Medicare
Peer Review Organization Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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NEW/REVISED MATERIAL--EFFECTIVE DATE: March 14, 2001

Section 9100, Statutory Background, title changed from "Background and Authority" to "Statutory Background" to accurately reflect contents; revised the section to improve general clarity. Revised second paragraph to state that the regulations require that HCFA request PROs to review cases where a medical opinion is necessary to determine a physician's or hospital's liability under section1867 (d)(1) of the Act. Added the titles of applicable statutory sections. Added the exception to review in cases where there was no screening exam or where delay would jeopardize the health or safety of individuals. Removed the reference to the ROs option to request review for the compliance determination because this review is not a statutory mandate.

Section 9110, Hospital Requirements, revised to improve clarity and correct grammatical errors. Added phrase to specify that facilities with specialized capabilities may not refuse to accept appropriate transfers from referring hospitals within the boundaries of the United States. Revised the fourth paragraph for general clarity. Changed "capabilities" to "capacity", added language to reflect that ED capacity includes ancillary services routinely available to the ED, added language to reflect that EMTALA applies regardless of Medicare status and ability to pay, and added language to specify that if a person refuses treatment or transfer, they must be advised by the hospital of the risks and benefits involved.

Section 9120, Hospital Penalties For Noncompliance, revised to improve clarity and correct grammatical errors. Revised to reflect that 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.

Section 9130, RO Responsibilities, revised to improve clarity, correct grammatical errors; and update addresses. Added "for a 60-day review" to clarify why the RO forwards documentation on a violation to the PRO. Specifies that the opportunity to discuss the case and the opportunity to submit additional information is a part of the 60-day review.

Section 9140, State Agency Surveys, revised to reflect that SA surveys may include medical record reviews, policy and procedure reviews, and staff interviews. Changes "the medical record of any patient whom the SA thinks may have been dumped" to "reviewed medical records that the SA believes may indicate violation(s) of §1867 requirements. Specifies that the RO forwards the medical records when requesting the 5-day advisory or the 60-day review.

Section 9150, PRO Review Responsibilities, Revised to update references, for general clarity and to clarify PRO responsibilities. Revised to clarify physician reviewer qualifications to included "actively practicing in his or her specialty and, whenever possible, board-certified. Clarified that, in the 5 day review, additional information may be acquired through record review or interview, but that the PRO reviewer should only consider the information available at the time of the individual's

visit. Revised to specify that the PRO must review the case and provide a report of findings to the originating RO, who is responsible for forwarding report to OIG. Revised section D. extensively to clarify the relationship of "stabilize" and transfer, to specify the criteria for an appropriate transfer, and to discuss patient refusal of transfer. A note has been added to emphasize that the PRO is precluded from disclosing information that would identify a PRO reviewer without his or her consent and that the PRO must ensure that each physician reviewer is aware of the potential need to serve as expert witnesses. The note also states that the PRO must maintain a file that contains the names of peer reviewers and that the names of individual who reviewed specific medical records are provided upon OIG's request for expert witnesses.

Exhibit 9-15, Physician Review Outline, Substantially revised to reflect changes to applicable manual provisions, to improve clarity and ease of use, to ensure questions were included in appropriate sections, with corresponding numbering changes, and to update office symbols. Added "and/or Physician" where name of alleged violating hospital is requested. Added space to identify if the hospital was a rural or primary care hospital. Current questions 1,2, 7 and 9 deleted. Note added after question 1 to provide additional guidance regarding medical screening examinations. Question 2.b.3. added to specify if a transfer posed a threat to a patient or her unborn child. Conforming changes made to the note to physician reviewer revised after question 2. Note added after question 3 to direct the reviewer to notify the RO if they are unable to asses whether the emergency medical condition was stabilized and to request additional information needed to make the assessment. Questions 3.b, c, d and question 5 added to elicit information on ongoing monitoring and follow-up planning. Section title "Responsibility of Receiving Hospitals" added before question 9.

Exhibit 9-16, 60-Day PRO Review: Opportunity for Discussion (Sample Letter to Physician/Hospital), revised for clarity and accuracy and to update references. Added parenthetical "commonly referred to as 'EMTALA" or "dumping" violations" and revised "their intention to terminate…" to read "HCFA is referring your case for possible sanctions as a result of this (these) violation(s).

Workload and Costs

These instructions do not represent any increase in workload or costs.

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

PART 9

SANCTION AND ABUSE ISSUES

Exhibits

9100. STATUTORY BACKGROUND

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

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

9110. HOSPITAL REQUIREMENTS

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. An emergency medical condition is defined as a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, psychiatric disturbances, and/or substance abuse, such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual or unborn child in serious jeopardy; serious impairment to any bodily function; or serious dysfunction of any bodily organ or part. With respect to a pregnant woman who is having contractions, an emergency condition occurs when there is inadequate time to effect a safe transfer to another hospital before delivery or when the transfer may pose a threat to the health or safety of the woman or the unborn child.

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

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

- Comply with the requirements of §1867;
- Have and enforce policies and procedures to ensure compliance;
- Maintain medical and other records related to individuals transferred to or from the hospital for 5 years from the date of transfer;

o 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

o Post in the emergency department (ED) a conspicuous sign(s) informing individuals of their rights under §1867 to examination and treatment, and appropriate transfer, as necessary, for emergency medical conditions and women in labor, regardless of ability to pay.

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

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

o 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 or her behalf.

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

9120. HOSPITAL PENALTIES FOR NONCOMPLIANCE

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

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

9130. RO RESPONSIBILITIES

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

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

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

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

When the RO determines that there is a violation, it will simultaneously forward all supporting documentation to you, for a 60-day review, and to OIG, Counsel to Inspector General, U.S. Department of Health and Human Services, Cohen Building - Room 5527, 330 Independence Avenue, S.W., Washington, D.C. 20201. The supporting documentation should include the SA report, a copy of the medical record(s), copies of letters to the hospital(s), and a copy of the 5-day advisory medical review, if such a review was requested by the RO. The RO should not delay forwarding the case if all documentation is not available. As a part of the 60-day review, you are required to provide the physician/hospital an opportunity to discuss the case and an opportunity to submit additional information. (See 42 CFR 489.24(g)(2) and §9150.C.)

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

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

9140. STATE AGENCY SURVEYS

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

9150. PRO REVIEW RESPONSIBILITIES

A. Peer Review.--Select a physician to review the case who is a specialist (actively practicing in his or her specialty and, whenever possible, board-certified) in either the specialty of the physician who attended the patient or the specialty indicated by the condition of the patient who's care is under review. Whenever possible, the physician reviewer should practice in a similar setting as that of the physician who attended the patient. Select a physician who agrees in writing to provide medical advice and to testify as an expert witness if necessary to properly adjudicate the case. Under most circumstances, you should be able to locate an acceptable specialist to review the case, but if you are unable to do so, notify the contact person in the referring RO immediately.

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

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

- o Had, could have had, and should have had available to him/her at the time of the individual's visit; and
- o Could have discovered reasonably and which was necessary to adequately care for the individual (i.e., the physician should have conducted an adequate history interview) at the time of the individual's visit.

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

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

- ? The individual had an emergency medical condition;
- o The individual's emergency medical condition was stabilized;
- o The individual was transferred appropriately;

- o The certification that the benefits of transfer outweighed the risks was correct; and
- ? There were any medical utilization or quality of care issues involved in the case.

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

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

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

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

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

1. 60 Calendar Day Timeframe.--The time frame is as follows:

Calendar Day 1:

You receive the record from HCFA.

Calendar Day 15:

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

Calendar Day 20:

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

Calendar Day 50:

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

Calendar Day 60:

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

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

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

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

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

To stabilize, as defined in 42 CFR 489.24(b) means, with respect to an emergency medical condition, to either provide the necessary treatment to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from, or occur during, the transfer of the individual from a facility, or, in relevant cases, that the woman has delivered the child and the placenta.

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

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

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

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

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

E. Review Process.--The RO will provide you with a copy of the patient's medical record(s), the ambulance record, if any, and instructions to use the assessment format entitled, "Physician Review Outline" (see Exhibit 9-1) or an alternative format that contains all the information listed in Exhibit 9-1. The Physician Review Outline summarizes the law's medical definitions within the text of its questions. The use of this document is highly recommended. If using this format, proceed as follows:

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

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

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

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

- Your physician reviewer must sign and date the completed document; and
- You fax the completed report by the review date given in subsection C.

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

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

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

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

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

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

Exhibit 9-15

Physician Review Outline

SECTION I
(RO COMPLETES IN MOST CASES. IF SA PHYSICIAN PERFORMS REVIEW, SA PHYSICIAN MAY COMPLETE.)

COMPLAINT CONTROL NUMBER:_____

NAME OF PATIENT:_____

AGE:_____

NAME OF ALLEGED VIOLATING HOSPITAL and/or

PHYSICIAN:_____

CITY, STATE:_____PROVIDER NUMBER:_____

DATE AND TIME OF ADMISSION TO EMERGENCY

SERVICES:_____

DATE AND TIME OF DISCHARGE FROM EMERGENCY

SERVICES:_____

NAME OF RECEIVING HOSPITAL (if applicable):_____

CITY, STATE:_____PROVIDER NUMBER:_____

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

MANNER OF TRANSPORT:_____

LOCATION AND DISTANCE FROM SENDING HOSPITAL:_____

RURAL OR PRIMARY CARE HOSPITAL:_____

SECTION II
(COMPLETED BY REVIEWING PHYSICIAN)

MEDICAL SCREENING EXAMINATION

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

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

   YES NO

Remarks/Rationale

_____
_____
_____
_____

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

YES ___ NO ___

Remarks/Rationale:

_____
_____
_____
_____

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

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

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

EMERGENCY CONDITION

2. Did this individual have an **EMERGENCY MEDICAL CONDITION**?

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

YES ___ NO ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

Note to Physician Reviewer:

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

STABILIZING TREATMENT

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

NOTE: If you are unable to assess whether the emergency medical condition was stabilized, you must notify the regional office and request from the regional office or the hospital, if appropriate, any additional information you may require to make the necessary assessments.

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

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

YES ___ NO ___

Remarks/Rationale:

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

YES ___ NO ___

Remarks/Rationale:

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

YES ___ NO ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___

Remarks/Rationale:

_____
_____
_____
_____

APPROPRIATE TRANSFERS

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

Note to PRO Reviewer:

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

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE _

Remarks/Rationale:

_____
_____
_____
_____

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

YES NO NOT APPLICABLE_____

Remarks/Rationale

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

RESPONSIBILITY OF RECEIVING HOSPITALS

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

YES ___ NO ___ NOT APPLICABLE ___

Remarks/Rationale:

_____
_____
_____
_____

DELAY IN TREATMENT

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

YES ___ NO ___

Remarks/Rationale:

_____
_____
_____
_____

Exhibit 9-15 (Cont.)

Physician Review Outline

QUALITY

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

    YES ___ NO ___

Remarks/Rationale:

_____
_____
_____
_____

SUMMARY OF FINDINGS:

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

_____

PHYSICIAN SIGNATURE:_____ DATE:_____

Exhibit 9-16

60-Day PRO Review: Opportunity for Discussion

(Sample Letter to Physician/Hospital)

(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 PRO), the Peer Review Organization for the State of (name of State), has received notification from the Health Care Financing Administration (HCFA) 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 HCFA is referring your case for possible sanctions as a result of this(these) violation(s). A list of the deficiencies were provided in separate correspondence sent to you on (date) by the Division of Medicaid and State Operations (DMSO), Region, in (State RO is located).

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

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

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

? The hospital and/or physician has the right to have legal counsel present during the meeting. (Name of PRO) 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 PRO) will make arrangements for a verbatim transcript of the meeting to be recorded in the event that HCFA or the Office of Inspector General (OIG) requests a transcript. If HCFA or OIG requests a transcript, the hospital and/or physician may request that HCFA 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 PRO) 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 PRO) 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 PRO). If additional information is requested, the hospital and/or physician will

Exhibit 9-16 (Cont.)

60-Day PRO Review: Opportunity for Discussion

(Sample Letter to Physician/Hospital)

Page 2- (Name of hospital administrator/physician)

have 5 calendar days from the date of the meeting to provide the requested information.

A report of (name of PRO) findings in this case will be submitted directly to the RO who will forward a copy to OIG. Upon request, the (referring RO) will provide copies of (name of PRO) 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 (PRO's contact person) at (PRO's phone number).

Sincerely,

_____
PRO Medical Director (or designated physician)

Enclosure