

Initial Sanction Notice of Substantial Violation in a Substantial Number of Cases

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:

- (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 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.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-0444 (Expires XX/XX/XXXX)**. The time required to complete this information collection is estimated to average 262 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ******CMS Disclosure****** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained.