HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents, Part 4	4-1 - 4-2 (2 pp.)	4-1 - 4-2 (2 pp.)
4020 - 4070 (Cont.)	4-5 - 4-10 (6 pp.)	4-5 - 4-10 (6 pp.)
4080 - 4080 (Cont.)	---	4-11 - 4-12 (2 pp.)
4105 - 4120	4-13 - 4-16 (4 pp.)	4-13 -4-16 (4 pp.)
4135 - 4135	4-19 (1 p.)	4-19 (1 p.)
4210 - 4210 (Cont.)	4-23 - 4-24 (2 pp.)	4-23 - 4-24 (2 pp.)
4230 (Cont.) - 4230 (Cont.)	4-27 - 4-28 (2 pp.)	4-27 - 4-28 (2 pp.)
4250 - 4255	4-31 - 4-32 (2pp.)	4-31 - 4-32 (2 pp.)
4410 - 4410 (Cont.)	4-47 - 4-48 (2 pp.)	4-47 - 4-48 (2 pp.)
4510 - 4590 (Cont.)	4-53 - 4-63 (11 pp.)	4-53 - 4-62 (10 pp.)
4620 - 4640	4-65 - 4-68 (4 pp.)	4-65 - 4-68 (4 pp.)
4705 - 4725 (Cont.)	4-121 - 4-124 (4 pp.)	4-121 - 4-124 (4 pp.)
7101 -7102	7-25 - 7-26 (2 pp.)	7-25 - 7-26 (2 pp.)
9220 - 9230	9-35 - 9-36 (2 pp.)	9-35 - 9-36 (2 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: April 9, 2001*

Throughout Part 4, revisions were also made to reflect recent recodification of the PRO regulations in the ***Federal Register*** effective November 24, 1999. The following parts were recodified: 42 CFR Part 466 is now Part 476, Part 473 is now Part 478, and Part 476 is now Part 480. The following sections were revised to reflect the recodification of Parts 476, 478, and 480.

Section 4105, Quality Review
Section 4110, Admission Review
Section 4125, Coverage Review
Section 4135, Discharge Review
Section 4210, Outlier Review
Section 4230, Limitation on Liability Determinations
Section 4240, Readmission Review
Section 4255, Circumvention of Prospective Payment System (PPS)
Section 4400, Introduction
Section 4410, Review Settings
Section 4510, Using Screening Criteria
Section 4530, Providing Opportunity for Discussion
Section 4550, Profiling Case Review Results
Section 4620, Physician Reviewers
Section 4630, Health Care Practitioners Other Than Physicians (HCPOTP)
Section 4640, Conflict of Interest
Section 4715, When an Action Plan is Not Needed
Section 4725, Additional Performance Improvement Activities
Section 7102, Denial and Reopening Time Frames

Section 4000, Introduction, deletes the 96-hour waiver request by critical access hospitals (CAHs) as a mandatory review category. This section also advises you that you must perform a full case review on all medical records referred under the Payment Error Prevention Program (PEPP) and conduct analysis of these review activities resulting from patterns of failing to provide medical records.

Section 4050, Hospital-Requested Higher-Weighted DRG Assignments, clarifies in section B that when reviewing hospital-requested higher-weighted DRG assignments, you must perform a medical necessity review, a quality review, and DRG validation.

Section 4070, Referrals, deletes reference to the Office of Inspector General (OIG) referring cases directly to you for review, and advises you on how anonymous referrals received from sources other than the regional office are to be handled. It also adds a new §4070.F that requires you to review all cases referred to you by the Clinical Data Abstraction Centers (CDACs) and a new §4070.G that advises you that all requests from outside agencies, including OIG and the Department of Justice (DOJ), must be in writing and submitted through your project officer and approved by HCFA's central office. The only exception to this policy concerns OIG referrals of cases of suspected anti-dumping violations.

Section 4080, Critical Access Hospital (CAH) Acute Care Inpatient Stays Review, is **deleted**. Section 403 of the Balanced Budget Refinement Act of 1999 amended §1820(c)(2)(B)(iii) of the Act to require a CAH to provide "inpatient care for a period that does not exceed, as determined on an annual average basis, 96 hours per patient." This new requirement was effective on November 29, 1999 (the date of enactment). Subsequently, this eliminates the requirement of PRO prior approval of a CAH acute care stay prior to the expiration of a 96-hour time period.

Section 4100, Introduction, deletes the reference to CAHs related to not repeating the portion of the review already completed. You will continue to review beneficiary complaints and hospital notices of noncoverage cases related to CAH admissions.

Section 4130, DRG Validation Review, advises you that when performing a DRG validation review, you are also required to review for medical necessity and quality.

Sections 4510 through 4590, changes the specific reference for Memoranda of Agreements from §3002.A to Part 3.

Section 4520, Requesting Medical Records/Reviewing Documentation, advises you in section A that you must issue technical denials for medical records not received by the CDACs from the hospitals within 45 days of the request for PEPP surveillance samples.

Section 4540, Adhering to Review Time Frames, advises you that for PEPP cases, the review time begins when you receive the medical records from the CDAC.

Section 4590, Reporting Requirements for Review Activities, requires you to report all review activities, including PEPP activities, into the Standard Data Processing System (SDPS).

Section 4650, Training, deletes reference to HCFA developing standard PRO training packages for physician and non-physician reviewers.

Section 7100, Authority, changes the specific reference for circumvention of the prospective payment system to §4255.

Section 7101, Types of Denial Determinations, advises you that initial denials include day outlier cases, if applicable.

Section 9200, Scope of PRO Fraud and Abuse Review Activities, clarifies that you must notify the Federal or State fraud and abuse enforcement agency whenever you identify possible practice or performance patterns of fraud or abuse situations, and that you may notify those agencies of incidents of suspected fraud or abuse that do not reflect a practice or performance pattern.

Section 9210, Review Responsibility, clarifies physician reviewer qualifications, and requires you to obtain approval from your project officer whenever you receive referrals from an outside agency, such as the OIG or DOJ, for case review under §§9200ff.

Section 9220, Evaluation Report, deletes reference to the Office of Inspector General (OIG).

Section 9230, Availability of Expert Witness, clarifies expert witness qualifications, and advises you to provide the names of individuals who reviewed the specific medical records to the outside agency when requested to provide expert witnesses.

Section 9240, Reopening of Cases, clarifies that you may review, reopen and/or revise an initial denial or reconsidered determination, or change in DRG determination whenever there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

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 4

CASE REVIEW

Section

Mandatory Case Review Requirements

Basic Case Review Activities

Additional Case Review Activities

Integrated Case Review/Physician Reviewer Assessment Format (PRAF)

Scope of Case Review

Section

Case Review Procedures

Personnel

Feedback and Action Plans for Individual Providers/Physicians

Exhibits

Exhibit

Mandatory Case Review Requirements

4000. INTRODUCTION

You are required to perform individual case review to fulfill mandatory review requirements. (See §4100.) Mandatory review categories include: alleged anti-dumping violations, requests for assistants at cataract surgery for specific codes, beneficiary complaints, hospital notices of noncoverage, beneficiary's requests for immediate review of Medicare+Choice (M+C) organization-issued notices of noncoverage, hospital-requested higher-weighted DRG adjustments, potential gross and flagrant violations (see Part 9), and Payment Error Prevention Program (PEPP) referrals (see Part 11). If in the course of conducting a mandatory review (e.g., beneficiary complaint) you determine that the case also involves another review area (e.g., a readmission within 31 days), you are required to perform the review for that area (in this case, the readmission).

As part of the PEPP (see Part 11) review, you are also required to conduct analyses of these mandatory review activities mentioned above to identify trends and patterns suggestive or indicative of:

- o Inappropriate, unreasonable, or medically unnecessary care (including setting of care issues);
- o Incorrect DRG assignment;
- o Inappropriate transfers;
- o Premature discharges; and
- o Insufficient, poor documentation, or patterns of failing to provide medical records.

4010. ANTI-DUMPING VIOLATIONS

Follow the instructions contained in Part 9, §9100 when reviewing anti-dumping violations.

4020. ASSISTANTS AT CATARACT SURGERY

A. Authority.--Section 1862(a)(15) of the Act prohibits payment for services of an assistant at cataract surgery unless, prior to the surgery, you have approved the use of an assistant based on the existence of a complicating medical condition.

NOTE: The assistant may be a physician or a physician's assistant, where authorized by State law.

B. Memoranda of Agreement (MOAs).--Initiate or amend, as necessary, your MOAs with hospitals, ambulatory surgical centers (ASCs), and carriers to include this review requirement. (See Part 3 of this manual.)

C. Notification of Review Requirement.--Notify ophthalmologists in the State of the requirements under §§1862(a)(15) and 1842(k)(l) and (2) of the Act that they obtain approval for an assistant before surgery, except in emergency situations, in order for them to bill beneficiaries for any amounts for which beneficiaries are liable by law.

Instruct physicians to notify you within a reasonable time frame (e.g., 48 hours) of rare instances when an assistant was used because an emergency arose with the patient during the surgical procedure. To obtain post-surgery approval, the physician must comply with your procedure(s).

Notify physicians at least 30 calendar days prior to implementation of this review activity. Include the following information:

- o The statutory requirement at §1862(a)(15) that precludes payment for services of an assistant unless prior approval is obtained from you;
- o Criteria you use in determining when an assistant is needed;
- o Information you need to perform the review (including the name of the proposed assistant) and requirements for notifying you when another assistant is substituted;
- o How to request approval (e.g., what records/forms are needed);
- o Time frames for submitting a request;
- o The process for obtaining an approval number on a postprocedure/prepayment basis (including the requirement to document the emergency);
- o Procedures for submitting records when you subsequently validate cases that you approved by phone, including the time frame for submittal and penalties for not submitting the required records. (See 42 CFR 1004.10.); and
- o The sanctions that may be applied if prior approval is not obtained, or if inaccurate information is given.

D. Review Procedures.--Conduct a review to determine if the use of an assistant is medically necessary based on a complicating medical condition. Review for medical necessity in all settings.

NOTE: Assistant at cataract surgery review is not performed for M+C organization cases.

The only Current Procedural Terminology (CPT)-6 codes that can be reviewed for medical necessity of an assistant are:

66852 66920 66930 66940 66986

Whenever you propose to deny the necessity of an assistant, provide the physician (and the assistant, if known) an opportunity to discuss the case and provide additional information as specified in §4530. If you determine that the assistant was not medically necessary, deny the services and send initial denial notices as specified in Part 7, §7100.

1. Preprocedure Review.--Review all requests for use of an assistant in a timely manner (i.e., before the surgery is performed). A request may be made by the surgeon, assistant, or designated staff. Therefore, prior to surgery, notify the surgeon and assistant of your determination. Establish validation procedures to ensure that the information provided at the time of your initial review is accurate. (See §§4020.F. and 4100.)

2. Postprocedure Review.--Review cases on a prepayment, postprocedure basis when physicians notify you that an assistant was used because an emergency arose with the patient during the surgical procedure. The carrier cannot pay for services of an assistant without your approval. Review the medical record and make a determination whether the medical situation constituted an emergency. If you determine during postprocedure review that the patient's circumstances constituted an emergency, provide the physician with an approval number.

If you determine that an emergency did not exist, whether or not an assistant was needed, deny payment. On an exception basis, you may approve the necessity for an assistant at non-emergency cataract surgery on a postprocedure/prepayment basis if you determine that circumstances unavoidably prevented the physician from obtaining approval. Evaluate the individual circumstances of each exception using your past review experience (i.e., your knowledge and past experience with that physician). Notify beneficiaries when you deny services of an assistant at cataract surgery. Inform beneficiaries that they are not responsible for the payment of the denied services and should notify the carrier if they are billed.

E. Role of the Carrier.--The carrier does not pay claims for an assistant for the codes listed in §4020.D unless it receives notice that you approved such use, either prior to the procedure or after the procedure (in cases of a medical emergency).

NOTE: The carrier is responsible for notifying the RO or the Office of Inspector General (OIG) of any billing violations.

Sections 1842(k)(l) and (2) of the Act provide that a physician may not knowingly and willfully present a claim or bill to a beneficiary for the services of an assistant without obtaining prior approval from the appropriate PRO. The physician may be sanctioned under §1842(j)(2) of the Act if it does so. If you identify a pattern of physician claims for an assistant filed without prior approval notify the carrier, which is responsible for instituting the sanctions.

F. Validation Activities.--You must perform a validation review on all (if small number of cases are reviewed) or at least a sample of the cases you reviewed. Your determination that services of an assistant are warranted by a complicating medical condition is not a guarantee of payment if subsequent validation review establishes that inaccurate information was provided at the time of the initial determination and that the services of the assistant were actually unwarranted. The surgeon, provider and/or anesthesiologist (if used) will not be denied payment because of the inaccurate information.

When you identify a physician who provided inaccurate information to obtain approval for use of an assistant, issue him/her a written notice (in addition to issuing an initial denial notice) containing the following information:

- An explanation of the physician's obligation to provide accurate information when requesting approval for use of an assistant at cataract surgery;
- The situation or circumstances that led you to believe that the physician is not fulfilling his/her obligation;
- Your authority and responsibility to report violations of obligations;
- A suggested method for correcting the situation and a time period for corrective action;
- The sanction that would be recommended, if a violation occurred again; and
- An invitation to discuss the situation with you.

When physicians display a pattern of providing inaccurate information, consider educational intervention or possible sanction action as specified in Part 9, §§9000-9070.

4030. BENEFICIARY COMPLAINTS

Follow the instructions contained in Part 5, §5000 when reviewing beneficiary complaints.

4040. HOSPITAL AND MEDICARE+CHOICE (M+C) ORGANIZATION NOTICES OF NONCOVERAGE

Follow the instructions contained in Part 7, §7000 when reviewing hospital and M+C organization notices of noncoverage.

4050. HOSPITAL-REQUESTED HIGHER-WEIGHTED DRG ASSIGNMENTS

A. Authority.--PROs are required to review hospital requests for higher-weighted DRG assignments as addressed in 42 CFR 412.60(d)(2) and 476.71(c)(2).

NOTE: These procedures do not apply to hospitals in prospective payment system (PPS) waivered/excluded areas, PPS excluded hospitals, or M+C organizations.

B. Review Process.--Hospitals submit requests for higher-weighted DRG assignment directly to the intermediary for processing and payment. All such requests granted by the intermediary are subsequently selected by HCFA for PRO review on a post-payment basis. When reviewing hospital-requested higher-weighted DRG assignments, perform a medical necessity review, a quality review, and DRG validation. The purpose of DRG validation is to ensure that diagnostic and procedural information and the discharge status of the patient, as coded and reported by the hospital on its claim, matches both the attending physician's description and the information contained in the patient's medical record. Send notification to all affected parties when your review confirms a higher-weighted DRG. (See §4130.) When your DRG validation results in lower payment, take appropriate action when you identify a coding error that results in increased payment while performing hospital-requested higher-weighted DRG assignments (see §4130.D.). Notify the hospital, practitioner, intermediary, and carrier as specified in §7100.

C. Re-reviews.--As specified in 42 CFR 478.15(a)(1), the hospital may request a re-review of your decision to change a DRG assignment when the change results in a lower payment to the hospital. (See §7300.) As specified in 42 CFR 478.15(c), no additional review or appeal is available to the hospital.

4060. POTENTIAL CONCERNS IDENTIFIED DURING PROJECT DATA COLLECTION (PDC)

Follow the instructions contained in §4105 when reviewing potential concerns identified during PDC.

4070. REFERRALS

Review all cases referred by HCFA and Clinical Data Abstractions Centers (CDACs). Review cases referred by intermediaries, carriers, the M+C organization appeals contractor, and State Medicaid and survey and certification agencies when the referrals are within your review authority. The scope of review depends on the reason for the referral. Referrals may involve fee for service (FFS) or M+C review.

NOTE: For anonymous complaints/referrals that you receive directly, analyze the nature and scope of the issues involved and take any necessary action(s) (including referral to the appropriate organizations) to ensure that the issues are appropriately addressed/resolved.

A. Referrals from the RO.--The RO will refer cases to you in the following circumstances:

o During the course of review of skilled nursing facility (SNF) cases, intermediaries may identify cases where the patient entered the SNF from a hospital but required a higher level of care. The intermediary should then refer these cases to the RO, which screens the cases to determine if there is agreement with the intermediary that the case might involve a premature discharge. If the RO concurs, it will request that you review the hospital stay in question. Review the medical records for quality of care and appropriateness of setting. If a case is questioned for quality of care or appropriateness of setting, follow the timing and process requirements specified under case review. Submit a written report to the RO on your findings;

o If the intermediary or carrier identifies a problem or potential problem with a provider or practitioner in an area subject to PRO review, it will be referred to the RO, which will refer it to you, if appropriate. With RO approval, you may accept certain categories of cases directly from another Medicare contractor (e.g., quality of care referrals from the carrier in your State);

o Complaints/referrals that are anonymous, from outside agencies (e.g., an alleged anti-dumping violation case, see Part 9), or sources other than the usual ones (beneficiary, beneficiary's representative, intermediary, or carrier) may be referred to you if the RO determines the complaint/referral is credible and within your review authority.

B. Referrals to the RO.--Throughout your review activities, be alert to the identification of cases that may require additional development. Forward these cases to the RO for analysis or additional development after your review. The ROs will refer policy issues identified by you to HCFA CO for consideration. The types of cases may include:

o Cases that may require additional policy clarification or regulatory changes; and

o Cases that are suspect of deviant practice patterns or other potential abuse situations.

C. Referrals from the Intermediary.--The intermediary is required to screen claims to determine whether specific services, items, or procedures are covered or excluded from coverage. In some cases, coverage depends upon meeting specific conditions of medical necessity and reasonableness, such as type and severity of illness. When a medical necessity determination is needed, the intermediary will refer the case to you for review prior to making its coverage determination. (See §4125.) The intermediary will also refer cases it receives via its OIG hotline regarding quality of care complaints. Review these cases using the procedures specified in Part 5, §§5000 through 5050. For fraud and abuse referrals, see Part 9.

D. Referrals to the Intermediary.--During the course of review, be alert for potential Medicare Secondary Payer (MSP) cases (e.g., automobile accidents). When you identify a potential secondary payer, notify the intermediary so that it can investigate, develop the case and take appropriate recovery action. For example, if during review you find that an admission for a broken hip was the result of an auto accident, notify the intermediary of potential MSP (e.g., automobile insurance) and complete your review independent of the intermediary referral. The intermediary remains solely responsible for developing the MSP aspects of the case.

If you identify any relevant outpatient services related to an admission that may not have been included in the DRG, notify the intermediary. (See Medicare Intermediary Manual (MIM), Part 3, §3600.) You may also refer cases to the intermediary related to billing issues.

E. Referrals From the Carrier.--If a carrier identifies a problem or potential problem with a provider or practitioner in your area, it will direct the case to the RO for referral to you, if appropriate. The carrier should be specific about the type of review and report format needed from you. The carrier will also refer cases to you when ASC procedures are terminated due to medical complications that increase the surgical risk to the patient. Perform quality review when these types of cases are referred to you.

F. Referrals From CDACs.--Review all cases referred to you by CDACs. (See Part 11000.)

G. Referrals From Outside Agencies.--All requests for your review from outside agencies, including OIG and the Department of Justice (DOJ), must be approved by HCFA central office. Every request must be in writing, must offer clear and cogent rationale, and must be submitted through your project officer in the HCFA regional office. For fraud and abuse referrals, follow the instructions in §§9200ff.

EXCEPTION: For cases that involve anti-dumping issues referred by OIG, follow the instructions in §§9100ff.

(The next page is 4-13.)

Basic Case Review Activities

4100. INTRODUCTION

When you receive a mandatory review case (§§4000 - 4070), perform the appropriate review for admission, quality, invasive procedure, length-of-stay, coverage, discharge review, DRG validation, and other post review activities (see Part 7). If you review a case concurrently (e.g., notice of noncoverage) and it is necessary to review the case again retrospectively for other requirements (e.g., beneficiary complaint), it is not necessary to repeat the portion of the review you have already completed, except in the case of assistants at cataract surgery. (For type of settings and review, see §§4520.B and 5005.B.)

Currently, the following PRO areas are paid under a different methodoloey than the one applicable under the Medicare prospective payment system (PPS): Maryland, the Finger Lakes area of New York, the Virgin Islands, and Guam. The contracts for these PRO areas are designed to consider the special review needs for their areas. If you conduct review in one of these areas, follow the instructions in your contract.

4105. QUALITY REVIEW

A. Authority and Scope.--This review includes potential circumvention of prospective payment system (see §4255), and beneficiary complaints about quality of care (see Part 5, §5000). Conduct fee for service (FFS) quality review to determine whether the quality of services met professionally recognized standards of health care as addressed under §§1154(a)(1)(B) and 1862(g) of the Act, and 42 CFR 476.71(a)(2). Conduct Medicare+Choice (M+C) quality review to determine whether the quality of services met professionally recognized standards of health care, including whether appropriate health care services were not provided or were provided in inappropriate settings, and whether enrollees had adequate access to health care services as addressed under §1154(a)(4)(B) of the Act and 42 CFR 476.72(a)(1). You must always be alert for potential quality concerns regardless of the reason for review. Conduct a quality review of all cases subject to Payment Error Prevention Program (PEPP) review.

B. Objectives.--Quality review objectives include:

- Determining if care provided is of adequate quality;
- Identifying the source(s) of quality concerns; and
- Determining the extent of systemic problems in the delivery of care that warrant an improvement plan.

C. Strategies to Employ.--Your quality review activities should employ the following strategies:

- Developing/updating quality screening criteria (see §4510);
- Using the Physician Reviewer Assessment Format (PRAF) (see §§4300-4325) to obtain more consistent medical case review decisions and more reliable data collection;
- Providing educational feedback to practitioners and providers to improve the quality of care process and patient outcomes;
- Identifying system-wide concerns (e.g., communications errors between a diagnostic laboratory and an inpatient unit) uncovered during project data collection; and

o Engaging in collaborative development of performance improvement projects designed to improve the process and outcomes of patient care.

D. Quality Review Process.--Use the PRAF as a tool to determine if care furnished to Medicare beneficiaries meets professionally recognized standards. Quality of care concerns are categorized in §§C.1 through C.99 of the PRAF. (See Exhibit 4-1.) The non-physician reviewer raises a quality concern when care provided results in a significant or potentially significant adverse effect on the patient. A significant adverse effect may be one or more of the following:

o Unnecessary prolonged treatment causes an extended hospital or SNF stay, readmission soon after discharge, or additional treatment(s);

o Serious medical complications;

o Serious physiological or anatomical impairment;

o Significant disability; and/or

o Avoidable death.

E. Notification of Quality Concerns to Affected Parties.--See §§7200-7250, and 7310 for instructions concerning the issuance of potential, final, and re-review of quality concern notices.

F. Quality Improvement Activities.--You may consider, as one option, initiating an improvement project when you determine that a pattern of quality concerns is established, unless an identified quality concern causes severe risk to health and/or safety, or is a gross and flagrant violation, or the pattern meets the definition of a substantial violation in a substantial number. (See 42 CFR 1004.1(b) and §9000.) (Use sound professional judgment to determine what constitutes a pattern.)

4110. ADMISSION REVIEW

Review of the record must indicate that inpatient hospital care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the patient at any time during the stay. (See 42 CFR 476.71(a)(6)). The patient must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis.

A. Determining Medical Necessity and Appropriateness of Admission.--Review the medical record and use appropriate criteria to determine if an admission to a PPS or non-PPS hospital should be referred for physician review. The case is referred to a physician reviewer when the non-physician reviewer cannot approve the hospitalization as necessary and/or another level of care would have been appropriate without posing a threat to the safety or health of the patient.

The physician reviewer must consider, in his/her review of the medical record, any pre-existing medical problems or extenuating circumstances that make admission of the patient medically necessary. Factors that may result in an inconvenience to a patient or family do not, by themselves, justify inpatient admission. When such factors affect the patient's health, consider them in determining whether inpatient hospitalization was appropriate.

Inpatient care rather than outpatient care may be determined necessary only if the patient's medical condition, safety or health would be significantly and directly threatened if care were provided in a less intensive setting. Without accompanying medical conditions, factors that may cause the patient inconvenience in terms of time and money needed to be cared for at home, or for travel to a doctor's office, or that may cause the patient to worry, do not justify admission to a hospital or approval of a higher-than-necessary level of care.

B. Determining Whether Covered Care was Given at Any Time During a Stay in a PPS Hospital.--When you determine that the patient did not require an inpatient level of care on admission, but that the patient's condition changed during the stay and inpatient care became medically necessary, review the case in accordance with the following procedures:

- The first day on which inpatient care is determined to be medically necessary is deemed to be the date of admission;

- The deemed date of admission applies when determining cost or day outlier status (i.e., days or services prior to the deemed date of admission are excluded for outlier purposes); and

- The diagnosis determined to be chiefly responsible for the patient's need for covered services on the deemed date of admission is the principal diagnosis.

Notify the appropriate Medicare intermediary/carrier when the determination affects payment.

4115. INVASIVE PROCEDURE REVIEW

An invasive procedure is any procedure that clearly involves an incision, excision, amputation, introduction, endoscopy, repair, destruction, suture, or manipulation. Invasive procedures also include any procedure that affects, or has the potential for affecting, the DRG, and is being reviewed.

Determine if invasive procedures performed were reasonable and medically necessary, and if the quality of care met professionally recognized standards of medical care. Use appropriate criteria for non-physician screening. If the admission and the procedure were medically necessary, but the procedure could have been performed on an outpatient basis if the patient had not already been in the hospital, do not deny the procedure or the admission.

When an invasive procedure was not medically necessary, follow these guidelines:

- If the admission was for the sole purpose of the performance of the noncovered procedure, and the patient never developed the need for a covered level of service, deny the admission;

- If the admission was appropriate, and not for the sole purpose of performing the procedure, deny the procedure (i.e., remove from the DRG calculation), but approve the admission;

- For a day outlier, if the patient was in the hospital for any day(s) solely for the performance of the procedure or for care related to the procedure, deny the day(s) and the invasive procedure;

- For a day outlier, if the patient was receiving the appropriate level of covered care for all hospital days, exclusive of the procedure or care related to the procedure, deny the procedure or service (see **NOTE** in §4210 on day outlier reviews);

- For a cost outlier, if the patient was in the hospital for any day(s) solely for the performance of the procedure or care related to the procedure, deny the costs for the day(s) and for the performance of the procedure; and

- For a cost outlier, if the patient was receiving the appropriate level of covered care for all hospital days, deny the procedure or service.

All medically unnecessary procedures represent quality of care problems as well as utilization problems.

4120. LENGTH-OF-STAY REVIEW

Determine whether the length-of-stay for PPS day outlier (see **NOTE** in §4210) (and cost outlier, when necessary) claims and for specialty hospital/unit claims is appropriate and medically necessary. If Medicare payment is applicable to only part of the stay, review the covered portion of the stay and enough of the rest of the medical record (if necessary) to answer any specific questions that may arise from review of the covered part of the stay. If a patient became Medicare-eligible during a hospital stay, review enough of the medical record prior to the initiation of Medicare benefits to acquire sufficient information to make a determination. Do not perform lengthy reviews of noncovered care. In PPS waivered/excluded areas, length-of-stay review is performed for all inpatient admissions.

4125. COVERAGE REVIEW

Items/services that are experimental or are not efficacious are excluded from coverage in all cases, regardless of patient illness, treatment history, or setting. Certain other items/services are also excluded from coverage in all cases even though needed by the patient (e.g., routine physical checkups or hearing aids). (See §1862(a) of the Act.)

The intermediary/carrier, within the parameters of Medicare policy, has the authority to determine whether specific items/services are covered or excluded from coverage. The intermediary/carrier must follow existing national Medicare policy (e.g., criteria in the Coverage Issues Manual). When no national policy exists, intermediaries/carriers have the authority to establish local coverage policy. For some items/services (e.g., blepharoplasty or breast reconstruction following mastectomy), coverage depends upon meeting specific conditions of medical necessity and reasonableness, such as type and severity of illness. The intermediary refers inpatient claims to you involving items/services that require a medical necessity determination before the claims can be considered covered and payment can be made. (See 42 CFR 476.86(c)(1).)

For those cases referred to you, review the medical record only for the reason for the referral. Deny items/services when you determine they are not medically necessary and issue denial notices as specified in §7100. Notify the appropriate Medicare carrier when your determination affects Part B payment.

Additionally, if in the review of any case you recognize an item/service that is excluded from coverage in all cases, notify the intermediary or carrier, as appropriate, for necessary action.

4130. DRG VALIDATION REVIEW

Perform DRG validation on PPS cases (including hospital-requested higher weighted DRG assignments), as appropriate. (See §1866(a)(1)(F) of the Act and 42 CFR 476.71(a)(4).) Review the medical record, for medical necessity review, quality review, and DRG validation. The purpose of DRG validation is to ensure that diagnostic and procedural information and the discharge status of the patient, as coded and reported by the hospital on its claim, matches both the attending physician's description and the information contained in the patient's medical record.

NOTE: For PPS waivered/excluded areas, follow the instructions in your contract rather than these procedures.

A. Coding.--Designate a registered records administrator (RRA) or accredited records technician (ART) as the individual responsible for the overall DRG validation process. Use individuals trained and experienced in ICD-9-CM coding to perform the DRG validation functions. The validation is to verify the accuracy of the hospital's ICD-9-CM coding of all diagnoses and procedures that affect the DRG.

4135. DISCHARGE REVIEW

PROs must conduct discharge review as specified in 42 CFR 476.71(a)(6). Use criteria to identify, for physician review, cases of potential premature discharge (i.e., the patient was not medically stable and/or discharge was not consistent with the patient's need for continued acute inpatient hospital care). (See §4510.) In length-of-stay review, identify cases of potential delayed discharge. For example, the patient was medically stable, and continued hospitalization was unnecessary, or nursing home placement or discharge to home with home care would have been appropriate in providing needed care without posing a threat to the safety or health of the patient.

Factors that may result in an inconvenience to a patient or family do not, by themselves, justify a prolonged stay in the hospital. When such factors affect the patient's health, consider them in determining whether continued inpatient hospitalization was appropriate. Inpatient care rather than outpatient care is required only if the patient's medical condition, safety or health would be significantly and directly threatened if care was provided in a less intensive setting. Without accompanying medical conditions, factors that may cause the patient inconvenience in terms of time and money needed to care for the patient at home or for travel to a physician's office, or that may cause the patient to worry, do not justify a continued hospital stay or justify your approval of a higher-than-necessary level of care.

(The next page is 4-23.)

Additional Case Review Activities

4200. INTRODUCTION

When you receive a mandatory review case (§4000), in addition to performing basic case review (§4100), you may also determine whether to perform the following fee-for-service (FFS) and Medicare+Choice (M+C) case review activities:

- o Outlier review (see NOTE in §4210);
- o Ambulatory surgery review;
- o Limitation on liability determinations;
- o Readmission review; and
- o Transfer review.

4210. OUTLIER REVIEW

You are authorized to perform outlier review as specified at §1886(d)(A)(5)(i and ii) of the Act and 42 CFR 476.71(a)(7). Outliers are defined as those cases that have either an extremely long length-of-stay (day outlier) or extremely high costs (cost outlier) when compared to most discharges classified in the same DRG (42 CFR 476.1). Outlier review is not performed for M+C organization cases or in PPS waivered/excluded areas/hospitals. In these areas/hospitals, length-of-stay review is performed (see §4120).

NOTE: Perform day outlier reviews only for discharges occurring during fiscal years ending on or before September 30, 1997.

A. Day Outlier Review.--Day outlier cases occur automatically at a specified point in time for each DRG. Eligibility for this additional Medicare payment is automatic, and the hospital need not request it. Day outlier cases are identified as cases where the length-of-stay exceeds the outlier cutoff, or threshold, for the assigned DRG. A case becomes an outlier on the day after the threshold day of the assigned DRG. (See 42 CFR 412.82.)

Cases identified as day outlier cases may lose or change their day outlier status if, as a result of review, the DRG assignment is changed and a new threshold is assigned, or if the outlier (or other) days are not approved. Perform all reviews (admission, quality, invasive procedure, coverage, DRG validation, documentation, and discharge) for day outlier cases whether or not the case is confirmed as an outlier.

Factors that may result in an inconvenience to a patient or family do not, by themselves, justify a prolonged stay in the hospital. When such factors affect the patient's health, consider them in determining whether continued inpatient hospitalization was appropriate. You may determine that inpatient care rather than outpatient care was required only if the patient's medical condition, safety or health would have been significantly and directly threatened had care been provided in a less intensive setting. Without accompanying medical conditions, factors that may have caused the patient inconvenience in terms of time and money needed to care for the patient at home or for travel to a physician's office, or which may have caused the patient to worry, do not justify a continued hospital stay, or justify your approval of a higher-than-necessary level of care.

Conduct review for the level of care between the admission and the day the outlier threshold is met, as well as each day beyond the threshold. Consider the following in your review determination:

o If the admission was not medically necessary and appropriate (i.e., no covered inpatient hospital care was needed or delivered during the stay), deny the admission.

o If the admission was medically necessary and appropriate, but an acute level of care was not required for some days of this stay, deny these noncovered days up to the amount of days above the outlier threshold. For appropriately admitted cases, charges for denied days cannot be used to reduce the DRG payment portion. Noncovered days are carved out of the outlier payment, not to exceed the number of days that occur after the day outlier threshold. (See 42 CFR 412.82 (d).)

o If the case is still an outlier after DRG validation, determine if all days in the stay were medically necessary and at an appropriate level of care. You may determine that continued inpatient hospitalization was unnecessary and that outpatient care (e.g., in a nursing home) would have been equally effective in providing needed care without posing a threat to the safety or health of the patient.

o If there is a three-day qualifying stay, approve days awaiting placement in a skilled nursing facility (SNF), and include them in calculating outlier status if the patient was receiving a Medicare-covered SNF level of care for the days in question and the record documents that Medicare SNF placement was being sought. (Days when a patient is awaiting a mental assessment needed for nursing home placement are considered as "days awaiting placement, no bed availability" so long as the patient is receiving at least a SNF level of care.)

NOTE: Verify that the hospital made a genuine effort to place the patient in a SNF within the normal out placement area as defined by local community standards. Although there are no specific guidelines for "placement area" or frequency with which the hospital must determine availability, there are general guidelines in the Medicare Intermediary Manual (MIM), Part 3, §3421.1.

B. Cost Outlier Review.--Cases identified as cost outlier cases may lose or change their cost outlier status if, as a result of review, the DRG assignment is changed. Perform all reviews (admission, quality, invasive procedure, coverage, DRG validation, documentation, and discharge) for cost outlier cases whether or not the case is confirmed as an outlier.

For cost outlier cases, the hospital must provide a copy of the itemized bill and medical records for review. The itemized bill must be sufficiently detailed for you to identify each item or service billed. If, after DRG validation is complete, the case still meets cost outlier criteria, use the appropriate medical records plus the itemized bill to determine that all services (including each day of care) provided were medically necessary and appropriate and that the services billed were:

o Not duplicatively or erroneously billed;

o Actually furnished; and

o Ordered by the physician.

When reviewing cost outlier cases, be alert to certain items such as combined billing. HCFA does not allow payment for combined billing (i.e., physician charges and inpatient charges) on the inpatient bill. The physician charges are to be included on a separate Part B billing. If you identify physician charges on the cost outlier bill (e.g., radiologist fees for reading x-rays), deny these charges. These are technical denials (i.e., not based on medical necessity and appropriateness).

- Charges for convenience items or services; and

- Provider billing errors.

NOTE: When you review a case that involves noncovered services, such as routine foot or dental care, you are essentially determining whether or not the services furnished were medically necessary. Therefore, when you determine that the services should be denied based on medical necessity, make a liability determination for all affected parties on a case-by-case basis.

B. Determining the Beneficiary's Liability.--The regulatory authority for determining that a beneficiary (or his/her representative) knew that services/items were excluded from coverage is found at 42 CFR 411.404. Presume that the beneficiary (or his/her representative) did not know that services/items were not covered (and, therefore, is not liable for payment) unless the evidence indicates that a written notice was given to the beneficiary (or his/her representative) prior to performance of the service.

The beneficiary (or his/her representative) may be determined to be liable when he/she received:

- A previous written denial notice because the same service/item did not meet Medicare coverage guidelines, or the beneficiary (or his/her representative) received a written notice concerning similar or reasonably comparable services/items furnished on a previous occasion. For example, the subject admission is solely for chemotherapy and the beneficiary (or his/her representative) previously received a written denial notice stating that admissions solely for chemotherapy are not covered;

- An appropriate written notice of noncoverage (prior to performance of the services) from a provider or practitioner for the services/items in question; or

- A written denial notice (prior to performance of the services) from you for the services/items in question (e.g., preadmission denials).

When you determine that the beneficiary (or his/her representative) is liable, he/she is held responsible for payment for the denied services/items. The settlement for the cost of care is resolved between the provider and/or practitioner and the beneficiary.

C. Determining the Provider/Practitioner's Liability.--The regulatory authority for determining that a provider or practitioner knew or could reasonably have been expected to know that services/items were noncovered is found at 42 CFR 411.406. Determine the provider's liability whenever your denial is based on medical necessity, appropriateness of setting, or custodial care. Determine the practitioner's liability only in those cases involving payment denials of surgical and cost outliers with physician component, and inpatient/ambulatory/outpatient surgical denials based on lack of medical necessity. (In these situations, the carrier automatically adjusts its records (under the A/B link process) upon receipt of your written or electronically submitted denial and liability determinations.)

A provider or practitioner is considered to have known of noncoverage and, therefore, is held liable for the denied services/items in any of the following circumstances:

- You, the intermediary, or the carrier informed the provider or practitioner that the services/items furnished were not covered, or that similar or reasonably comparable services/items were not covered;

o The utilization review group or committee for the provider or the beneficiary's attending physician informed the provider that these services/items were not covered;

o The provider or practitioner could have been expected to have known that the services/items were excluded from coverage based on receipt of HCFA notices, manual issuances, bulletins or other written guides or directives from intermediaries/carriers or PROs, including notification of PRO screening criteria specific to the condition of the beneficiary for whom the furnished services/items are at issue. The provider or practitioner may challenge your determination that it had knowledge of noncovered services/items based on general screening criteria. However, it is appropriate to use general screening criteria in conjunction with other types of notification (e.g., prior denial notice for similar services/items);

o The provider or practitioner was notified of the categories subject to preadmission review and certification, and did not obtain the required review, and the services are subsequently determined to be medically unnecessary. Do not, however, automatically hold the provider financially liable when it makes a timely request, in accordance with its agreement with you, for preadmission review and you do not review the case (42 CFR 476.78(b)(6)(ii)); or

o The provider or practitioner knows what are considered acceptable standards of practice by the local medical community.

There may be additional circumstances where the provider or practitioner is also liable if it can be shown that it had prior knowledge that the services/items were not covered.

If a provider or practitioner is in doubt as to whether a service/item is covered, it may contact you for advice.

The physician's limitation on liability for payment under §1879 of the Act (when physician accepts assignment) or protection from making a refund to the beneficiary or his/her representative under §1842(l) of the Act (when physician does not accept assignment) is based on your determination of whether or not the beneficiary or physician knew that the services were noncovered. Unless there is evidence to the contrary (e.g., the physician annotated in the medical record that he/she has given the beneficiary a written advanced notice), presume that the beneficiary (or his/her representative) had no knowledge that Medicare would not pay for the denied services provided by the physician. On a case-by-case basis, this presumption may be challenged by the physician at the time you offer the physician an opportunity to discuss the case. At the same time, ask the physician if he/she accepted assignment if you were unable to determine this from your review of the medical record. The physician should be able to provide you with the information you need, as well as a copy of the written advance notice that he/she gave the beneficiary (or his/her representative).

D. Determining Liability When a Hospital-Issued Notice of Noncoverage (HINN) is Involved.--After the hospital issues a notice of noncoverage, the beneficiary (or his/her representative) is considered to have knowledge that services are not covered and is liable for customary charges as shown below.

1. Preadmission HINN.--The beneficiary (or his/her representative) is liable for customary charges for all services furnished if he/she enters the hospital after receipt of a preadmission HINN.

NOTE: This liability determination also applies to direct NF swing-bed admissions.

2. Admission HINN.--Determine liability as follows:

2. Requesting a Refund.--For refund of denied inpatient and outpatient hospital services, the beneficiary (or his/her representative) should contact the intermediary. For refund of ambulatory surgical services and services furnished by physicians accepting assignment, the beneficiary (or his/her representative) should contact the carrier. For refund of services furnished by physicians not accepting assignment, the beneficiary (or his/her representative) should contact the physician.

4240. READMISSION REVIEW

Readmission review involves admissions to an acute, general, short-term hospital occurring less than 31 calendar days from the date of discharge from the same or another acute, general, short-term hospital. (See §1154(a)(13) and 42 CFR 476.71(a)(8)(ii).) Neither the day of discharge nor the day of admission is counted when determining whether a readmission has occurred.

A. Medical Review Procedures.--Obtain the appropriate medical records for the initial admission and readmission. Perform case review on both stays. Analyze the cases specifically to determine whether the patient was prematurely discharged from the first confinement, thus causing readmission. Perform an analysis of the stay at the first hospital to determine the cause(s) and extent of any problem(s) (e.g., incomplete or substandard treatment). Consider the information available to the attending physician who discharged the patient from the first confinement. Do not base a determination of a premature discharge on information that the physician or provider could not have known, or events that could not have been anticipated at the time of discharge.

Review both the initial admission and the readmission at the same time unless one of them has previously been reviewed. In these cases, use, at a minimum, the PRAF case summary of the other admission in addition to the medical record of the case under review.

B. Review Involving Two PROs.--During the course of your review, you may identify a readmission where the initial stay was not in your State. If you identify a possible utilization or quality of care problem relating to the initial admission, send your findings to the responsible PRO.

C. Denials.--Deny readmissions under the following circumstances:

- If the readmission was medically unnecessary;
- If the readmission resulted from a premature discharge from the same hospital; or
- If the readmission was a result of circumvention of PPS by the same hospital. (See §4255.)

4250. TRANSFER REVIEW

Transfers are identified by the code entered on the bill and by the entries in the medical record. Transfers are planned admissions to a second hospital/excluded unit. Transfer review involves transfers between hospitals (e.g., from a PPS hospital to either a second PPS hospital or a second specialty hospital/unit) and transfers within a PPS hospital to an excluded unit in the same hospital. Using the relevant medical records, perform case review for medical necessity and appropriateness of admission for the admission and discharge from the first hospital and the second hospital/excluded unit. In the case of transfers to distinct part psychiatric units, the claim must show that the diagnosis necessitating the transfer was psychiatric in nature, and that the patient received active psychiatric treatment. (See §1814(a)(2)(A) of the Act.) When review involves two PROs, follow instructions in §4240.B.

4255. CIRCUMVENTION OF PROSPECTIVE PAYMENT SYSTEM (PPS)

A. Background.--Section 1886(f)(2) of the Act provides specific actions that the Secretary may take when you determine that a provider of Medicare services took an action with the intent of circumventing PPS, and that action resulted in unnecessary admissions, premature discharges and readmissions, or multiple readmissions. The Secretary may have you:

- o Deny Part A payment with respect to inpatient hospital services; or
- o Require appropriate corrective action to prevent or correct the inappropriate practice.

Actions taken pursuant to §1886(f)(2) of the Act and 42 CFR 476.71(a)(8) and (d) are in addition to the medical necessity, quality, and level of care determinations you make under §1154 of the Act. Because the denial actions specified in this part are made pursuant to §1886(f)(2) of the Act, providers are generally entitled to a hearing and judicial review of the denial determination.

Section 1862(d) of the Act, the statutory authority to appeal §1886(f)(2) of the Act denials, was repealed and replaced with §1128 (c) through (g) of the Act. When §1128 of the Act replaced §1862(d) of the Act, it appears that the right to a hearing of denials made in accordance with §1886(f)(2) of the Act was not specifically addressed. However, §1128(f) of the Act provides that, ". . . .any entity that is excluded (or directed to be excluded) from participation under this section is entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in §205(b) . . . ." Section 205(b) of the Act gives the Secretary, on his/her own motion, the authority to hold hearings and other proceedings as necessary. Therefore, while §1128 of the Act does not specifically address §1886(f)(2) of the Act denials, it does not remove the provider's right to due process.

These determinations are not made under §1154 or §§1862(a)(1) or (a)(9) of the Act; therefore, the limitation on liability provisions of §1879 of the Act are not applicable and the provider will be held liable. The beneficiary will not be charged for services denied under these instructions.

The Secretary may terminate a hospital's provider agreement under §1866(b)(2)(A) of the Act for failure to comply substantially with corrective action required under §1866(f)(2)(B) of the Act. In addition, under §1128(b)(13) of the Act, the Secretary may exclude a hospital from participation in any program under Title XVIII of the Act, and from any State health care program, if the hospital fails to comply substantially with a corrective action.

B. PRO Review Responsibilities.--Perform readmission and transfer review as described in §§4240 and 4250. Review the medical record for both the initial admission and the readmission or transfer. Complete the Physician Reviewer Assessment Format (PRAF) in accordance with §§4300-4325 for each case where the first level physician reviewer believes there is a potential quality concern. Monitor early readmission and transfer/discharge activities, including potential circumvention of PPS, in your State/jurisdiction. (See §§4240 and 4250.) Report any substantial issues identified and any resulting analyses to your project officer.

C. Types of Prohibited Actions That Circumvent PPS.--Following are the four types of prohibited actions:

1. Premature Discharge of Patient That Results in Subsequent Readmission of Patient to Same Hospital.--This prohibited action occurs when a patient is discharged even though he/she should have remained in the hospital for further testing or treatment or was not medically stable at the time of discharge. A patient is not medically stable when, in your judgment, the patient's condition is such that it is medically unsound to discharge or transfer the patient. Evidence such as elevated temperature, postoperative wound draining or bleeding, or abnormal laboratory studies on the day of discharge indicate that a patient may have been prematurely discharged from the hospital.

Scope of Case Review

4400. INTRODUCTION

You are authorized to conduct fee-for-service (FFS) review under §1154 of the Social Security Act (the Act) and 42 CFR, Part 476, Subpart C. You are also authorized to conduct Medicare+Choice (M+C) organization review under §1154(a)(4) of the Act and 42 CFR 476.70 and 476.72.

For FFS cases, you are to review services provided by PPS and non-PPS providers who are located in your State or review area. For M+C cases, you are to review services provided by M+C organizations in the State covered by the organization's contract (except for beneficiary's immediate review request of the Notice of Discharge and Medicare Appeals Rights, see Part 7). Where the M+C organization's immediate service area crosses State lines, your review responsibility extends across State lines also (i.e., review remains the responsibility of the PRO in the State in which the M+C organization has its contract).

Stays in PPS-excluded units/hospitals can be lengthy and must meet specific Medicare coverage requirements (e.g., for rehabilitation therapy) as discussed in the Medicare Intermediary Manual (MIM) §§3102, 3130, 3132.1, and 3634. When reviewing long stays in PPS-excluded units/hospitals, review only the days eligible for Medicare coverage.

4405. REVIEW OF MEDICARE SERVICES

The objectives of case review are dependent on whether you are conducting FFS or M+C organization review. Review FFS and M+C services reimbursed under Medicare when all of the following conditions are met:

A. Types of Services.--The services were covered by Medicare, regardless of whether they were covered for this particular beneficiary or whether Medicare payment was made. (See 42 CFR 424.5(a)(1).) For example, review the Medicare-covered services provided in a Medicare-certified SNF or SNF distinct part of a hospital even if the beneficiary's SNF days may have been exhausted at the time. Consult the intermediary if you have questions as to whether the services are covered by Medicare.

B. Sources of Services.--The services were furnished by a provider, non-participating hospital, or supplier that was, at the time it furnished the services, qualified to have payment made to it. (See 42 CFR 424.5(a)(2).)

C. Recipient of Services.--The recipient of the service(s) in question must be a Medicare beneficiary. (See 42 CFR 424.5(a)(3).) If it is not apparent that the case involves a Medicare beneficiary, check the Beneficiary Eligibility Status Tapes (BEST) through the RO, the Social Security office or the intermediary/carrier to determine Medicare status.

4410. REVIEW SETTINGS

Conduct a utilization and/or quality review applicable to the review setting.

o Utilization Review.--A review focused on determining the medical necessity and reasonableness of the items/services furnished or to be furnished to a patient; and the appropriateness of the care settings. (See §1862(a) of the Act and 42 CFR 476.71(a)(1).) As a result of your review, you may make an initial denial determination with respect to the above issues. (See 42 CFR 476.83.) This review does not apply to M+C organization settings.

o Quality Review.--A review focused on determining whether the quality of the services meets professionally recognized standards of care. (See 42 CFR 476.71(a)(2).) For M+C organization settings, the review includes whether appropriate health care services have not been provided or have been provided in inappropriate settings. (See 42 CFR 476.72(a)(1).) Perform FFS (may include utilization and/or quality) and M+C (includes quality only) review of services furnished in health care settings specified below:

- Ambulatory Surgery Performed in Ambulatory Surgical Centers (ASCs) and Hospital Outpatient Areas (HOPAs).--ASCs are distinct entities that operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization. ASCs must meet the Conditions for Coverage specified in 42 CFR Part 416, Subpart C. HOPAs must meet the Conditions for Participation (CoP) specified in 42 CFR, Part 482. (Conduct utilization and quality review for both ASC and HOPAs.)

- Comprehensive Outpatient Rehabilitation Facilities (CORFs).--CORFs provide diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons. CORFs must meet the CoP specified in 42 CFR, Part 485, Subpart B. (Conduct quality review only.)

- Home Health Agencies (HHAs).--HHAs are public or private agencies that specialize in giving skilled nursing services and other therapeutic services, such as physical therapy, in the home. HHAs must meet the CoP specified in 42 CFR, Part 484. (Conduct quality review only.)

- Hospices.--Hospices are public agencies or private organizations that are primarily engaged in providing care to terminally ill individuals. Hospices must meet the CoP specified in 42 CFR, Part 418. (Conduct quality review only.)

- Hospitals.--Hospitals (including emergency services/departments) are acute care, general hospitals, psychiatric hospitals, or rehabilitation hospitals that are subject to the provisions of the prospective payment system (PPS) or cost reimbursement. Inpatient hospitals must meet the CoP specified in 42 CFR, Part 482. (Conduct utilization and quality review.)

- Inpatient Hospital Units.--These units are distinct-part, separately certified PPS-excluded units within PPS hospitals (e.g., psychiatric and rehabilitation). PPS-excluded hospital units must meet the CoP specified in 42 CFR, Part 482. (Conduct utilization and quality review.)

- Providers of Outpatient Physical Therapy and Speech/Language Pathology Services. --These providers must meet the CoP specified in 42 CFR, Part 485, Subpart H. (Conduct quality review only.)

- Critical Access Hospitals (CAHs).--CAHs offer emergency care and short-term inpatient care. CAHs must meet the CoP specified in 42 CFR, Part 485, Subpart F. (Conduct utilization and quality review.)

- Skilled Nursing Facilities (SNFs).--SNFs are specially qualified facilities that have the staff and equipment to provide nursing care or rehabilitation services and other health-related services. SNFs must meet the CoP specified in 42 CFR 483, Subpart B. (Conduct quality review only.)

- SNF Swing-Beds.--These are inpatient hospitals that have beds certified as swing beds or CAHs that provide post-hospital SNF care. Inpatient hospital swing beds must meet the CoP specified in 42 CFR 482.66. (Conduct quality and utilization review.) CAH swing beds must meet the CoP specified in 485.645. (Conduct utilization and quality review.)

Case Review Procedures

4500. INTRODUCTION

Other fee-for-service (FFS) and Medicare+Choice(M+C) organization review procedures include:

- Using screening criteria;
- Requesting medical records/reviewing documentation;
- Affording practitioners and providers an opportunity to discuss potential initial denials, DRG assignment changes, and potential quality of care concerns;
- Adhering to timing of review requirements;
- Profiling case review results;
- Maintaining memoranda of agreements (MOAs) with providers, payers, and State licensing/certification agencies, and Medicare+Choice (M+C) organizations; and
- Monitoring hospital's physician acknowledgment statements.

4510. USING SCREENING CRITERIA

You are to establish written criteria or obtain national criteria (e.g., INTERQUAL) for non-physician reviewer use when screening FFS and M+C organization cases for referral for physician review. (See 42 CFR 476.100.) Criteria must be based on typical patterns of practice in your area for each review setting. For M+C organization review, use FFS criteria plus additional criteria unique to M+C organizations. Criteria must be reassessed regularly and updated as necessary to reflect current standards of practice.

Consult with physicians/practitioners actively engaged in practice in the State when establishing or updating criteria. Also request comments from physician organizations (e.g., State medical societies, the osteopathic society, and specialty societies), the State Hospital Association, and the Medicare carrier(s) in the State. Attempt to develop mutually satisfactory time frames for comment periods. Involve health care practitioners other than physicians (HCPOTPs) in the development of criteria used in the review of services delivered by HCPOTPs. (See 42 CFR 476.102(a).)

Notify provider, physician, and M+C organizations within the State of newly established or revised criteria at least 30 calendar days prior to implementation. New PRO contractors must notify provider, physician, and M+C organizations within 30 calendar days of their contract effective date. Provide copies of criteria to providers/practitioners/M+C organizations, upon request. Provide copies of criteria to carriers upon mutual agreement. Do not send copies of your criteria to HCFA for approval, but you must have copies available for HCFA's review upon request.

NOTE: If the screening criteria you use are copyrighted, provide the provider/practitioner with the information on how and where a copy of the screening criteria may be obtained, and any associated costs.

Specify in your MOA with providers, M+C organizations, and payers how they will provide input in the development/amendment process and how you will notify them when you are establishing the criteria you will use. (See Part 3.)

4520. REQUESTING MEDICAL RECORDS/REVIEWING DOCUMENTATION

A. Requesting Medical Records.--You are authorized to access and obtain medical records, pertinent to health care services furnished to Medicare patients, held by any provider in your review area. (See 42 CFR 480.111.) A provider claiming Medicare payment must permit you to examine its medical records as necessary for you to perform your review functions. (See 42 CFR 476.88(a).)

Providers must cooperate in the conduct of your review by photocopying and delivering all required information within 30 days of a request. (See 42 CFR 476.78(b)(2).) If a provider does not provide the requested information within the prescribed time frame, you may deny the claim. (See 42 CFR 476.90(b).) Specify in your MOA with providers and M+C organizations the method/time frames for submission of medical records. (See Part 3.)

Under the Payment Error Prevention Program (PEPP), the Clinical Data Abstraction Centers (CDACs) are responsible for making the initial request for the surveillance sample of medical records as well as performing a screening review. The CDACs request 93 records per State per month. Hospitals are expected to deliver the requested medical records to the CDAC within 30 days. For these records, the CDACs mark a record as cancelled (not received) **45 days after the date of the request.** The CDACs are instructed to forward any records received after the past due date to you. The CDACs do not perform any screening review on these late records.

You must perform a full review of all cases you receive from the CDAC under PEPP. If a requested record is not received, then the documentation necessary to establish payment is missing and a payment error has occurred. Issue a technical denial (see §7101.B) for all requested records not received within the required time frame.

1. Onsite Review.--Onsite review is a non-physician review performed at a provider or M+C organization site. For M+C organization cases, do not perform review onsite unless you have reached an agreement with the M+C organization to perform review at the organization's or provider's site.

Afford providers/M+C organizations adequate time to locate medical records before an onsite review. Establish mutually agreeable time frames for giving notice to providers/M+C organizations. Occasionally, you may be unable to provide sufficient notice to a provider/M+C organization because of logistical problems. For example, the reviewer completes a review at an area provider/M+C organization at a time earlier than anticipated, and in the interest of efficiency, needs to begin the onsite review at the next scheduled provider/M+C organization immediately. You and the provider/M+C organization should agree on a method to accommodate these requests. Once you begin your review, the provider/M+C organization may not change or request amendment to the content of the record or to the Medicare claim.

When the non-physician reviewer determines that a case requires physician review, the reviewer will request that the provider/M+C organization photocopy and submit the records to you. The total time between the original request for onsite review and the submission of the copied records to you must not exceed 30 calendar days. Schedule your onsite review in such a way to ensure that the provider/M+C organization has sufficient time to photocopy and submit records should off-site review be necessary.

2. Off-site Review.--Off-site review is a non-physician review performed at a PRO site. For M+C cases, perform the review at your site unless you have reached an agreement with the M+C organization to perform the review at the organization's or provider's site.

Allow the provider/M+C organization 30 calendar days from the date of your request to locate and submit a copy of the medical records to you. Advise the provider/M+C organization of the action you will take if the records are not furnished within the 30-day time frame. (See §4520.C.)

If the M+C organization is unable to obtain medical records from a provider, or if the provider charges the M+C organization a significantly higher amount than Medicare pays for photocopying costs, the M+C organization may ask you to obtain the records directly from the provider. The M+C organization must submit its request in sufficient time so that the timing of review requirements are not adversely affected.

NOTE: This requirement does not apply to the beneficiary's immediate PRO review request of a Notice of Discharge and Medicare Appeals Rights. (See Part 7.)

3. Failure to Submit Medical Records.--When an inpatient hospital, ASC, or swing-bed provider fails to submit the medical records for a FFS patient within the prescribed time frames, issue a technical denial and record a documentation error. (See §7101.B.) If the provider submits the medical records after the technical denial is made, reopen the case as specified in §7102.B. When a case is reopened, do not instruct the intermediary to adjust the technical denial until your review is completed. If an M+C organization fails to submit medical records within 30 calendar days from the date of your request, record a documentation error.

When medical records are not submitted within the prescribed time frames in all other situations (or an inpatient hospital, ASC, or swing-bed provider displays a pattern of failing to submit medical records for FFS patients), refer the case to your RO project officer. In cases involving FFS patients, the project officer will collaborate with the Division of Medicaid and State Operations to threaten revocation of the provider's Provider Agreement for failure to comply with the terms of the agreement. In cases involving M+C beneficiaries, the project officer will consult with the Center for Health Plans and Providers regarding regulatory or contractual actions that may be taken.

B. Reviewing Documentation.--Collect patient data required by 42 CFR 476.78(b)(2), including medical records. The medical record should contain documentation to justify admission, services furnished, and when pertinent, continued care. The documentation should support the diagnoses and treatments performed and describe the patient's progress and response to medication and treatment.

1. Medical Record Requirements.--Medical records are to conform to the following regulatory requirements for content:

- Ambulatory surgical centers (ASCs) are to meet the requirements specified in 42 CFR 416.47(b).
- Comprehensive outpatient rehabilitation facilities (CORFs) are to meet the requirements specified in 42 CFR 485.60(a).
- Home health agencies (HHAs) are to meet the requirements specified in 42 CFR 484.48.
- Hospices are to meet the requirements specified in 42 CFR 418.74(a).
- Hospital outpatient areas (HOPAs) are to meet the requirements specified in 42 CFR 482.24(c).
- Inpatient hospitals/units are to meet the requirements specified in 42 CFR 482.24(c).
- Providers of outpatient physical therapy and speech/language pathology services are to meet the requirements specified in 42 CFR 485.721(b).
- Psychiatric hospitals are to meet the requirements specified in 42 CFR 482.61.

o Rehabilitation hospitals are to meet the requirements specified in 42 CFR 482.24(c).

o Critical access hospitals (CAHs) are to meet the requirements specified in 42 CFR 485.638(a)(4).

o Skilled nursing facilities (SNFs) and SNF swing-beds are to meet the requirements specified in 42 CFR 483.75(l)(5).

o Community mental health centers (CMHCs) are to meet the requirements specified in 42 CFR 424.24(e)(2).

2. Establishing Documentation Guidelines.--PROs may establish guidelines for the components of a medical record that must be physically present to proceed with a review (e.g., pathology report when tissue is removed). Guidelines must be consistent with the regulatory Conditions of Participation in 42 CFR Subchapter E regarding providers/suppliers of care.

NOTE: Documentation guidelines are not guidelines as to actual clinical practices. They should address only what must be present in the facility's medical record for review to proceed.

When establishing or changing documentation guidelines:

o Consult with the provider and physician communities within the State. Request comments from physician organizations such as State medical societies, the osteopathic society, specialty societies, and from provider organizations such as the State Hospital Association. Attempt to develop mutually satisfactory time frames for comment periods.

o Involve health care practitioners other than physicians (HCPOTPs) for guidelines used in the review of services delivered by HCPOTPs.

o Collaborate with other PROs, when appropriate.

o Notify provider, physician, and M+C organizations within the State at least 30 calendar days prior to implementation. New PRO contractors must notify provider, physician, and M+C organizations within 30 calendar days of their contract effective date.

o Provide a copy to providers/practitioners/M+C organizations upon request.

o Reassess regularly and update as necessary.

Specify in your MOA with providers/M+C organizations and payers the method for them to provide input in the development process and of notifying them when the guidelines you will use are established. (See Part 3.)

C. Medical Record Incomplete or Illegible.--If the non-physician reviewer cannot complete review because a portion of the record is missing or illegible, record a documentation error and request the provider/M+C organization to submit the necessary documentation within 15 calendar days. If an inpatient hospital, ASC, or swing-bed provider does not submit the requested documentation for a FFS patient within the allotted time frame, issue a technical denial as specified in §7101.B. If the requested documentation is submitted after the technical denial is made, reopen the case as specified in §7102. If other providers (including inpatient hospitals for M+C organization patients) do not submit the requested documentation, refer the problem to your RO project officer. Do not allow additional time beyond the allotted 15 days before taking corrective action.

In most cases, when a portion(s) of the medical record is absent or illegible, your non-physician reviewers can determine the presence of documentation errors. Occasionally, a non-physician reviewer may not be able to determine if a documentation error exists (i.e., the non-physician reviewer cannot determine whether a missing report is crucial to complete the review). In these cases, a physician reviewer must make the determination. At this point in the review, the physician reviewer is to address only the question of the missing/illegible documentation. A complete review would be performed by a physician reviewer at a later time if the case is referred.

PRO physician and non-physician reviewers are expected to be proficient in deciphering a variety of handwriting styles and copy qualities. Make all reasonable efforts to read medical records as supplied by the facility. At least two reviewers must attempt to locate and/or read the problematic section(s) of the record prior to requesting missing/illegible documentation. If the review is performed onsite, seek assistance from the provider/M+C organization in locating or reading the problematic section(s).

D. Missing Physician Documentation.--Record a documentation error if information required for a physician reviewer to make a determination is not found in the body of the medical record. In this situation, the physician reviewer must request additional information from the provider/M+C organization/physician(s) prior to making a review determination.

E. Recording Documentation Errors.--Record a documentation error in cases where a non-physician or physician reviewer must request additional information from a provider or M+C organization because a determination cannot be made on the basis of the medical record alone. A documentation error occurs when:

- The provider/M+C organization fails to produce the medical record;
- The documentation necessary for the non-physician reviewer to make a review determination is illegible or is missing from the medical record; or
- The physician reviewer must request additional documentation from the attending physician.

Specify in your MOA with providers/M+C organizations and payers the method/time frames for them to provide additional information. (See Part 3.)

A single record can have more than one documentation error. For example: the record was provided to you untimely--error one; when you did receive it, it was missing necessary documentation--error two; after the provider sent the missing documentation, the physician reviewer did not have enough information to make a review decision--error three.

Do not record a documentation error if you subsequently determine that the requested information was:

- In the medical record and simply overlooked; or
- Not documented in the medical record because the care was not furnished;

F. Examples of Documentation Errors.--Following are examples of how a documentation error should be recorded by a non-physician reviewer. The examples address possible documentation errors for a percutaneous transluminal coronary angioplasty (PTCA). A non-physician reviewer may determine that a cardiac catheterization report, or its equivalent, should be included in the medical record to establish the medical necessity/appropriateness of a PTCA. Equivalent documentation should contain the information normally found in a catheterization report (e.g., coronary arteries involved, extent of blockage).

o There is evidence in the medical record that the catheterization was performed, but the report is missing. However, the information that would normally be contained in the report is given in a detailed progress note in the medical record. In this case:

- Do not record a documentation error; and

- Proceed with the review.

o There is evidence in the medical record that the catheterization was performed, but there is no report or equivalent entry. In this case:

- Record a documentation error;

- Request the report or its equivalent from the provider; and

+ If the provider supplies the requested report within the required time frame, proceed with the review; or

+ If the provider fails to supply the requested report within the required time-frame, issue a technical denial and do not proceed with the review.

o There is no evidence in the medical record that a catheterization was performed. In this case:

- Request the report or its equivalent from the provider; and

+ If the provider supplies a report or its equivalent within the required time-frame, record a documentation error and proceed with the review;

+ If the provider acknowledges that the catheterization was performed, but does not supply the report or its equivalent within the required time frame, record a documentation error, issue a technical denial, and do not proceed with the review;

+ If the provider does not supply the report or its equivalent within the required time frame, record a documentation error, issue a technical denial, and do not proceed with the review;

+ If the provider acknowledges that the catheterization was not performed, do not record a documentation error at this point and proceed with the review. If, when the case is referred, the physician reviewer must make a determination as to whether a medical necessity/quality of care concern exists. If an initial denial is issued, it is a medical necessity denial and a quality of care concern.

G. Requesting Action Plans.--Determine whether a pattern of documentation errors exists. Request an action plan from a provider for correcting documentation errors in the following situations:

o When a pattern seriously and repeatedly impedes review; or

o When a pattern seriously threatens the quality of care (e.g., relevant documentation important in assuring adequate care is missing in physicians'/nurses' notes and the lack of this documentation could threaten the quality of care).

4530. PROVIDING OPPORTUNITY FOR DISCUSSION

When you identify a potential utilization, DRG assignment, or quality concern, notify providers/practitioners/M+C organization in writing of the opportunity for discussion. Give them 20 calendar days from the date of your notice for oral discussion with appropriate PRO personnel, and/or to submit written comments/information prior to making your final determination. (See §1154(a)(3) of the Act and 42 CFR 476.93.) Consider any information submitted when reaching your final determination. Send a final determination notice whenever an opportunity for discussion is afforded. (See §7230 for notice requirements for potential quality concerns. Modify these notices accordingly when addressing potential utilization and DRG validation concerns.)

Take all reasonable measures to ensure that practitioners/providers/M+C organizations have an opportunity to discuss the potential concern. For example, provide a toll-free telephone number available during normal business hours or advise that you will accept collect calls if you do not have a toll-free number. Document the content of telephone or personal conversations with practitioners/providers/M+C organizations.

Specify in your MOA with providers/M+C organizations to whom you will send your Aopportunity for discussion@ notices, and the method those parties should use to submit additional information to you in response to such notices. (See Part 3.)

A. Practitioners.--Afford practitioners an opportunity for discussion in accordance with the following guidelines:

- Afford involved physicians an opportunity to discuss the concern(s) directly with a PRO physician. (You are encouraged to provide physicians an opportunity to discuss the case with a like specialist.)

- Afford involved HCPOTPs an opportunity to discuss the concern(s) directly with a PRO HCPOTP, if available, or with a PRO physician who is a specialist in the type of services under review.

- If the involved practitioner is out of town for an extended period of time, document that he/she is unavailable and when he/she will return. Hold the case until the practitioner is available to discuss it. Notify the practitioner when he/she returns and allow the customary 20-day period for reply. This situation is not expected to occur frequently.

- Contact the admitting physician directly to obtain additional information in situations where the attending physician did not admit the patient and cannot provide the relevant facts.

- When the attending and admitting physicians are in the same group practice, continue to direct your correspondence and discussions to the attending physician. In these situations, it is not unreasonable to expect the attending and admitting physicians to consult on the case.

B. Providers/M+C Organizations.--Afford providers/M+C organizations an opportunity for discussion in accordance with the following guidelines:

- Afford providers/M+C organizations an opportunity to discuss the concern(s) with a PRO physician if the provider's/M+C organization's representative is a physician. If the provider/M+C organization's representative is a nurse or other staff person, use knowledgeable non-physician staff for the discussion, as appropriate.

o For cases reviewed on a preadmission basis (e.g., assistant at cataract surgery), if the physician does not know which provider will furnish the services, document the file accordingly. In this situation you will be unable to offer the provider an opportunity for discussion.

o M+C organizations may coordinate responses with the physician/provider and forward one combined response to you.

4540. ADHERING TO REVIEW TIME FRAMES

A. Review Beginning/Completion Dates.--The time frame for FFS and M+C retrospective review begins when you have adequate information to request medical records. For PEPP cases (including DRG validation), the review time begins when you receive the medical records from CDAC. If you receive an incomplete medical record from CDAC, follow the review time frames specified in §4540.B. The review of a case ends with a completion date as follows:

o When a case is not referred for physician review, the review completion date is the date the review of the medical record is completed.

o When a case is referred for physician review and the physician reviewer indicates that no further review is necessary, the review completion date is the date the physician reviewer assessment format (PRAF) is completed.

o When an opportunity to discuss a case has been afforded the physician/provider/M+C organization, the review completion date is the date the final notice is sent to all parties. Do not issue an initial denial, DRG assignment change, or confirmed quality concern notice until the earlier of either completion of the discussion or 20 calendar days after the date you make a preliminary notification to the physician/provider/M+C organization. When a case is questioned by the physician for quality of care, and is also questioned for DRG validity or utilization, do not send notices at separate times. Notices should be sent to comply with the review deadline for quality of care.

Within the general time frames of review, you may accelerate your review in some areas and use the time gained in other areas.

B. Review Time Frames.--The time frames for questioned cases include the 20-day opportunity for discussion requirement as specified in §4530. When a provider/M+C organization submits an incomplete or partially illegible medical record, add 15 calendar days to the review time frames specified below.

1. Retrospective Review.--Complete review within the following time frames:

o 60 calendar days for an unquestioned case (30 days for PEPP cases);

o 90 calendar days for a case questioned for DRG validity or by the physician reviewer for utilization (60 days for PEPP cases); or

o 100 calendar days for a case questioned by the physician reviewer for quality of care (70 days for PEPP cases).

2. Reopenings.--Complete review within the following time frames:

o 30 calendar days for an unquestioned case;

o 50 calendar days (from receipt of request) for a case questioned for DRG validity or by the physician reviewer for utilization; or

- 60 calendar days (from receipt of request) for a case questioned by the physician reviewer for quality of care.

4550. PROFILING CASE REVIEW RESULTS

You are required to build a database of information collected from all case review activities. The principal purpose of this database is to generate PPS and non-PPS provider/M+C organization profiles to use as a data source in conducting your State analysis for use in your Payment Error Prevention Program (see Part 11 of this manual), and to identify possible interventions, including cooperative projects and beneficiary communications activities. You are to generate routine and ad hoc provider profiles whenever necessary. You are not required to disseminate reports on a regular basis. However, produce them upon request by PPS and non-PPS providers/M+C organizations or by HCFA. Reports disseminated to PPS and non-PPS providers/M+C organizations are governed by the confidentiality regulations contained in 42 CFR Part 480.

Use profiles to determine if individual concerns, when considered as a whole, or a pattern of quality concerns might be indicative of a systemic concern. A systemic concern is one that reflects the PPS and non-PPS providers'/M+C organization's internal policies/procedures or a general problem that exists within the medical community. For example, the M+C organization only permits enrollees to have a certain number of a particular diagnostic study within a given time frame, or the PPS/non-PPS hospital's system for consultation referrals causes delay in the provision of necessary care.

When you suspect the existence of a systemic problem, request information from the PPS or non-PPS provider/M+C organization regarding its systems/guidelines governing the issue, including how the PPS or non-PPS provider/M+C organization monitors the provision of the services in question. You may request this type of information based on one or more reviews. If, for example, you believe the PPS or non-PPS provider/M+C organization guidelines for a specific test/condition are a concern, you may request the specific guidelines in this area and work with the PPS or non-PPS provider/M+C organization to correct any concerns. The intent is to see whether the problem derives from the PPS or non-PPS provider's/M+C organization's internal directives or whether the directives are acceptable. However, the PPS or non-PPS provider/M+C organization does not have the ability to monitor that its directives are being followed.

4560. MAINTAINING MEMORANDA OF AGREEMENTS (MOAs)

Maintain MOAs with providers, payers, M+C organizations and State licensing/certification agencies as instructed in Part 3.

4570. PREPAYMENT REVIEW SYSTEM (PRS) IMPLEMENTATION

Your request to intermediaries and carriers to implement preprocedure and prepayment review of a procedure, diagnosis, provider, or practitioner must conform with the negotiated memoranda of agreements (MOAs) between you and the payers outlining the conditions for necessary data exchange requirements. (See Part 3.)

4580. MONITORING HOSPITALS' PHYSICIAN ACKNOWLEDGMENT STATEMENTS

A. Background.--Regulations at 42 CFR 412.46 (one of the conditions at 42 CFR 412, subpart C) require hospitals to obtain only one signed acknowledgment from physicians who are being granted admitting privileges at a particular hospital. The physician must complete the acknowledgment at the time that he/she is granted admitting privileges at the hospital or before, or at the time the physician admits his/her first patient to the hospital. When the hospital submits a claim, it must have on file a signed and dated acknowledgment from the attending physician that the physician has received the notice specified in 42 CFR 412.46(b). Existing acknowledgments signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

Hospitals must meet the conditions specified in 42 CFR 412, subpart C to receive payment under the PPS for inpatient hospital services furnished to Medicare beneficiaries. If a hospital fails to comply fully with these conditions with respect to one or more Medicare beneficiaries, HCFA may, as appropriate:

- o Withhold Medicare payment in full or in part to the hospital until the hospital provides adequate assurances of compliance; or

- o Terminate the hospital's provider agreement.

B. Monitoring Requirements.--On an ongoing basis, monitor hospitals to ensure that they are appropriately obtaining the acknowledgment statements from physicians with new admitting privileges as required at 42 CFR 412.46. You may perform this activity offsite or onsite the hospital setting. To perform this activity, you must do the following:

- o Establish a monitoring plan using the hospitals' own internal procedures to secure the acknowledgment statements from physicians. Your plan must ensure that each hospital, in your review area, is in compliance with the acknowledgment requirement;

- o Coordinate, as necessary, with the intermediary and hospitals in your review area to develop and implement your plan. For example, you may coordinate with the intermediary to establish a mechanism to facilitate reporting by the intermediary when the intermediary is aware/has knowledge that a hospital is not obtaining appropriate acknowledgment(s) before billing; and

- o Provide your project officer with a copy of your monitoring plan.

C. Reporting Requirements.--If you determine that corrective action is necessary:

- o Notify the hospital that it must correct the deficiency immediately. Concurrently, inform the appropriate HCFA Associate Regional Administrator through your project officer; and

- o If the problem continues, or a pattern of noncompliance is established, refer the case to the appropriate HCFA Associate Regional Administrator for further action(s) through your project officer.

4590. REPORTING REQUIREMENTS FOR REVIEW ACTIVITIES

A. Reporting On Case Review.--Report all your review activities, including PEPP activities, into the Standard Data Processing System (SDPS) as specified in your contract, the SDPS Data Base Administrator Guide, or other administrative directives.

B. PRO and Intermediary Information Exchange.--After completing case review, report to the intermediary and the provider, as specified in the Standard Data Processing System Data Base Administrator Guide, any claims that need adjustment because of:

- o A change in the DRG;
- o Admission denied;
- o Day outlier days denied (see **NOTE** in §4210);
- o Cost outlier services denied;
- o Non-prospective payment system (PPS) hospital or skilled nursing facility (SNF) swing-bed days denied;
- o Incorrect date for hospital to begin charging the beneficiary;
- o Failure to provide medical documentation for review (see §4520A.3);
- o Partial or complete reversals of a previous PRO decision;
- o Change in discharge status in a PPS hospital;
- o Deemed admission denials or approvals;
- o Readmission/transfer denied;
- o Assistant-at-cataract denied; and
- o Outpatient services denied.

(The next page is 4-65.)

Personnel

4600. INTRODUCTION

You must have access to a sufficient number of non-physician reviewers to screen medical records and physician reviewers to make PRO determinations for fee-for-service (FFS) and M+C cases under review as specified in your contract.

4610. NON-PHYSICIAN REVIEWERS

Use non-physician reviewers with the necessary clinical education and experience to perform medical record screening. Non-physician reviewers must be familiar with your review norms and criteria. Reviewers who perform DRG validation must be trained and experienced in ICD-9-CM and CPT-4/HCPCS coding. At least one registered records administrator (RRA) or accredited records technician (ART) must be employed to oversee the overall coding and DRG validation process.

4620. PHYSICIAN REVIEWERS

A. Eligibility Requirements.--A physician reviewer must be a doctor of medicine, osteopathy, dentistry, podiatry, or optometry, or another individual who is authorized under Federal or State law to practice medicine, surgery, osteopathy, dentistry, podiatry, or optometry. (See §1154(c), 42 CFR 476.1, and 42 CFR 476.98(a).)

Only a physician reviewer can make a final determination concerning another physician. A final determination is a decision made by your physician reviewer that a potential utilization or quality concern is or is not a confirmed utilization or quality concern. The determination can be made only after complying with all applicable review requirements, including affording opportunity for discussion. (See §4530.)

B. Active Practice Requirements.--Your physician reviewers must either be engaged in active practice in the State or be military physicians who actively practice in a military or VA health care facility in your State, even though the physician's license to practice has been issued by a different State. If the M+C organization's immediate services area includes the provision of services in an adjacent state, use actively practicing physicians who are licensed and provide care in the adjacent State to review these services.

Active practice means that the physician usually practices (on a routine basis) a minimum of 20 hours per week. Temporary interruptions of a short-term nature are acceptable as long as the physician clearly has an ongoing, active practice throughout the year and the physician's involvement in the practice averages 20 hours per week during the year. The "routine basis" requirement is met if a physician sees Medicare beneficiaries on an ongoing basis throughout the year, regardless of the total number of contacts with these beneficiaries.

Active practice must also include active staff privileges in a health care facility on a regular basis. (See 42 CFR 476.1.) Doctors of medicine, osteopathy, or dentistry must have active staff privileges in one or more hospitals in the State. Doctors of podiatry must have active staff privileges in one or more facilities in the State. Doctors of optometry are not required to have staff privileges. Note that emergency room physicians and dentists who do not have admitting privileges in an acute care hospital can meet the requirement of active staff privileges as it is defined in this regulation.

Accept the physician's certification that he/she is in active practice with active staff privileges in the State (the hospital/facility must be specified) unless there is reason to believe otherwise. In questionable cases, have the physician provide documentation. The physician's certification must be renewed on a biennial basis. Inspect biennially each physician reviewer's license to practice in your State.

C. Licensure Requirements.--Generally, the physician reviewer must have the same licensure as the physician whose services are under review. That is, a licensed doctor of medicine, osteopathy, dentistry, podiatry, or optometry must be reviewed by another licensed doctor of medicine, osteopathy, dentistry, podiatry, or optometry respectively. (See §1154(c) of the Act.)

If use of the required reviewer is impractical, would create an unavoidable potential conflict of interest, or would compromise the effectiveness or efficiency of your review process, you may use a licensed doctor of medicine or osteopathy to review the services furnished by any physician. (A dentist, optometrist, or podiatrist can only review services furnished by other physicians with the same licensure.)

D. Specialty Requirements.--The physician reviewer must generally be a specialist in the same field as the physician whose services are under review. For example, assign an internist to review care furnished by an internist, an orthopedist to review care furnished by an orthopedist, etc., regardless of the type of services under review. In the case of psychiatric and physical rehabilitation services, however, make arrangements to ensure that (to the extent possible) initial review of such services are made by a physician who is trained in psychiatry or physical rehabilitation (as appropriate). (See §1154(a)(7) of the Act.) For reconsideration reviews, the regulations at 42 CFR 478.28 generally require the physician reviewer to be a specialist in the type of services under review.

Whenever possible, use physician reviewers who are certified by a specialty board recognized by the American Board of Medical Specialties (for M.D.s) or by a specialty board under the auspices of the American Osteopathic Association (for D.O.s). Each prospective board-certified physician reviewer must provide evidence of that certification.

If use of the required reviewer is impractical, would create an unavoidable potential conflict of interest, or would compromise the effectiveness or efficiency of your review process, use another physician reviewer whose practice and experience is relevant to the facts and circumstances of the case to be reviewed. In these cases, use the most appropriate reviewer available. (See 42 CFR 476.98(a)(2).)

E. Setting Requirements.--Generally, the physician reviewer must practice in a setting similar to the setting in which the physician whose services are under review practices. If use of the required reviewer is impractical, would create an unavoidable potential conflict of interest, or would compromise the effectiveness or efficiency of your review process, you may use a physician reviewer who practices in a different setting than the physician whose services are under review.

Whenever possible, use M+C organization physicians when physician review of M+C services is required. An M+C physician is a physician who, as a regular part of his/her practice, provides care that is paid for by an M+C organization. These physicians may be employed by a staff model M+C organization or work under arrangements with an organization (e.g., an Independent Practice Association (IPA) model).

F. Hierarchy of Exceptions.--The concept of peer review requires that, whenever possible, PROs use physician reviewers whose licensure, specialty, and practice setting are the same as (or similar to) those of the physician whose services are under review. Consider these variables when assigning cases to physician reviewers.

Your goal is to match all the variables--licensure, specialty, and practice setting. When this is not possible, document the reasons for your physician reviewer selection. There are valid reasons for failing to match all variables for every case (e.g., your pool of physician reviewers in a rare specialty is too small when also considering the physician reviewer requirements needed for a possible reconsideration).

When you cannot meet all reviewer requirements for a particular case, apply the exceptions in §§4620.C through F. in specific order to retain the more significant requirements as much as possible. When an exception is necessary:

- Try to resolve the problem by using the exception for similar setting requirements before using the exception for the specialty or licensure requirements;
- If unsuccessful, try to resolve the problem by using the exception for the specialty requirements before using the exception for licensure requirements; or
- As a last resort, use the exception for the licensure requirements.

G. First Level Physician Reviewers.--First level physician review occurs in every case where a non-physician reviewer has identified a potential concern requiring a clinical decision. (See §4310.) First level physician reviewers must meet the physician reviewer requirements outlined in §§4620.A through F.

H. Second Level Physician Reviewers.--Second level physician review occurs when a potential concern is identified and the provider/practitioner/M+C organization responds to your opportunity for discussion. (See §§4315 and 4530.) Second level physician reviewers must meet the physician reviewer requirements outlined in §§4620.A through F. The second level physician reviewer may be the same person that performed the initial review.

I. Third Level Physician Reviewers.--Third level physician review occurs when the provider/practitioner/M+C organization requests a reconsideration/re-review. (See §4320.) To conduct reconsiderations, reviewers must meet the qualification requirements outlined in §7420.A. (See 42 CFR 478.28.) To conduct DRG validation re-reviews, reviewers must meet the qualification requirements outlined in §7300.C. To conduct quality re-reviews, reviewers must meet the qualification requirements outlined in §7310.C.

4630. HEALTH CARE PRACTITIONERS OTHER THAN PHYSICIANS (HCPOTP)

An HCPOTP is a person credentialed in a recognized health care discipline and who provides the services of that discipline to patients (e.g., a nurse anesthetist). An HCPOTP peer is an individual credentialed in the same health care discipline. (See 42 CFR 476.1, 42 CFR 476.98(b), and 42 CFR 476.102.)

When the services being reviewed are furnished by a HCPOTP, use a physician reviewer who is a specialist in the type of services under review. In this case, your physician reviewer must also consult with an HCPOTP peer before making the determination. (See 42 CFR 476.102(a)(3).)

For services furnished by an HCPOTP, you must meet the requirements for consultation with a peer practitioner, unless you have been unable to obtain a roster of peer practitioners available to perform review, or the practitioner is precluded from performing review because he/she has, or is perceived to have, a conflict of interest. If the services of the appropriate consultant are not available, adequately document this fact.

4640. CONFLICT OF INTEREST

A person may not review health care services, make initial denial determinations, or make changes as a result of DRG validation, if he/she has, or is perceived to have, a conflict of interest. (See §1154(b)(l) of the Act.) You must make every effort to avoid potential conflicts of interest. A case should not be assigned to a physician reviewer if the reviewer:

- Participated in the development or execution of the beneficiary's treatment plan;
- Is an associate or close competitor of the physician under review;
- Is a member of the beneficiary's family; or
- Is a governing body member, officer, partner, 5 percent or more owner, or managing employee of the health care facility where the services were or are to be furnished. (See 42 CFR 476.98(d).)

PROs must also be aware of potential conflicts of interest specific to M+C organization review. For example:

- Only FFS physicians reviewing the quality of M+C organization services;
- M+C organization physicians reviewing care provided or arranged for by an M+C organization from which these physicians receive financial benefit; or
- Physicians who perform services for one M+C organization and review services of another M+C organization that competes directly with their M+C organization for enrollment of area Medicare beneficiaries.

Whenever possible, also avoid assigning a case to a physician reviewer if the reviewer actively practices in the same hospital as the physician under review. Finally, avoid potential conflicts of interest when selecting physicians to serve on your quality improvement and sanction committees.

4650. TRAINING

Provide training for physician and non-physician (including HCPOTP) reviewers to improve the case review process continuously. The purpose of training is to enhance the likelihood that determinations are both reliable and valid. Focus training on the application of clinical knowledge utilizing HCFA's directives in the review of health care issues of the Medicare population. Include training beyond the mechanical aspects of review procedures (e.g., worksheet completion, timekeeping).

You are responsible for the training of your reviewers (including the development of any training materials). Also, conduct training to address needs that have been identified during your own internal quality control monitoring, or needs that have been identified by HCFA or other HCFA contractors. To minimize expenses and maximize exchange of ideas, you are encouraged to collaborate with other PROs, hospitals, M+C organizations, academic institutions, and professional societies to develop courses. All training materials developed by you are the property of the Federal Government to be reported to the RO project officer, and are to be available to HCFA upon request.

A. Training Plans.--Develop training plans, accompanied by individual course descriptions, for non-physician and physician reviewers. Update plans as necessary. Keep your RO project officer informed of your training plans and make your plans available to HCFA upon request. In developing training plans:

Feedback and Action Plans for Individual Physicians and Providers

4700. INTRODUCTION

The review process provides opportunities for feedback to and from you, as well as to and from providers and practitioners. When you identify a single confirmed concern, notify the provider and the physician(s) involved. The practitioner and/or provider may use the notification process as an opportunity to correct identified concerns before a pattern develops. If the concern requires an adjustment to be made (e.g., a denial or DRG adjustment), proceed with the adjustment. Unless a concern causes severe risk or is a gross and flagrant violation that meets §1156(b) of the Act, no other PRO performance improvement activity is required until a pattern of concerns is established. (See §9000 for further instructions concerning violations of the practitioners'/providers' statutory obligations.)

NOTE: You may institute project data collection as the result of a single case review. Project data collection is not, in itself, considered a PRO performance improvement activity, but rather a way for you to gather data to help you better understand patterns of concerns which may require performance improvement activities, or to monitor the results of performance improvement activities.

If a physician provided care in more than one setting (e.g., an inpatient acute care setting and a SNF), use all information at your disposal concerning the care furnished in the combination of these settings to determine whether to proceed with an improvement activity. You may work with one, several, or all of the providers concerned to improve the level of the physician's performance; however, you may not share information among providers. (See §§10000-10090.)

Use all the information available to determine where the feedback and action plan process can be utilized most efficiently and effectively to improve overall performance. Prioritize performance improvement activities in terms of their effect on Medicare beneficiaries, benefits to the program, and the feasibility of improvement. Concerns believed to be systemic (e.g., consistent upcoding for DRG enhancement, consistent failure in effective discharge planning) should receive priority consideration.

4705. FEEDBACK TO THE PROVIDER AND INVOLVED PHYSICIANS

When you have identified a pattern of concerns for a physician or provider, work with the provider and the involved physicians to identify remediable problems (e.g., poor communication between the pharmacy and the nursing units, causing medication errors) that have given rise to the pattern of concerns. The provider is to review the information you have provided to identify any underlying problems that are the root cause of the identified pattern of concerns. The provider is expected to develop an action plan to address the pattern of concerns or to provide convincing evidence that an action plan is not needed.

Work with both the administrative and the medical staffs of the provider (e.g., a hospital quality assurance committee) when providing information, and developing, implementing, and monitoring action plans. Where the source of the quality, utilization, documentation, or DRG concern is a physician, notify him/her that you will work with him/her and the provider in a cooperative effort to improve performance.

NOTE: Use the opportunities you have in providing individual feedback to provide positive feedback to providers and physicians in order to reinforce best practices in quality, utilization, and documentation of care.

4710. REQUEST FOR AN ACTION PLAN

Require the provider to develop an action plan for all patterns of concerns except gross and flagrant situations, for which the sanction process applies. (See §§9000-9045.) Your initial request for an action plan must include a summary of the findings that are the basis for the request. You may include suggestions for an appropriate action plan. Provide assistance to the provider by identifying the pattern of concerns as narrowly as your data allows. (For example, is a pattern of post-operative infections linked to a specific surgeon, or to a specific type of procedure?) You may also share information concerning best practices providing you maintain appropriate confidentiality.

Inform the provider that the action plan must:

- Describe the expected outcome (goals) of the action plan. The stated outcome must be measurable;
- State what the provider believes to be the underlying cause of the pattern of concerns and how it identified the cause;
- Describe the specific actions the provider will take to correct the underlying cause of the pattern of concerns;
- Provide a time frame for initiating and completing the action plan;
- Where a physician is the source of the pattern of concerns, obtain an acknowledgment by the physician that he/she will cooperate with the provider in the action plan; and
- Describe the process the provider will use internally to ensure that the actions resolve the pattern of concerns.

Review the provider-developed action plan and determine whether it will effectively address the pattern of concerns you have identified. If you determine that the action plan is inadequate or inappropriate, work with the provider to develop an improved plan.

NOTE: Where a physician is the source of the pattern of concerns, consider face-to-face discussions with a respected peer (furnished by you or the provider) as part of the action plan.

4715. WHEN AN ACTION PLAN IS NOT NEEDED

You are not expected to obtain an action plan when:

- A case is referred to a Federal or State enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare program (see 42 CFR 480.106(b));
- The provider can offer an explanation for the identified pattern of concerns and you accept the explanation as satisfactory (e.g., you failed to consider an element in your data analysis that satisfactorily explained the identified pattern);
- After diligent inquiry, neither you nor the provider can identify a reason for the identified pattern of concerns;
- The provider has already identified the problem underlying the pattern of concerns and has taken action to correct it (e.g., a Medicare coder who has been making numerous errors has been retrained and is now performing well);

- The identified pattern of concerns is the same as that previously identified and occurred prior to or during the time when action was being taken to improve the pattern; or

- The source of the concern is a physician and the physician has retired, expired, or moved his/her practice out of the State.

NOTE: When a physician has moved his/her practice out of the State, and you have quality or utilization concerns which require action, forward the information to the PRO in the new State of practice. Provide your project officer with a copy of any concerns forwarded to another PRO.

4720. PROVIDER IMPLEMENTATION OF AN ACTION PLAN

If the provider's action plan meets your approval, the provider is expected to implement the plan according to the agreed-upon time frame. Notify the provider/practitioner(s) promptly whenever an action plan is concluded or significantly modified.

4725. ADDITIONAL PERFORMANCE IMPROVEMENT ACTIVITIES

If a provider's action plan is not successful (i.e., the stated outcome has not been achieved) within the stated time frame, meet with the provider to discuss the continued pattern of concerns, identify reasons for failure of the plan, and attempt to develop a modified plan. Share with the provider any data you have that would assist in explaining the difficulties experienced with the original action plan and in developing a modified plan.

It is expected that, in most instances, a satisfactory action plan will be developed by the provider, or by the provider with your assistance, and that the plan will correct the pattern of concern. However, there are occasions when:

- The provider is unwilling or unable to formulate a satisfactory action plan within the required time frame;

- An action plan cannot be satisfactorily modified;

- A provider formulates a satisfactory action plan but fails to adequately follow through on its implementation; or

- A provider continues to be unsuccessful in resolving identified patterns of concerns.

In these cases, identify and implement appropriate actions to improve performance and correct the identified pattern of concerns. Use your assessment of the nature and magnitude of the pattern of concerns, and your previous experience with the provider and/or practitioner involved, to identify the appropriate action. Utilize the least intrusive action(s) necessary to correct the behavior involved. Actions you may take include:

- Imposition of a PRO-directed action plan;

- Direct negotiation of an action plan with a physician when a physician is the source of the pattern of concerns;

- Referral to the HCFA RO (or to a State survey agency through the RO) for a facility investigation for compliance with the facility's Medicare provider agreement;

o Referral to the State Board of Licensing according to your agreement. (Federal and State licensing and accreditation bodies are responsible for the professional licensure of a practitioner, or the accreditation of a particular institution. Federal regulations at 42 CFR 480.138 require you to disclose confidential information to State and Federal licensing bodies, upon request, to the extent required by the agency to carry out its function under Federal or State law. You may also provide this information without a request.);

o Referral to the Medicare carrier (for a physician with an identified pattern of utilization or other concerns as appropriate); and/or

o Referral to the OIG for possible sanction action. (See §9000 for development of a sanction recommendation of a substantial violation in a subtantial number of cases.)

See Exhibit 4-2 for a flow diagram depicting the integration of your performance improvement actions with your review process.

In instances where a physician is the source of a utilization, documentation, DRG, or quality of care pattern of concerns, if you and the provider are unable to reach agreement on an action plan, or if an action plan (including a modified action plan) is not successful, negotiate an action plan directly with the physician. Educational actions you recommend must be designed to correct the root cause(s) of the pattern of concerns.

In order to successfully employ educational actions, you must:

o Be knowledgeable concerning the availability of specific continuing medical education courses and consider recommending attendance at courses which address the categories of concern;

o Be knowledgeable concerning various self-education tools and consider recommending the use of such tools when appropriate. (In general, these modalities may be utilized to correct very specific behaviors or when lesser grades of correction are required.);

o Contact teaching institutions about their willingness and ability to provide mini-residency courses which address specific categories of concerns and consider recommending attendance at such mini-residency courses to address appropriate behaviors of concern;

o Be knowledgeable concerning the rules regarding board certification examinations and consider recommending taking (not necessarily passing) board certification exams; and

o Be knowledgeable concerning the availability of courses and certifications to address special needs, and consider recommending such courses/certifications (e.g., Advanced Cardiac Life Support certification for physicians with a pattern of concerns in emergent care situations).

Customize educational actions to address the particular behavior causing the pattern of concerns. Do not disclose concerns with the performance of individual practitioners to educational bodies without the practitioner's written consent. (See §§10000-10090.)

Denial Determinations

7100. AUTHORITY

Deny claims in accordance with 42 CFR 476.83 when you determine that health care services furnished or proposed to be furnished to a beneficiary are noncovered because they are not medically necessary and reasonable (§1862(a)(1) of the Act), or constitute custodial care (§1862(a)(9) of the Act). In addition, PROs may deny Part A claims when a hospital circumvents the prospective payment system (PPS) through unnecessary admissions or readmissions in accordance with §1886(f)(2) of the Act. (Deny claims only as specified in §4255.) If, as a result of diagnosis-related group (DRG) validation, you determine that the diagnosis and/or procedures billed by the hospital should be changed and the DRG is affected, change the DRG assignment in accordance with 42 CFR part 476. Provide written notification of initial denial determinations and DRG assignment changes to all affected parties as specified in 42 CFR 476.94.

7101. TYPES OF DENIAL DETERMINATIONS

Initial and technical denials apply to services/items furnished in acute/specialty hospitals (including swing-beds), and hospital outpatient/ambulatory surgical centers, hereafter referred to as providers.

A. Initial Denials.--Initial denial determinations are subject to reconsideration and further appeals. These types of denials include:

- o Preadmisions;
- o Admission;
- o Continued stay;
- o Circumvention of PPS;
- o Services/procedures; and
- o Cost outliers (and day outliers, if applicable).

NOTE: Render initial denial determinations only after you have afforded the provider/practitioner an opportunity for discussion.

B. Technical Denials.--Technical denial determinations are not subject to reconsideration and further appeals, but may be subject to re-review/reopening. (See §7102.B.) These types of denials include:

- o Medical record not submitted timely (42 CFR 476.90(b)); and
- o Billing errors (including cost outlier denials due to duplicative billing for services or for services not actually furnished or not ordered by the physician).

NOTE: Opportunity for discussion does not apply to technical denials.

C. DRG Assignment Changes.--DRG assignment changes may result from your correction of technical coding errors, or your correction of diagnostic, procedure, or discharge status information and the related codes. Changes to the DRG coding information are not subject to reconsideration and further appeals. These changes are, however, subject to re-review/reopening when they result in a revised DRG assignment and lower payment. (See 42 CFR 478.15 and 478.48.)

NOTE: Render DRG assignment changes only after you have afforded the provider/practitioner an opportunity for discussion.

7102. DENIAL AND REOPENING TIME FRAMES

A. Initial Denial Determinations and DRG Assignment Changes.--Render an initial denial determination or DRG assignment change within one year of the payment date of the claim containing the service(s) in question. (See 42 CFR 476.96(a)(1).)

If the RO approves the action in writing, you may render an initial denial determination or DRG assignment change after one year, but within four years of the payment date of the claim containing the service(s) in question. (See 42 CFR 476.96(b)(1).)

NOTE: These time frames also apply to technical denial determinations.

Issue notices to all appropriate parties as specified in §§7105-7115. Process reconsideration requests as specified in §§7400-7440.

B. Reopenings of Initial Denial Determinations and DRG Assignment Changes.--Conduct reopenings as specified below. Issue notices to all appropriate parties if the reopening results in a change in your initial denial determination or a change in DRG assignment. (See §§7105-7115.)

1. Reopening Within One Year.--You may reopen an initial denial determination or DRG assignment change within 1 year of the date of your decision. (See 42 CFR 476.96(a)(2).)

NOTE: You may reopen a technical denial determination within one year of the date of your decision when you deny the claim for lack of medical record information, and the information is subsequently provided. (Do not reopen any other types of technical denial determinations.)

2. Reopening After One Year But Within Four Years.--You may reopen an initial denial determination or DRG assignment change after one year, but within 4 years of the date of your decision if: (See 42 CFR 476.96(b)(2).)

- You receive additional information on the patient's condition which affects the basis of the prior decision;

NOTE: The additional information is generally part of the medical record for the stay in question. There may be exceptions, however, such as additional information related to other hospital stays, physician notes, etc. Addendum orders (i.e., where the physician did not order a service/procedure and retroactively writes such an order) are not considered "additional information."

Fraud and Abuse

9200. SCOPE OF PRO FRAUD AND ABUSE REVIEW ACTIVITIES

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

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

9210. REVIEW RESPONSIBILITY

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

- Analyze the request to determine the appropriate staff hours and associated budget you will require; and
- Submit both the request and your cost analysis to your PO.

NOTE: DO NOT BEGIN TO PERFORM THE WORK.

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

9220. EVALUATION REPORT

Your written report must contain:

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

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

9230. AVAILABILITY OF EXPERT WITNESS

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

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

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

9240. REOPENING OF CASES

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

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

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

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