for the determination;*

2. *Sanction to be imposed (e.g., exclusion or monetary penalty);*

3. *Effective date and, if appropriate, the duration of the exclusion;*

4. *Appeal rights of the practitioner or other person;*

5. *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*

6. *In the case of exclusion, the earliest date OIG will accept a request for reinstatement.*

9050.4 – Patient Notification
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9050.4.1 – Practitioner Elects to Inform Patients
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

OIG will provide a sanctioned practitioner or other person an opportunity to elect to inform each of their patients of the sanction action. To elect this option, the sanctioned practitioner or other person must, within 30 calendar days of receiving OIG's notice, inform both new patients and existing patients through written notice, based on a suggested (non-mandatory) model that OIG provide to the sanctioned individual, of the sanction and, in the case of exclusion, its effective date.

Receipt of OIG's notice is presumed to be five (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.

***NOTE**: For the purpose 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 the practitioner or other person has treated 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.*

9050.4.2 – Sanctioned Party Is a Hospital – Notification Requirements
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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.

9050.4.3 – Provider or Other Person Certification Provisions
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The certification will state that the practitioner or other person:

1. *Has informed each of his/her 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;*

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

3. *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;*

4. *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*

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

If the sanctioned practitioner or other person

(1) Does not inform his/her patients and does not return the required certification within the 30-day period; or

(2) 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; and*

- *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.*

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, and the Administrative Law Judge (ALJ) decides that he/she poses a risk to program beneficiaries, the sanctioned practitioner or other person would have 30 days from the date of receiving 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 five (5) days after the date of the ALJ's decision, unless there is a reasonable showing to the contrary.

9050.4.4 – Notice to Other Interested Parties

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

In addition to notifying patients and the notice required by a hospital, the OIG provides notice of the sanction to the following entities as appropriate:

1. *The QIO that originated the sanction report;*
2. *QIOs in adjacent areas;*
3. *State Medicaid fraud control units and State licensing and accreditation bodies;*
4. *Appropriate program contractors and State agencies;*
5. *Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, health maintenance organizations, and federally funded community health centers where the practitioner or other person works;*
6. *Medical societies and other professional organizations; and*
7. *Medicare administrative contractors (MACs), MHPs, health care repayment plans, and other affected agencies and organizations.*

9050.5 – Imposing an Exclusion Sanction – OIG Responsibilities

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If an exclusion sanction is imposed 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).)

1. *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*
2. *Notice of sanction is provided as specified in §9050.4.4.*

9055 – Effect of an Exclusion Sanction on Medicare Payments and Services

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9055.1 – Payment to an Excluded Practitioner or Other Person – Regulatory Requirements

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

1. *Payment will not be made under the Medicare, Medicaid, or any other Federal health care programs as defined in §1128B(f) of the Act, including State health care programs as defined in §1128(h), to an excluded practitioner or other person for items or services furnished, ordered, or prescribed during the period of exclusion.*

2. *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.*

3. *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.*

9055.2 – Exceptions to Denial of Medicare Payment (Exclusion) – Regulatory Requirements

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Unless the HHS 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 thirty (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;*

- *Home health services and hospice care items furnished under a plan established before the effective date of the exclusion; or*

- *Any health care items that a practitioner, provider, or supplier orders from an excluded manufacturer before the effective date of the exclusion and delivered within thirty (30) days of the effective date of such exclusion.*

9055.3 – CMS Payment to Beneficiaries – Regulatory Requirements

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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:

1. *The first claim for payment of benefits covered under Medicare Part B the beneficiary submits will be paid, and the beneficiary will be immediately notified of the exclusion.*

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

9060 – Reinstatement after Exclusion by OIG
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Exclusion will remain in effect until:

1. *OIG's decision to exclude is reversed on appeal; or*

2. *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) OIG may also consider compliance with the certification obligation in connection with notice to patients at the time of reinstatement.*

9065 – Appeal Rights of the Excluded Practitioner or Other Person
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9065.1 – Appeal Reversal
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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

9065.2 – Right to Pre-exclusion Preliminary Hearing(s)
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 more than 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. A request for a preliminary hearing may stay the exclusion pending the decision of the ALJ at the preliminary hearing. The preliminary hearing decision is not appealable or subject to

further administrative or judicial review. (See 42 CFR §1004.140(a)(4).)

9065.3 – Right to an Administrative Review
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 ALJ's decision, he/she may appeal that decision and obtain a final determination from the Department Appeals Board (DAB). (See 42 CFR §1005.21.)

9065.4 – Right to Judicial Review
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Any practitioner or other person dissatisfied with the DAB's final decision may file a civil action in accordance with the provision of §205(g) of the Act. (See 42 CFR §1005.21(k).)

9 – Section 2 – Emergency Medical Treatment and Labor Act
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9100 – Introduction and Organization of Sections 9100–9135
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Sections 9100–9135 provide a comprehensive description of the Emergency Medical Treatment and Labor Act (EMTALA) statutory and regulatory requirements and the supporting QIO review process and procedures. In addition, these sections provide a clear description of the process that QIOs must follow when they receive a request for review from the CMS Division of Survey and Certification (DSC). The process involves a coordinated effort between the CMS DSC and the QIO.

In 1986, Congress enacted EMTALA to ensure public access to *hospital* emergency services regardless of ability to pay. Section 1867 of the Social Security Act imposes specific obligations on Medicare-participating hospitals. *Hospitals* that offer emergency services *are required* to provide a medical screening examination *to individuals who "come to the emergency department" to determine if they have* an emergency medical condition, regardless of an individual's ability to pay. Hospitals are then required to provide stabilizing treatment for *individuals* with emergency medical conditions. If a hospital within its capability is unable to stabilize an individual, or if the individual requests, an appropriate transfer should occur. *Hospitals with specialized capabilities, regardless of whether they offer emergency services, must accept appropriate transfers of individuals requiring those specialized capabilities, if they have capacity at the time of the transfer request.*

9105 – Authority Related to EMTALA
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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." 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.

Sections 1866 and 1867 prohibit hospitals with emergency departments from turning away or transferring individuals without screening for emergency medical conditions and stabilizing such conditions or transferring the individual if they lack the capability to provide stabilizing treatment. Section 1867 also requires hospitals with specialized capabilities, regardless of whether they also have emergency departments, to accept appropriate transfers of individuals needing those capabilities, assuming there is capacity at the time of the transfer request. Hospitals are required to maintain on-call lists of physicians who will come to the hospital to provide stabilizing treatment. Both hospitals and physicians who violate EMTALA requirements are subject to enforcement actions; in the case of hospitals this may include both termination of its participation in Medicare as well as civil monetary penalties. Physicians are subject to civil monetary penalties and also potentially to exclusion from the Medicare program.

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90), PL 101-508, added §1867(d)(3). This section, titled "Consultation with Quality Improvement Organizations," requires a 60-day QIO review related to EMTALA cases, unless the delay would jeopardize the health or safety of individuals. The 5-day review is required before CMS makes a compliance determination as part of the process of terminating a hospital's participation in Medicare; the 60-day review is required before OIG imposes civil monetary penalties. The QIO review is to consider whether an individual had an emergency medical condition; the appropriateness of a medical screen examination, stabilizing treatment, or an appropriate transfer; and whether the individual's condition had been stabilized. For the 60-day review, the QIO must also offer the involved physician(s) and hospital(s) an opportunity to discuss the case and submit additional information before the QIO completes its review.

The following are applicable Code of Federal Regulations (CFR) references:

***42 CFR §489.20.l –** requires hospitals, as part of their agreement with the Medicare program, (provider agreement) to comply with the EMTALA regulations at 42 CFR §489.24.*

***42 CFR §489.20.m –** requires a hospital to report to CMS or the State Survey Agency any time it believes it received an inappropriate transfer of an individual with an unstable emergency medical condition.*

***42 CFR §489.20.q –** requires a hospital to post conspicuous signs specifying individuals' EMTALA rights in its emergency department or other places that individuals entering the*

emergency department are likely to notice.

42 CFR §489.20.r – *requires transferring and receiving hospitals to maintain records of transfers for 5 years; requires hospitals to maintain an on-call list of physicians to provide stabilizing treatment for individuals with emergency medical conditions and to maintain a log of each individual who comes to the emergency department.*

42 CFR §489.24 – *Explains the responsibilities of a hospital with an emergency room to provide appropriate medical treatment to an individual who comes to an emergency department. These responsibilities include an appropriate medical screening examination within the capabilities of the hospital's emergency department, including ancillary services.*

42 CFR §489.24(b) – *Provides definitions used in §489.24.*

42 CFR §489.24(d) – *Explains the hospital's responsibility to provide necessary stabilizing treatment for any individual who comes to the emergency department (whether eligible for Medicare benefits or not) and when the hospital determines that the individual has an emergency medical condition.*

42 CFR §489.24(f) *– Explains recipient hospital responsibilities, regardless of whether or not the recipient hospital has an emergency department. Includes the requirement to accept appropriate transfers of individuals who require specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.*

42 CFR §489.24(g) – *If a hospital fails to meet the requirements of 42 CFR §489.24 (a)–(f), CMS may terminate the provider agreement in accordance with §489.53.*

42 CFR §489.24(h)–(i) – *Describes the QIO consultative role and obligations to CMS for the 60-day review to provide a medical opinion to determine a physician's or hospital's liability under §1867(d)(1) of the Act.* ***42 CFR §480.132 –*** *Provides the general requirements for disclosure of patient information.*

42 CFR §480.133 – *Provides the general requirements for disclosure of information about Peer Review practitioners, reviewers, and institutions.*

9110 – Definitions Related to EMTALA Review Activities

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Definitions provided below that refer to EMTALA are further described in 42 CFR §489.24 (b):

1. Emergency Medical Condition *means:*

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:

i. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

ii. Serious impairment to bodily functions;

iii. Serious dysfunction of any bodily organ or part; or

B. With respect to a pregnant woman who is having contractions:

i. That there is inadequate time to effect a safe transfer to another hospital before delivery; or

ii. That transfer may pose a threat to the health or safety of the woman or the unborn child.

2. Labor *means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his/her scope of practice as defined in hospital medical staff bylaws and State law certifies that, after a reasonable time of observation, the woman is in false labor.*

3. Participating Hospital *means (1) a hospital or (2) a critical access hospital as defined in §1861(mm)(1) of the Act that has entered into a Medicare provider agreement under §1866 of the Act.*

4. "To Stabilize" *with respect to an emergency medical condition as defined in 1.A above, means to provide such medical treatment of the condition as may be necessary 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, with respect to an emergency medical condition as defined in 1.B, that the woman has delivered the child and the placenta.*

5. Stabilized –*with respect to an emergency medical condition as defined above in 1.A, means that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition as defined in 1.B above, that the woman has delivered the child and placenta.*

6. Transfer *means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an*

individual who has been declared dead or leaves the facility without the permission of any such person.

***7. Capacity** means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds, and equipment, and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.*

9115 – Hospital Requirements

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Congress enacted the above provisions to prevent hospitals from refusing to treat individuals requiring emergency care or inappropriately transferring or discharging individuals with unstabilized emergency conditions. Refer to §9110 for the full definition of an emergency medical condition.

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

- *Ensure compliance with and meet the requirements of §1867;*
- *Maintain medical and other records related to individuals transferred to or from the hospital for five (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, treatment, and appropriate transfer, as necessary, for emergency medical conditions and women in labor, regardless of ability to pay.*

Section 1867 of the Act, as interpreted at 42 CFR 489.24(b), requires participating hospitals with emergency departments, as defined in the regulations, to provide an appropriate medical screening examination within the capacity of the hospital's emergency department, including ancillary services routinely available to the emergency department, to anyone (whether or not eligible for Medicare benefits and regardless of ability to pay) who comes by him/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) 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 unstabilized 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/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 unstabilized patients. Appropriate transfers must be effected through qualified persons and transportation equipment (if medically necessary) to a receiving hospital that has available space and qualified personnel to treat the individual and that has agreed to accept the individual. The medical record must accompany the individual.

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. This is the case regardless of whether the hospital with specialized capabilities has an emergency department or not.

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 to inquire about the individual's method of payment or insurance status. In addition, 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.

9120 – Hospital Penalties for Noncompliance

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Hospitals that fail to meet the requirements of §1867 *or the EMTALA-related requirements of §1866* may have their *Medicare* provider agreements terminated. In addition, a hospital with fewer than 100 beds is subject to *an OIG-levied* 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 or a qualified medical person because either practitioner refuses to authorize the transfer of an individual with an emergency condition that has not been stabilized or against any employee because the employee reports a violation of an EMTALA requirement.

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. *There is no CMS, QIO, or OIG involvement in any private civil actions.*

9125 – CMS Regional Office Responsibilities

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

When the CMS Regional Office Division of Survey and Certification (DSC) receives a complaint, information, or an allegation about inappropriate or lack of emergency medical screening, stabilizing treatment, appropriate transfer, or failure to accept an appropriate transfer, DSC is responsible for authorizing the State Survey Agency to conduct an investigation and develop a report of this investigation for the Regional Office DSC's consideration. If the Regional Office DSC finds that the case involves a possible violation of §1867 and this determination rests wholly or in part on the clinical aspects of the case, then the DSC must consult with the QIO before determining whether the hospital has violated EMTALA, unless delay in obtaining a QIO review would jeopardize the health or safety of individuals. Clinical aspects of the case may include questions such as whether the individual had an emergency medical condition, whether there was an appropriate medical screening examination, whether a hospital had the capability to provide stabilizing treatment, whether an individual's emergency medical condition was stabilized, whether a transfer was appropriate, whether a recipient hospital had the required capability and capacity to provide stabilizing treatment and any other questions as necessary.

See §9130 for the process followed when CMS has questions or concerns about a QIO review.

The Regional Office DSC must send the following information/documents to the QIO:

- *All relevant information for clinical review (e.g., medical record, draft State Agency Report [Form CMS 2567], and other items as listed on the EMTALA Physician Review Checklist in Appendix 9-11);*
- *EMTALA Physician Review Document Checklist (Appendix 9-11);*
- *EMTALA Physician Review Worksheet (Appendix 9-12);and*

- *EMTALA Case Resolution of Disagreement Worksheet (Appendix 9-13)when applicable.*

  ***NOTE:** The Regional Office DSC uses this worksheet to document information and actions when issues are identified with the QIO process/decisions. (See §9130.)*

If the Regional Office *DSC* determines that there is a violation *and the case meets the criteria for referral that OIG established, DSC* will forward all supporting documentation to the QIO for a 60-day review*, when applicable to the facts of the case, at the same time it makes the referral* to OIG. The supporting documentation *provided to the QIO* should include the State Agency report, a copy of the medical record(s), copies of letters to the hospital(s*) from CMS regarding any enforcement actions*, and a copy of the five (5)-day advisory medical review. The Regional Office should not delay forwarding the case to the QIO if all documentation is not available.

As a part of the 60-day review, the QIO is required to provide the physician/hospital an opportunity to discuss the case and an opportunity to submit additional information. (See 42 CFR §489.24(h)(2) and *§9135.2.1.*)

The QIO 60-day review required to *support OIG enforcement* is considered a separate review and has no substantive bearing on the original Regional Office *DSC* determination *related to CMS enforcement*. If there is a discrepancy between the five (5)-day and 60-day review findings, that discrepancy may affect whether OIG pursues the case for CMPs or physician exclusion, but it *may* not change the Regional Office's original determination of noncompliance. The Regional Office *DSC* will have already followed its procedures and taken *enforcement* action as appropriate to protect other individuals who seek emergency care at the hospital.

The Regional Office *DSC* may*, but is not obligated to,* release the *five (5) day* QIO review results to the affected physician and/or hospital, and to the individual or his/her representative. *The sixty (60) day review remains confidential until such time as the OIG investigation is complete.* The QIO physician reviewer's identity is confidential unless he/she consents to release his/her identity in accordance with the disclosure regulations. (See 42 CFR §§480.132 and 480.133.) *The QIO physician peer reviewer identity is kept confidential from all requestors, including DSC, unless the reviewer agrees to the release of his/her identity. See 42 CFR §§480.139(a) and 489.24(i). Furthermore, the physician peer reviewer name is redacted from all documentation provided to CMS and other parties, unless the physician agrees to release his/her name.*

***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).*

***NOTE:** The hospital and/or practitioner may only contact the CMS Regional Office DSC if they have questions about the EMTALA review, and they may **NOT** contact the QIO during the five (5)-day review period.*

9130 – QIO 5-Day Review Responsibilities
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

If the Regional Office DSC finds that the case involves a possible violation of §1867 and this determination rests wholly or in part on the clinical aspects of the case, the DSC must consult with the QIO before determining whether the hospital has violated EMTALA, unless delaying to obtain a QIO review would jeopardize the health or safety of individuals. Clinical aspects of the case may include questions such as whether the individual had an emergency medical condition, whether there was an appropriate medical screening examination, whether a hospital had the capability to provide stabilizing treatment, whether an individual's emergency medical condition was stabilized, whether a transfer was appropriate, whether a recipient hospital had the required capability and capacity to provide stabilizing treatment, and any other questions as necessary.

In reviewing cases, the QIO physician reviewer should consider information that the treating physician:

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

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

The Regional Office *DSC* may also require the QIO to participate in an informal discussion that the Regional Office sets up with the affected physician/hospital to discuss the case.

NOTE: CMS has the authority and responsibility to determine whether the law has been violated. The QIO physician reviewer ***MUST NOT*** state an opinion about whether a violation has occurred.

9130.1 – Physician Reviewer Selection/Qualifications
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO should select a physician to review the case who is a specialist (actively practicing in his/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 whose 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 *conduct the review in accordance with the requirements in §9130.2* and to testify as an expert witness, if necessary, to properly

adjudicate the case.

NOTE: A QIO is precluded from disclosing information that would identify a *QIO physician* reviewer without his/her consent (42 CFR 480.133(a)(2)(iii)). Therefore, the QIO 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/her availability for expert witness testimony. QIOs must maintain a file containing the names of *physician* reviewers. Upon request from OIG, QIOs must provide the names of individuals who reviewed specific medical records to serve as expert witnesses.

9130.2 – QIO Physician Review Process Description

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO will conduct a 5-day review when the Regional Office *DSC requests*. The QIO physician peer reviewer will:

1. Provide his/her clinical assessment of the case based solely on the documentation the CMS Regional Office *DSC provides*;

2. Not state whether an EMTALA violation occurred; *and*

3. Complete the necessary paperwork, including:

    - EMTALA Physician Review Document Checklist (*Appendix 9-11*); and

    - EMTALA Physician Review Worksheet (*Appendix 9-12*).

NOTE: It is ***NOT*** permissible for the QIO to offer a meeting to discuss the EMTALA review case with the hospital and/or practitioner(s). If the QIO physician reviewer needs additional information, the QIO is to communicate directly with the CMS Regional Office DSC that assigned the case.

The QIO must forward the original EMTALA Physician Review Worksheet (*Appendix 9-12*) provided by the Regional Office *DSC* to the QIO physician peer reviewer for completion.

- The QIO *can use the Physician Reviewer Worksheet provided by DSC* as an original form to be completed by the Physician Reviewer. In addition, the QIO physician reviewer **MUST** include a legibly written *(if not completed electronically) response* and complete rationale for **EACH** question on the EMTALA Physician Review Worksheet. (See *Appendix 9-12*.)

  NOTE: CMS highly recommends that the QIO Physician Reviewer be well versed on key regulatory definitions, such as “emergency medical condition” and “stabilized” as well as the criteria for appropriate EMTALA medical screening

examinations and transfers. (*The QIO must provide all reviewers with the link to CMS's interpretive guidelines explaining the EMTALA requirements in detail and encourage reviewers to consult this guidance when they have questions about any aspects of the Physician Review Worksheet. This guidance is available at: http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf.)* The QIO should enter the physician reviewer responses from the EMTALA Physician Review Worksheet (*Appendix* 9-12) verbatim into the CMS-designated review *system if available, and keep a file copy for their records in accordance with record keeping requirements.*

- The QIO **MUST NOT** change the physician reviewer response unless the physician reviewer gives his/her approval. approval should be noted on the original EMTALA Physician Review Worksheet.

- A copy of the original EMTALA Physician Review Worksheet (with the physician reviewer's name redacted) should be forwarded to the CMS Regional Office *DSC*.

NOTE: See the EMTALA Physician Review Document Checklist (*Appendix 9-11*) for a complete list of documents that the QIO physician peer reviewer reviewed. This checklist MUST be sent to the Regional Office DSC upon *review* completion.

When completing the EMTALA Physician Review Worksheet *(Appendix 9-12*), the QIO physician reviewer should **NOT** provide a statement or opinion on either of the following:

- His or her opinion as to whether an EMTALA violation occurred; and/or

- Other observations about the case that are not specifically asked to be addressed (e.g., personal comments regarding the case).

The criteria for an acceptable EMTALA physician review are as follows:

1. The review must meet all timeliness, administrative, and clinical requirements; and

2. The review must be consistent with:

    - Accepted standards of medical practice;

    - EMTALA statutory definitions;

    - Evidence-based clinical standards; and

    - Sound clinical judgment.

If the CMS Regional Office *DSC* identifies an **administrative** concern *with the EMTALA Physician Review Worksheet*, the *DSC* will make a request to correct the issues. This may

involve a direct discussion *between* the QIO and *DSC* Regional Office.

***NOTE**: A concern with the EMTALA Physician Review Worksheet is considered administrative when the review is incomplete, unclear, internally inconsistent, and/or suggests an apparent lack of understanding of the EMTALA standards that govern the review.*

If the CMS Regional Office *DSC* identifies a concern *with the clinical components of the review*, then the *DSC* representative, CMS *designated representative*, and *COR* will discuss the case. As a result of this discussion, one or more of the following may occur:

1. The QIO *COR* will ask for a re-review by the same physician reviewer, or

2. The QIO *COR* will ask for a re-review *(which would be the second re-review if the same physician who did the initial review has already conducted a re-review)* by a completely new QIO physician reviewer.

NOTE: A concern is *considered* **clinical** when the opinion rendered appears biased, does not follow accepted standards of medical practice, or addresses issues outside the expert competency of the QIO physician reviewer.

9135 – QIO Review Responsibilities – 60-Day Review

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The Regional Office DSC will notify the QIO of EMTALA cases that it is referring to OIG. Before OIG can assess a CMP or exclude a physician from the Medicare program, the QIO must review the case and provide a report of the findings to the originating Regional Office, which is responsible for forwarding the report to OIG. The QIO review includes offering the involved physician(s) and hospital(s) an opportunity to discuss the case and to submit additional information before OIG may impose sanctions.

For the 60-Day EMTALA Review Process, the QIO will follow the Physician Peer Review five (5)-day EMTALA Review Process described in §9130.2. In addition, the following instructions also apply for the 60-day review process.

The QIO must provide a written notice of the opportunities to the affected physician/hospital (see 42 CFR §489.24(h)(2)) and arrange the meeting either by telephone or face-to-face. The letter should identify the name of the individual and the date he/she presented to the emergency room. (See Appendix 9-16, 60-Day QIO Review-Opportunity for Discussion Model Letter.)

Notify OIG at the appropriate CMS Regional Office of the time and date the hospital and, if applicable, the physician are meeting with the QIO, or notify OIG that the hospital and, if appropriate, the physician have declined the opportunity to do so.

The hospital and/or the physician have the right to legal counsel present during the

meeting. However, the QIO may control the attorney's scope, extent, and manner of any questioning or any other presentation. The QIO may also have legal counsel present. The QIO may reasonably limit the number of witnesses and length of testimony if such testimony is irrelevant or repetitive. The QIO is not obligated to consider any additional information that the hospital and/or the physician submit after the meeting, unless the QIO requests them to submit additional information to support their assertions before the end of the meeting. In this case, the QIO provides the hospital and/or the physician additional time, not to exceed five (5) calendar days from the meeting, to submit the relevant information. The QIO is required to keep a recording of the hospital and/or practitioner meeting. However, it is not necessary to hire a professional stenographer to produce a written transcript of the meeting. An audio recording is acceptable unless a written transcript subsequently is requested by CMS Regional Office DSC or OIG.

*If the hospital and/or practitioner(s) elect to discuss the case with the QIO during a formal meeting, the QIO and physician peer reviewer **WILL NOT** provide a clinical opinion about the case during this meeting.*

If the hospital and/or practitioner request a copy of the QIO physician peer review five (5)-day review results, they should be directed to contact the CMS Regional Office DSC, which is responsible for addressing and fulfilling all requests for documents from the hospital and/or physician involved in the case.

Considering all the information on the case, the QIO sends its 60-day physician review worksheet along with pertinent documentation to the Regional Office DSC, who will forward a copy to OIG.

9135.1 – Physician Reviewer Selection/Qualification

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

***NOTE:** The QIO should make every effort to have the same physician peer reviewer complete both the five (5)-day and 60-day EMTALA reviews for the same case.*

The QIO should select a physician to review the case who is a specialist (actively practicing in his/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 whose 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 conduct the review in accordance with the requirements in §9130.2 and §9135 and to testify as an expert witness, if necessary, to properly adjudicate the case.

9135.2 – QIO Physician Review Process Description

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9135.2.1 – 60-Calendar-Day Timeframe
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The timeframe is as follows:

***Calendar Day 1**: The QIO receives the record from the CMS Regional Office DSC.*

***Calendar Day 15**: Notify the involved hospital and, if appropriate, the involved physician via certified letter, return receipt requested. The letter should inform the hospital and/or physician that the QIO is reviewing the case as well as the opportunity to discuss the case (in person or by phone). Inform the hospital/physician that they may submit additional information within 30 calendar days of receiving the letter. (See Appendix 9-16, 60-Day QIO Review-Opportunity for Discussion Model 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.*

When a meeting is scheduled, notify the Regional Office DSC and OIG of the time and date.

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

***Calendar Day 50:** Discussion and hospital/physician submission of data, if desired, is complete.*

***Calendar Day 60:** The QIO completes the review. The Regional Office DSC must receive the QIO final physician review and report (facsimile or through a secure electronic system approved by CMS) no later than close of business on calendar day 60. If submitted electronically, a signed hard copy must be sent to the DSC by mail. The QIO 60-day report must contain:*

- *The name of the hospital or physician (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; and*
- *The completed QIO physician review worksheet.*

***NOTE**: Do not state an opinion or conclusion about whether a violation has occurred.*

9135.3 – Reporting Results of the Review to CMS
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Submit to CMS a report of cases referred to the QIO for review and entered into the CMS designated review system. The required data will be submitted in accordance with the QIO Manual Chapter 10 confidentiality and disclosure instructions.

9 – Section 3 – Fraud and Abuse
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9200 – Scope of QIO Fraud and Abuse Review Activities
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

In accordance with the QIO contract *and 42 CFR Part 476, the QIO must* make available the medical expertise necessary to *conduct reviews and* render quality of care and medical necessity decisions in cases CMS refers to the QIO. The referrals may involve Medicare services in settings other than those normally covered by the QIO reviews.

If the QIO identifies possible practice or performance patterns of fraud or abuse situations during its regular case review activity, regardless of whether these situations/issues are within the QIO area of responsibility, *the QIO should* notify the Federal or State fraud and abuse enforcement agency that has jurisdiction, or in the case of a provider, the appropriate intermediary component *pursuant to 42 CFR §480.133. See also 42 CFR §480.137.*

9210 – *QIO* Review Responsibility
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9210.1 – CMS Approval Process – Referrals to the QIO from Any Source Other than CMS
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Every request should be in writing, offer clear and cogent rationale, and be submitted through the COR for the QIO contract. After receiving such a request, the QIO should, consistent with the contract:

- *Analyze the request to determine the appropriate staff hours and associated budget the QIO will require; and*
- *Submit both the request and the QIO cost analysis to the QIO COR.*
- *In the event that the QIO receives a fraud or abuse review referral from*

any source other than CMS, it should notify the CMS COR before the QIO conducts the review.

9210.2 – QIO Fraud and Abuse Review Process

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

When the QIO receives a referral or request for a fraud and abuse review, the QIO should notify the CMS COR. For these cases, the QIO will investigate the issues and decide on any matters involving medical necessity or quality of care. The QIO should provide written evaluations of all cases to CMS or the outside agency, as appropriate, within 45 calendar days of receiving the referral or within the timeframe agreed upon between the QIO and CMS.

Physician reviewers should be board-certified (although this 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 the QIO on the day the case is referred for investigation. Therefore, the entire 45 days is available for the QIO to complete the review.

9220 – Evaluation Report *Requirements*

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO written report should contain:

1. *The physician review* findings as to the medical appropriateness, necessity, and quality of the services provided;

2. The basis for *the* determination; and

3. When applicable, *any* advice on additional development needed to properly adjudicate any remaining issues.

The report must be signed by *the QIO* authorized representative (e.g., the Executive Director or Medical Director) and include the titles and qualifications of the physician reviewer(s).

When the QIO forwards the report, the QIO should include with it all *materials* that CMS or the outside agency provided to the QIO. *After reviewing the cases included in the QIO* report, *the* QIO *can* initiate a sanction investigation and recommendation if the issues found are within *the QIO* area of responsibility. Otherwise, the QIO involvement with the particular case usually ends with the evaluation report submitted to CMS.

9230 – Availability of Expert Witness
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

9230.1 – Testimony
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Physician reviewers who participate in the medical record review process must be available for expert witness testimony about the medical findings contained in the QIO evaluation report. When asked to serve in the role of expert witness, the physician reviewer in each case will be provided with instructions from the referring component.

9230.2 – Expert Witness Qualifications
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Expert witnesses should be board-certified (although this is not required) and actively practicing in the same specialty or specialties as the physician or physicians who treated the patient whose case 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. The QIO must ensure that physician reviewers are aware of the potential need to serve as expert witnesses. Prior to reviewing a case, the QIO should secure a statement of willingness to serve as an expert witness from the physician reviewers to certify his/her availability for expert witness testimony.

9230.3 – Maintenance of Review Files
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

The QIO should maintain a file that contains the names of physician reviewers who reviews these cases. Upon request from OIG, DOJ, or another outside agency for expert witnesses, the QIO will provide the names of individuals who reviewed specific medical records.

9240 – Reopening of Cases – *Regulatory Guidance*
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Cases that the QIO previously reviewed may be reopened at any time under the following circumstances:

- A QIO or its subcontractor may review and issue denial of payment any time there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud. An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud. (42 CFR §476.96(c)).

- 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, *and* that does not support a formal finding of fraud, *then the QIO should* reopen and revise 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)).

Appendices

Appendix 9-1 – Office of Council to the Inspector General *Mailing Address*

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Exclusions/Civil Monetary Penalties Contact:
Office of Council to the Inspector General
Chief, Administrative and Civil Remedies Branch
330 Independence Avenue, SW
Cohen Building Room 5527
Washington, DC 20201

Fraud Questions:
Assistant Special Agent in Charge
Investigations Branch
(800)-447-8477

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

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 (QIO) 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*(a)* 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 (*HHS*), and if a final determination is made by the Secretary through the Office of Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE EXCLUDED FROM PARTICIPATING IN *PROGRAMS UNDER TITLES V, XVIII, XIX, AND XX of the Social Security Act (including* THE MEDICARE PROGRAM AND ANY STATE HEALTH CARE PROGRAM AS DEFINED IN §1128(h) OF THE ACT) EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME *OF AT LEAST 1 YEAR* 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 "Additional Information" section 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 (42 U.S.C. 1320c-5) imposes 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 HHS 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 HHS OIG, along with a recommendation for *an* appropriate sanction. 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 *program* and State health care programs, *such as Medicaid,* 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) (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 That 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 second 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 2 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 1 week prior to admission. Her post-operative course was eventful in that she had an elevated temperature of 103–104° on the third and fourth 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. Because 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 (name of QIO) considered 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 §1156, you may, within *30* days of the date of receiving 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) (the 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 final determination as to whether such care failed to comply with the statutory obligations of §1156 of the Act *and its recommendation about the appropriate sanction.*

- 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; and

(2) Summary of Information Used in Determining Findings.

Enclosure 1: Overview of Sanction Process for Substantial 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 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 a substantial violation
Final sanction notice recommendation to OIG
Thirty days to submit additional information

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.

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

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 (QIO) for the State of (name of State*), 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 §1156*(a)* 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 *(HHS),* and if a final determination is made by the Secretary through the Office of Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE EXCLUDED FROM PARTICIPATING IN *PROGRAMS UNDER TITLES V, XVIII, XIX, AND XX OF THE SOCIAL SECURITY ACT (INCLUDING* THE MEDICARE PROGRAM AND ANY

STATE HEALTH CARE PROGRAM AS DEFINED IN §1128(h) OF THE ACT) EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME *OF AT LEAST 1 YEAR* 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 *QIO's* final determination 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 "Additional Information" section 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 (the health care services and items furnished in your hospital) (if applicable: and the additional information you submitted to [name of QIO]). 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 (name of QIO) used in arriving at this initial determination is enclosed. Also enclosed is a detailed case synopsis identifying each case (name of QIO) reviewed, the issues (name of QIO) raised, your response to the issues raised, and (name of QIO)'s final determination. (See *Appendix* 9-4 for Synopsis of Cases.)

It has also been determined that the violations of (your obligations) (your hospital's obligations) under §1156 of the Act are serious enough to warrant recommending to the HHS 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 receiving 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 *five* (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'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) (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; and

(4) Current QIO Instruction.

Enclosure 1: Overview of Sanction Process for Substantial Violations

INITIAL SANCTION NOTICE

Thirty (30) days to submit additional information and/or request a meeting and consideration of a corrective action (if applicable)

QIO DECISION

Not a substantial second sanction notice* violation
Thirty (30) days to submit additional information and/or request a meeting and consideration of corrective action (if appropriate)

*The enclosed letter is a second sanction notice.

QIO DECISION

Not a substantial violation		***Violation recommendation to OIG***	
Final sanction notice		*Thirty days to submit additional information to OIG and consideration of*	

OIG DECISION

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

Appendix 9-4 – Synopsis of Cases for Use with 30-Day Letter

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

(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*)*

Example: An 80-year-old *patient* 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. *The patient* 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 80 year old *patient* 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. *The* ongoing treatment of his condition is so dependent upon such items as dietary habits, it is most important that this *information* 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/*her* 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/*her* 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)

Example: A 73-year-old *patient* admitted to hospital because of leg cramps. 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 *the patient* responded to touch as if *the* 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.

6. 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 that 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 *patient* with past history of myocardial ischemia admitted with acute crushing chest pain radiating down his left arm. *Patient* 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 *the* 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 *the patient* complained of crushing chest pain, unlike any he had ever experienced.

2. The initial enzymes many times will not indicate the presence of an acute infarct. Since the admission history states that *the patient* 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 patient'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 that 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)

Example: 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 was not stable, why were additional diagnostic studies not performed or fluid replacement not 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 three 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 pointing out that the physician, upon admission, must

not have believed that the patient was not 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.

Appendix 9-5 – Initial Sanction Notice of Gross and Flagrant Violation

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 *(*QIO*)* 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 §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 (*HHS*), and if a final determination is made by the Secretary through the Office of Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE EXCLUDED FROM PARTICIPATING IN *PROGRAMS UNDER TITLES V, XVIII, XIX, AND XX OF THE SOCIAL SECURITY ACT (INCLUDING* THE MEDICARE PROGRAM AND ANY STATE HEALTH CARE PROGRAM AS DEFINED IN §1128(h) OF THE ACT) EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME *OF AT LEAST 1 YEAR* 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 "Additional Information" section explains how to submit 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 (42 U.S.C. 1320c-5) imposes 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 HHS* 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 HHS 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 §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 *(name of QIO)* used in arriving at this initial determination is enclosed. Also enclosed is a detailed case synopsis identifying each case *(name of QIO)* reviewed, the issues *(name of QIO)* raised, your response to the issues raised, and *(name of QIO)'s* final determination. (See *Appendix 9-6* for Sample Synopsis of a Case.)

It has also been initially determined that the violations of (your) (your hospital's) obligations under §1156 of the Act are serious enough to warrant recommending to *HHS* 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 receiving this letter, additional information that 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 *five* (*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) (your 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 that 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; and

(4) Current QIO Instructions.

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

INITIAL SANCTION NOTICE*

Thirty (30) days to submit additional information and/or request a meeting and consideration of corrective action (if appropriate)

QIO DECISION

Not a gross violation	Final sanction recommendation and flagrant notice	Not a substantial violation	Final 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

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.

Appendix 9-6 - Synopsis of Cases for Use with 30-Day Letter

(Gross and Flagrant Violations Only)

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Case #: _____ Physician: _____

Admitted: _____ Discharged: _____

Example:

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 *patient* was admitted in a comatose state from a nursing home with the diagnosis of diabetes mellitus with hyperosmolar coma. The patient's initial blood sugar was 926, *with no* 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. *The patient* was given 5% dextrose in water and large amount of insulin; however, *the patient* 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 that 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 rehydrate 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.

Appendix 9-7 – Final QIO Sanction Notice

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

(Name and Address of Practitioner or Provider)

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

As you are aware, on (date), (name of QIO), *the Quality Improvement Organization (QIO) for the State of (Name of State),* 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 §1156 of the Social Security Act (the Act).

Section 1156 of the Act (42 U.S.C. 1320c-5) *imposes* 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 §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 Inspector General (OIG), that (you) (your hospital) be:

1. Excluded from participating (as a provider) in the Medicare program and any State health care program as defined in §1128(h) of the Act for a period of _____ years;

   OR

2. Required to pay to the United States Government a monetary penalty in the amount of _____ as a condition for [your] [your hospitals] 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 §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 *(name of QIO)* used in arriving at this determination is enclosed. Also enclosed is a detailed case synopsis identifying each case *(name of QIO)* reviewed, the issues *(name of QIO)* raised and *to which you* responded, and a clear statement of the factual bases for the *(name of QIO)'s* determination 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 receiving 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 Inspector General
Administrative and Civil Remedies Branch – Social Security Act §1156 Coordinator
330 Independence Avenue, SW
Mail Stop: Room 5527
Cohen Building
Washington, DC 20201

If OIG agrees with our recommendation and determines that (you are) (your hospital is) either unwilling or unable to comply with your obligations under §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 receiving 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

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

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

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 (QIO) 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 ***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 (HHS), and if a final determination is made by the Secretary through the Office of Inspector General (OIG) to impose a sanction, (YOU) (YOUR HOSPITAL) MAY BE *EXCLUDED FROMPARTICIPATING IN PROGRAMS UNDER TITLES V, XVIII, XIX, AND XX OF THE SOCIAL SECURITY ACT (INCLUDING* THE MEDICARE PROGRAM AND ANY STATE HEALTH CARE PROGRAM AS DEFINED IN §1128(h) OF THE ACT) EITHER PERMANENTLY OR FOR A SPECIFIED PERIOD OF TIME *OF AT LEAST 1* YEAR 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 "Additional Information" section explains how to submit additional information and/or request a meeting that covers/includes these violations. Although no sanction recommendation based on the substantial viola tions 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 (WITH RESPECT TO GROSS AND FLAGRANT VIOLATIONS) 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 BASED ON A GROSS AND FLAGRANT VIOLATION(S). Therefore, because of the serious nature of a *QIO's* final determination 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 (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 *HHS* 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 HHS 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 §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 *(name of QIO)* used in arriving at this initial determination is enclosed. Also enclosed is a detailed case synopsis identifying each case *(name of QIO)* reviewed, the issues *(name of QIO)* raised, your response to the issues raised, and *(name of QIO)* final determination. (See *Appendix 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) (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 That Do Not Meet Professionally Recognized Standards of Care:

1. Chart No. _____ Admission Date _____

- Conclusion:

2. Chart No. _____ Admission Date _____

- Conclusion:

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 receiving this letter, additional information for both gross and flagrant violation(s) and substantial violations that 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 this case. 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) that 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; and

(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)

NOTE: *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

*The enclosed letter is a combined initial sanction notice.

Appendix 9-11 – EMTALA Physician Review Document Checklist
(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

Instructions:

- The CMS Regional Office Division of Survey and Certification will indicate whether each of the documents listed below is included in the EMTALA review package. All of the documents listed should be included in the package, if available.

- The QIO Physician Reviewer will mark "Yes" for each document reviewed and "No" for each document included in the EMTALA review package but not reviewed. The *Physician Reviewer should review all documents included in the package.*

Document Name	**Included in Package? Yes/No/Not Applicable *(N/A)***	**Reviewed by BFCC-QI Physician Reviewer Yes/No/Not Applicable *(N/A)***
Hospital Medical Record(s): Initial Facility		
Hospital Medical Record(s): Facility to which patient was transferred		
Ambulance Report		
Form CMS-2567, Statement of Deficiencies and Plan of Correction (marked as "Draft" for 5-Day review, "Final" for 60-Day review)		
Transcripts of notes of relevant interviews (staff, patient, family, other witnesses, etc.)		
Hospital census as provided by the facility, including capacity of relevant units (such as ICU, inpatient psychiatric unit, OB unit)		
Staffing schedules (by unit)		

Document Name	Included in Package? Yes/No/Not Applicable *(N/A)*	Reviewed by BFCC-QI Physician Reviewer Yes/No/Not Applicable *(N/A)*
Description of hospital services/capabilities		
Physician on-call schedule at the time of case, including description of specialty/ privileges		
Patient written transfer request (if not in medical record)		
Relevant hospital policies/ procedures/protocols		
Police report and/or court order(s) for involuntary commitment		
Other		
Other		
Other		

Appendix 9-12 – EMTALA Physician Review Worksheet

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

5 - Day Review ☐ ☐ ***60 - Day Review***

NOTE*: A separate Worksheet must be completed by the QIO Physician Reviewer for each medical record reviewed. To facilitate accurate completion, the CMS Regional Office (RO) will complete Section I for each medical record sent to the QIO along with the request for review. The RO must label each medical record with the unique patient identifier as found on the draft Form CMS 2567.*

SECTION I

*Complaint Control Number:*_____ *Patient Identifier Number on Draft 2567:*

Name of Patient: _____ *DOB:* _____

Name of Alleged Violating Hospital and/or Physician: _____

_____

City: _____ *State:* _____ *CMS Certification Number:* _____

Date and Time of Admission to Emergency Services: _____

Date and Time of Discharge from Emergency Services: _____

Name of Receiving Hospital (if applicable): _____

Receiving Hospital Location:

City: _____ *State:* _____ *CMS Certification Number:* _____

*Date and Time of Admission to Receiving Hospital (if applicable):*_____

Manner of Transport: _____

Receiving Hospital Distance from Sending Hospital (if applicable and known): _____

SECTION II

Note to Physician Reviewer: *Please complete the following questions to address issues related to EMTALA. Please be sure to include your clinical rationale for your findings, and make any summary comments and comments on other aspects of the case in the summary section on the last page of this document. Please keep in mind that the purpose of your comments is to provide your clinical perspective on the care rendered, for the CMS 5-day EMTALA review or for the OIG 60-day EMTALA review.*

Therefore, please refrain from making ANY statements about whether or not a violation of EMTALA has occurred, as that decision is the responsibility of CMS and the OIG only.

(Violations of EMTALA may also constitute negligence under state malpractice law. However, determining negligence is not part of and should not be mentioned in your EMTALA review.)

MEDICAL SCREENING EXAMINATION

Note to Physician Reviewer: *Depending upon an individual's presenting symptoms, an appropriate medical screening examination can range 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, some of which may require the services of an on-call specialist to order, conduct or interpret.*

A hospital must provide appropriate screening services within the full capabilities of its staff and facilities, including access to specialists who are on call.

An ***Emergency Medical Condition*** *is defined as* ***EITHER****: (1) 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 individual's health (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; or serious impairment to bodily functions; or serious dysfunction of any bodily organ or part;* ***OR*** *(2) with respect to a pregnant woman who is having contractions, that there is inadequate time to effect a safe transfer to another hospital before delivery, or that the transfer may pose a threat to the health or safety of the woman or the unborn child. (See 42 CFR 489.24(b))*

1. Did the hospital provide a medical screening examination that was, within reasonable clinical confidence, sufficient to determine whether or not an EMERGENCY MEDICAL CONDITION (as defined above) existed? More specifically:

1a. Was the medical screening examination appropriate given all of the individual's medical complaints and signs and symptoms at the time the individual presented?

YES ☐ ☐ ***NO***

Please explain your clinical rationale: _____

_____

_____

1b. Was the medical screening examination appropriate given the hospital's capabilities - including ancillary services routinely available and consultations by on–call specialist physicians?

YES ☐ ☐ ***NO***

Please explain your clinical rationale: _____

_____

_____

_____

1c. Is there any evidence that there was an inappropriately long delay, based on the individual's clinical presentation, between the individual's arrival and the provision of an appropriate medical screening examination?

YES ☐ ☐ ***NO***

Please explain your clinical rationale: _____

_____

_____

EMERGENCY MEDICAL CONDITION

2. Did this individual have an EMERGENCY MEDICAL CONDITION as defined by Part (1) of the definition noted above? *(Individual conditions meeting the definition in Part 2 above are addressed in subsequent questions.)*

☐ ***YES*** ☐ ***NO***

Please explain your clinical rationale:

_____

_____

_____

_____

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

☐ ***YES*** ☐ ***NO***

Please explain your clinical rationale: _____

_____

_____

_____

(If "NO" is checked, skip questions #3a & #3b and proceed to #4)

3a. ***If "YES"*** *is checked in #3* ***and the pregnant woman was transferred/discharged, at the time of transfer/discharge, 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*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

_____

3b. If "YES" is checked in #3 and the pregnant woman with contractions was transferred/discharged, at the time of transfer/discharge could it be determined, with reasonable medical certainty, that the transfer/discharge would not pose a threat to the health or safety of the pregnant woman or the unborn child?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

STABILIZING TREATMENT

Note to Physician Reviewer: *Terms relating to "stabilization" are specifically defined under EMTALA. These terms DO NOT REFLECT the common usage in the medical profession, but instead focus on the medical risks associated with a particular transfer/discharge. Thus, when answering questions related to "stability" for EMTALA, please be very careful to refer to the definition provided below. In addition, the clinical outcome of an individual's condition is not a proper basis for determining whether a person transferred was stabilized. However, the individual's outcome may be a "red flag" indicating that a more thorough evaluation of the individual's condition at the time of transfer was needed.*

Under EMTALA, ***to stabilize*** *means, with respect to part 1 of the definition of an "emergency medical condition," to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer/discharge of the individual from the hospital, or in the case of part 2 of the definition, concerning a pregnant woman having contractions, that the pregnant woman has delivered the child and placenta.*

4. If the individual had an emergency medical condition (EMC), was the EMC "stabilized" (as defined above) prior to the time of the individual's transfer or discharge?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

_____

Note to Physician Reviewer: *A hospital must provide appropriate stabilizing treatment services for an emergency medical condition within the full capabilities of its staff and facilities, including access to specialists who are on call.*

5a. Is there any evidence that the hospital was equipped with such staff, services, or equipment necessary to "stabilize" the individual's emergency medical condition??

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

_____

5b. If the hospital had the capability to stabilize the individual and the individual's emergency medical condition was not stabilized prior to transfer/discharge, is there any information available to indicate WHY the emergency medical condition was NOT "stabilized" prior to discharge/transfer?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

If yes, does this rationale have a sound clinical basis? _____

_____

_____

_____

_____

5c. Is there any evidence that there was an inappropriately long delay, based on the individual's clinical presentation, between the individual's arrival and the provision of appropriate stabilizing treatment for the individual's emergency medical condition?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

_____

_____

Note to Physician Reviewer: *A hospital is required to inform the individual or the individual's legal representative of the risks and benefits of further examination and treatment. If the individual/representative then refuses to consent to further examination or treatment, the medical record must contain a description of the examination or treatment, or both, which was refused, as well as documentation of the individual/representative having been informed of these risks/benefits.*

6. Does the medical record indicate the individual refused to consent to necessary stabilizing treatment?

☐ ***YES*** ☐ ***NO***

(If "NO" is checked, skip question #6a and proceed to #7)

6a. If "YES" is checked and if the medical record contains a description of the communication to the individual/legal representative of the risks and benefits and benefits of further examination or treatment, was this communication appropriate, based on the information available to the hospital at the time of the refusal?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain: _____

_____

_____

_____

_____

APPROPRIATE TRANSFERS

7a. If your response to question 5a was "NO" finding that the hospital was not capable of stabilizing the individual's emergency medical condition, what were the required specialized capabilities that the hospital lacked?

_____

_____

_____

_____

7b. If the individual was transferred to another hospital, did the sending hospital provide further examination and stabilizing treatment, within its capacity (including ancillary services routinely available to it) to minimize the risks of transfer to the individual's health and, where relevant, the health of the unborn child?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

_____

_____

8. If the individual was transferred to another hospital, to minimize the risks of transfer, were qualified personnel and transportation equipment, including medically appropriate life support measures, used to effect (i.e., accomplish) the transfer?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

_____

9a. If this individual was transferred to another hospital for stabilizing treatment of an unstabilized emergency medical condition, do you find that, considering the individual's clinical condition at the time of transfer and any other pertinent information available at that point in time, the medical benefits reasonably expected from appropriate medical treatment at the

other hospital outweighed the increased risk to the individual (or woman in labor or unborn child) from being transferred?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain your clinical rationale: _____

_____

_____

Note to physician reviewer: *The physician certification required for an appropriate transfer must be in writing, must contain a summary of the specific risks and benefits pertaining to this individual's clinical situation, and must be placed in the individual's medical record.*

9b. Do you find that the summary of risks and benefits of transfer contained in the physician certification was appropriate, based on the information available to the hospital at the time of transfer about the individual's condition?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A****

Please explain: _____

_____

_____

**Check N/A not only if this case does not involve a transfer, but also if there was no physician certification in the medical record*

9c. If the transfer was at the request of the individual or the individual's legal representative, rather than based on a physician's certification of the benefits outweighing the risks, and the medical record documents this, do you find that the likely risks of the transfer were identified for the individual/representative?

☐ ***YES*** ☐ ***NO***

Please explain your clinical rationale: _____

_____

_____

_____

10. Does the documentation suggest that the transferring hospital sent to the receiving hospital all available and pertinent medical documentation related to the emergency medical condition?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain: _____

_____

_____

RESPONSIBILITY OF HOSPITALS WITH SPECIALIZED DIAGNOSTIC OR TREATMENT CAPABILITIES OR FACILITIES

Note to Physician Reviewer: *While "specialized capabilities or facilities" include such facilities as burn units, shock-trauma units, neonatal intensive care units or regional referral centers, it also includes many more clinical characteristics. Most simply, if an individual with an emergency medical condition needs services to stabilize that condition that cannot be made available in a clinically appropriate timeframe at the hospital where the individual presented, but which are available at another hospital, the hospital with these capabilities/services must accept a request for transfer, if it has the capacity to provide the needed stabilizing treatment.*

11. Is there any evidence that a Medicare-participating hospital that refused a transfer request has specialized capabilities or services (not available at the sending hospital) that the individual required?

☐ ***YES*** ☐ ***NO*** ☐ ***N/A***

Please explain: _____

_____

_____

(If "NO" or "N/A" is checked, skip question #11a and go to #12.)

11.a If "YES" is checked in #11, is there evidence that the hospital with specialized capabilities or services lacked the capacity to treat the individual requesting stabilizing treatment, at the time of the request?

Please explain:

_____

_____

_____

_____

QUALITY

12. Do you have any specific concerns about the quality of care rendered to the individual that have not already been addressed fully above?

☐ ***YES*** ☐ ***NO***

If yes, please explain your clinical rationale: _____

_____

_____

_____

_____

SUMMARY OF FINDINGS:

13. Please summarize the key facts of the case below and any concerns or clarifications to your answers above with regard to this case. Remember, do not state an opinion regarding whether EMTALA was violated.

_____

_____

_____

_____

I agree to provide medical advice to the Centers for Medicare & Medicaid Services and/or the Office of Inspector General, as necessary, to properly adjudicate any issues and to testify as an expert witness on behalf of the Office of Inspector General, if necessary.

Physician Reviewer Name (printed): _____

Physician Reviewer Signature: _____

Specialty: _____ ***Date:*** _____

Case ID: _____

Time Required to Complete This Review: _____ ***hours*** _____ ***minutes***

Appendix 9-13 – EMTALA Resolution of Disagreement Worksheet

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

QIO Physician Reviewer's Review of EMTALA Case

Resolution of Disagreement (ROD) Worksheet

Request Date: < Insert current date>

To: < Insert DQI PO name>

From: <Insert CMS RO DSC and CMO name>

Contact information: <Insert CMS RO DSC phone number and email>

Facility: < Insert facility name>

Survey Date: <Insert date of facility survey>

QIO Review Date: <Insert date of QIO review>

Type of QIO Review (check one): ___ 5-day review ___ 60-day review

---

SECTION I: (To be completed by RO DSC)

*Summary of **RO DSC** concerns and/or reason for disagreement with QIO review:*

<Please be as specific as possible including references to sources of material used to back-up concerns (e.g. medical record, PR Worksheet, etc). Bulleted statements are acceptable as long as they are complete.>

Attachments:

__ Physician Review Worksheet

__ Medical Record/s

__ Other (Explain) _____

SECTION II: (To be completed by RO CMO)

*Summary of **RO CMO** concerns and/or reason for disagreement with QIO review:*

<Please be as specific as possible including references to sources of material used to back-up concerns (e.g. medical record, PR Worksheet, etc). Bulleted statements are acceptable as long as they are complete.>

Summary of RO DSC and CMO concerns (check all that apply):

____ Incomplete review
____Opinion inconsistent with accepted standards of practice
____Opinion outside of professional scope
____Lack of understanding of EMTALA regulations
____Evidence of biased opinion or conflict of interest

SECTION III: (To be completed by RO DQI PO)

- *Date received: <Insert date DQI PO received the ROD Form>*

<u>Case Review with QIO DQI PO</u>

- *Meeting Date: < Insert date DQI PO met with DSC and CMO representatives to discuss concerns and/or areas of disagreement and next steps>*

- *Meeting participants: <Insert name, title and RO affiliation of participants>*

- *Meeting summary: < Insert additional pertinent notes and/or areas of agreement from the discussion>*

- *Next steps: <Insert the agreed upon next steps by CMS staff.>*

Example: "All of the meeting participants agreed to discuss the review with the QIO Medical Director and to request a re-review based on the concerns identified above. The DQI PO will make arrangements for the meeting which will include….."

CMS Staff Case Review with QIO Medical Director

- *Meeting Date: < Insert date CMS Staff and QIO Medical Director met to review the case.>*

- *Meeting participants: <Insert name, title and RO affiliation of participants>*

- *Meeting summary: < Insert additional pertinent notes and/or areas of agreement from the discussion>*

- *Next steps: <Insert the agreed upon next steps by CMS staff and QIO Medical Director by checking one of the following.>*

____ Request for re-review of initial review
____ Request for 2nd 5-day review
____ Referred to OIG for 60 day review
____ 60-day review opinion different from 5-day review
____ Other (explain): _____

Final PO Action

- *Forward a copy of the ROD Worksheet to the designated RO Beneficiary Protection Lead for tracking purposes.*

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

(Rev. 24, Issued: 02-12-16, Effective: 03-14-16, Implementation: 03-14-16)

(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 was provided in separate correspondence sent to you on (date) by the Division of *Survey & Certification*, Region, in *(*State where 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 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 receiving this notice. A meeting, should you request one, must occur within that 30-day time period. The date of receiving 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 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 *five* (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

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R24QIO	02/12/2016	QIO Manual Chapter 9 – "Sanction, Emergency Medical Treatment and Labor Act (EMTALA), and Fraud and Abuse"	03/14/2016	N/A
R12QIO	10/03/2003	Change in Terminology to CMS and QIO	N/A	N/A

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