
CMS Manual System

Pub. 100-10 Medicare Quality Improvement Organizations

**Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)**

Transmittal 2

Date: JULY 11, 2003

CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
4		Table of Contents	
4		4000 - 4735	
4 - Exhibits		Exhibits 4-1, 4-1A	

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 11, 2003

Throughout Chapter 4, revisions were made to reflect the recent name changes of the "Payment Error Prevention Program (PEPP)" to "Hospital Payment Monitoring Program (HPMP)" and "Health Care Financing Administration (HCFA)" to "Centers for Medicare & Medicaid Services (CMS)" and "Peer Review Organization (PRO)" to "Quality Improvement Organization (QIO)."

Section 4000 - Introduction reflects the name change for PEPP and notices issued by Medicare + Choice Organizations (M+CO). It also refers the reader to the Review Categories and Timeframes documents of the Standard Data Processing System (SDPS) User's Guide.

Section 4070 - Referrals instructs the QIO to conduct a medical record review and make a medical necessity initial determination when an intermediary refers a case involving coverage issues. This section also clarifies that the QIO may refer cases to the carrier related to Part B physician's services.

Section 4100 - Introduction makes reference to new Exhibit 4-1.

Section 4105 - Quality Review reflects the name change for PEPP.

Section 4130 - DRG Validation Review makes reference to Exhibit 4-1. It also clarifies that when a case is questioned for both DRG change and quality concerns, notices are sent to comply with the quality review completion timeframes.

Section 4230 - Limitation on Liability Determinations clarifies that no Medicare payment will be made if the provider or practitioner is held liable for the denied services/items that "no program payment will be made" when any of the listed circumstances in that section had occurred.

Section 4320 - Third Level Physician Review deletes reference to former Exhibit 4-1.

Section 4325 - Use of the Physician Reviewer Assessment Format deletes reference to Exhibit 4-1.

Section 4410 - Review Settings revises the hospital settings to indicate when utilization and quality reviews apply.

Section 4500 - Introduction adds the word “quality” to correctly refer to “internal quality control” activities and refers QIOs to Chapter 13 of the QIO Manual for IQC activities instructions.

Section 4520 - Requesting Medical Records/Reviewing Documentation reflects the name change of PEPP to HPMP. This section also deletes language referencing Memorandum of Agreement (MOA). QIOs are to follow the MOA instructions found in Chapter 3 of the QIO Manual. This section specifies that QIO case review is performed offsite from the provider facility. It also reflects new re-designation of subsections. This section deletes the instructions pertaining to onsite review and offsite review by non-physician reviewers because all non-physician review is performed at a QIO site. It also requires QIOs to send reminder notices to providers or practitioners if medical records are not received by the 15th day from the request date. It directs QIOs to issue a technical denial for failure to submit medical records by the 45th day from the date of the request for such records. For HPMP cases, the Clinical Data Abstraction Centers (CDACs) must close the case by day 31 if medical records are not received. It specifies that for HPMP cases, the QIO must conduct a utilization review and a Diagnosis Related Groups (DRG) validation. If quality concerns are detected, the QIO must conduct a quality review.

Section 4530 - Providing Opportunity for Discussion deletes the paragraph pertaining to MOA. QIOs are to follow the MOA instructions found in Chapter 3 of the QIO Manual. This section also reflects the name change of PEPP to HPMP.

Section 4540 - Adhering to Review Timeframes clarifies that different timeframes apply to each category of review and makes reference to new Exhibit 4-1A.

Section 4580 - Monitoring Hospitals’ Physician Acknowledgment Statements specifies that at least annually, the QIO monitors the hospitals’ compliance with securing the physician acknowledgment statements to ensure that appropriate payment is made under the Medicare PPS program. This section delineates the general procedures to conduct the QIOs monitoring activities.

Section 4590 - Reporting Requirement for Review Activities reflects the name change of PEPP to HPMP.

Exhibit 4-1 - Model Physician Reviewer Assessment Format was deleted.

Exhibit 4-1 - Standard Mandatory Case Review Process flow chart was added.

Exhibit 4-1A - Standard Mandatory Case Review Process Timeframes chart was added.

Workload and Costs: These instructions do not represent an increase in workloads or costs.

NOTE: Normally red, italic font identifies new material. However, because this release is a new manual, normal text font is used for the initial release.

Quality Improvement Organization Manual

Chapter 4 - Case Review

TABLE OF CONTENTS (Rev. 2, 07-11-03)

MANDATORY CASE REVIEW REQUIREMENTS

- 4000 - Introduction
- 4010 - Anti-dumping Violations
- 4020 - Assistants at Cataract Surgery
- 4030 - Beneficiary Complaints
- 4040 - Hospital and Medicare + Choice Organization (M+CO) Notices of Non-coverage
- 4050 - Hospital-requested Higher-weighted Diagnosis Related Groups (DRG) Assignments
- 4060 - Potential Concerns Identified During Project Data Collection (PDC)
- 4070 - Referrals

BASIC CASE REVIEW ACTIVITIES

- 4100 - Introduction
- 4105 - Quality Review
- 4110 - Admission/Discharge Review
- 4115 - Invasive Procedure Review
- 4120 - Length-of-Stay Review
- 4125 - Coverage Review
- 4130 - DRG Validation Review

ADDITIONAL CASE REVIEW ACTIVITIES

- 4200 - Introduction
- 4210 - Outlier Review
- 4230 - Limitation on Liability Determinations
- 4240 - Readmission Review
- 4250 - Transfer Review
- 4255 - Circumvention of Prospective Payment System (PPS)
- 4260 - Onsite Review

INTEGRATED CASE REVIEW/PHYSICIAN REVIEWER ASSESSMENT FORMAT (PRAF)

- 4300 - Introduction
- 4305 - Non-physician Review
- 4310 - First Level Physician Review
- 4312 - Action Following Opportunity for Discussion

- 4315 - Second Level Physician Review
- 4320 - Third Level Physician Review
- 4325 - Use of the Physician Reviewer Assessment Format (PRAF)

SCOPE OF CASE REVIEW

- 4400 - Introduction
- 4405 - Review of Medicare Services
- 4410 - Review Settings

CASE REVIEW PROCEDURES

- 4500 - Introduction
- 4510 - Using Screening Criteria
- 4520 - Requesting Medical Records/Reviewing Documentation
- 4530 - Providing Opportunity for Discussion
- 4540 - Adhering to Review Timeframes
- 4550 - Profiling Case Review Results
- 4560 - Maintaining Memoranda of Agreements (MOAs)
- 4570 - Prepayment Review System (PRS) Implementation
- 4580 - Monitoring Hospitals' Physician Acknowledgment Statements
- 4590 - Reporting Requirements for Review Activities

PERSONNEL

- 4600 - Introduction
- 4610 - Non-physician Reviewers
- 4620 - Physician Reviewers
- 4630 - Health Care Practitioners Other Than Physicians (HCPOTP)
- 4640 - Conflict of Interest
- 4650 - Training

FEEDBACK AND ACTION PLANS FOR INDIVIDUAL PROVIDERS/PHYSICIANS

- 4700 - Introduction
- 4705 - Feedback to the Provider and Involved Physicians
- 4710 - Request for an Action Plan
- 4715 - When an Action Plan Is Not Needed
- 4720 - Provider Implementation of an Action Plan
- 4725 - Additional Performance Improvement Actions
- 4730 - Monitoring Performance Improvement Actions
- 4735 - Timing Requirements for Performance Improvement Activities

EXHIBITS

- Exhibit 4-1 - Standard Mandatory Case Review Process

Exhibit 4-1A - Standard Mandatory Case Review Process Timeframes

4000 - Introduction - (Rev. 2, 07-11-03)

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-Issued Notices of Non-coverage (HINN), beneficiary's requests for immediate review of Notices of Discharge and Medicare Appeal Rights (NODMAR), hospital-requested higher-weighted Diagnosis Related Groups (DRG) adjustments, potential gross and flagrant violations in one or more instances or substantial violations in a substantial number of cases (See Chapter 9), and Hospital Payment Monitoring Program (HPMP) cases (See Chapter 11). If in the course of conducting a mandatory review (e.g., beneficiary complaint) you determine that the case also involves another review category (e.g., a readmission within 31 days), you are required to perform the review for that category as well (in this case, the readmission) (See Exhibit 4-1A for review categories and timeframes).

As part of the HPMP (See Chapter 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:

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

4010 - Anti-dumping Violations - (Rev. 2, 07-11-03)

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

4020 - Assistants at Cataract Surgery - (Rev. 2, 07-11-03)

A. Authority -- §1862(a)(15) of the Social Security Act (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. Although there are very few requests for approval of assistants of cataract surgery, it remains a Quality Improvement Organization (QIO) review requirement.

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

B. 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 must 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 timeframe (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).

After the effective date of your contract, notify physicians at least 30 calendar days prior to implementation of this review activity. Include the following information:

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

C. 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 Medicare + Choice Organization (M+CO) 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 Chapter 7, §7100.

- Pre-procedure Review -- Review all requests for use of an assistant in a timely manner (e.g., 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).
- Post-procedure Review -- Review cases on a prepayment, post-procedure 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 post-procedure 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 post-procedure/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.

D. 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 Regional Office (RO) or the Office of Inspector General (OIG) of any billing violations.

§§1842(k)(1) 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 QIO. The physician may be sanctioned under §1842(j)(2) of the Act if he or she does so. If you identify a pattern of physician claims

for an assistant filed without prior approval, notify the carrier that is responsible for instituting the sanctions.

E. Validation Activities -- Request records retrospectively in order to validate the accuracy of the information received on a pre-procedure basis. 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 Chapter 9, §9000.

4030 - Beneficiary Complaints - (Rev. 2, 07-11-03)

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

4040 - Hospital and Medicare + Choice Organization (M+CO) Notices of Non-coverage - (Rev. 2, 07-11-03)

Follow the instructions contained in Chapter 7, §7000 when reviewing hospital and M+CO notices of non-coverage.

4050 - Hospital-requested Higher-weighted DRG Assignments - (Rev. 2, 07-11-03)

A. Authority -- QIOs 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)-waived/excluded areas, PPS-excluded hospitals, or M+COs.

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 CMS for QIO review on a post-payment basis. When reviewing hospital-requested higher-weighted DRG assignments, perform a medical necessity review and DRG validation (See §4130) (You are also required to perform a quality review if you believe that there may be a potential quality of care concern). 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, match both the attending physician's description and the information contained in the patient's medical record. Refer the case for a physician review if medical judgment is needed when changing the narrative diagnosis that the codes were based upon. 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) - (Rev. 2, 07-11-03)

Follow the instructions contained in §4105 when reviewing potential concerns identified during Project Data Collection (PDC).

4070 - Referrals - (Rev. 2, 07-11-03)

Review all cases referred by CMS and Clinical Data Abstractions Centers (CDACs). Review cases referred by intermediaries, carriers, the M+CO appeals contractor, and State Medicaid survey and certification agencies (and other sources) 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 Regional Office (RO) -- The RO will refer cases to you in the following circumstances:

- 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;
- If the intermediary or carrier identifies a problem or potential problem with a provider or practitioner in an area subject to QIO 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); and
- Complaints/referrals that are anonymous, from outside agencies (e.g., an alleged anti-dumping violation case, see Chapter 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 CMS Central Office (CO) for consideration. The types of cases may include:

- Cases that may require additional policy clarification; and
- Cases that suggest 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

without making a coverage determination. Conduct a medical record review following Chapter 4 procedures and make a medical necessity initial determination. Perform a quality review if you believe that there may be potential quality of care concern(s) (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 Chapter 5. For fraud and abuse referrals, see Chapter 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), Chapter 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 Ambulatory Surgical/Surgery Center (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. You may also refer cases to the carrier related to Part B physicians' services.

F. Referrals From CDACs -- Review all cases referred to you by CDACs under the Hospital Payment Monitoring Program (See Chapter 11).

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 CMS CO. Every request must be in writing, must offer clear and cogent rationale, and must be submitted through your Project Officer in the CMS RO. For fraud and abuse referrals, follow the instructions in §9200.

H. Anonymous Referrals -- You are required to review any anonymous referrals that you believe are serious or urgent in nature. When review findings warrant, take corrective action and follow the instructions and timeframes applicable to the type of case under review.

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

4100 - Introduction - (Rev. 2, 07-11-03)

When you receive a mandatory review case (See §§4000 - 4070), perform the appropriate review for admission/discharge, quality, invasive procedure, length-of-stay, coverage, DRG validation, and other post review activities (See Chapter 7). If you review a case (e.g., notice of non-coverage) and it is necessary to review the case again 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 §§4410 and 5005.B) (See Exhibit 4-1 for the case review process).

Currently, the following QIO areas are paid under a different methodology 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 QIO 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 - (Rev. 2, 07-11-03)

A. Authority and Scope -- This review includes potential circumvention of PPS (See §4255) and beneficiary complaints about quality of care (See Chapter 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. For example, although you are not required to perform a quality review in all cases subject to Hospital Payment Monitoring Program (HPMP) review, conduct a quality review if such concerns are raised by your reviewers.

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
- 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 is categorized in C.1 through C.99 of the PRAF (See the electronic PRAF screen of the Case Review Information System). 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:

- Unnecessary prolonged treatment causes an extended hospital or SNF stay, readmission soon after discharge, or additional treatment(s);
- Serious medical complications;
- Serious physiological or anatomical impairment;
- Significant disability; and/or
- 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 of cases (See 42 CFR 1004.1(b) and §9000) (Use sound professional judgment to determine what constitutes a pattern).

4110 - Admission/Discharge Review - (Rev. 2, 07-11-03)

QIOs must conduct review of admissions and discharges as specified in 42 CFR 476.71(a)(6). Review of the medical 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. 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/Discharge -- 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. Similarly, 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 on screening criteria).

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 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.

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 - (Rev. 2, 07-11-03)

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 non-covered 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 - (Rev. 2, 07-11-03)

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. 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 (See §4110).

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 non-covered care. In PPS waived/excluded areas, length-of-stay review is performed for all inpatient admissions.

4125 - Coverage Review - (Rev. 2, 07-11-03)

With certain exceptions established by regulation and National Coverage Decisions (See Coverage Issues Manual, §30-1), 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 to determine whether the admission is appropriate because the patient has other concurrent medical conditions that

would require an inpatient level of care. 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 - (Rev. 2, 07-11-03)

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 and DRG validation (You are also required to perform a quality review if you believe that there may be a potential quality of care concern). 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. Refer the case for a physician review if medical judgment is needed when changing the narrative diagnosis that the codes were based upon. Your reviewer must use his or her professional judgment and discretion in considering the information contained on a hospital's physician query form along with the rest of the medical record. If the physician query form is leading in nature or if it introduces new information, the non-physician reviewer must refer the case to the physician reviewer.

NOTE: For PPS waived/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.

Base your DRG validation upon accepted principles of coding practice. Be consistent with guidelines established for ICD-9-CM coding, the Uniform Hospital Discharge Data Set data element definitions, and coding clarifications issued by CMS. Do not change these guidelines or institute new coding requirements that do not conform to established coding rules.

Verify a hospital's coding in accordance with the coding principles reflected in the current edition of the ICD-9-CM Coding Manual, Volumes 1 through 3, and the official National Center for Health Statistics and CMS addenda, which update the ICD-9-CM Manual annually. The annual addenda are effective on October 1 of each year and apply to discharges occurring on or after October 1. Use only ICD-9-CM Manual volumes based on official ICD-9-CM Addendum and updates when performing DRG validation.

Hospitals are not required to code minor diagnostic and therapeutic procedures (e.g., imaging studies, physical, occupational, respiratory therapy), but may do so at their discretion.

B. Diagnoses -- Ensure that the hospital reports the principal diagnosis and all relevant secondary diagnoses on the claim. The relevant diagnoses are those that affect DRG assignment. The claim form provides space for reporting nine diagnoses. The hospital must identify the principal diagnosis when secondary diagnoses are also reported. When a comorbid condition, complication, or secondary diagnosis affecting the DRG assignment is not listed on the hospital's claim but is indicated in the medical record, insert the appropriate code on the claim form. If the hospital already reported the maximum nine diagnoses, delete a code that does not affect DRG assignment, and insert the new code.

You are not required to place additional diagnoses on the claim as long as all conditions that affect the DRG are reflected in the diagnoses already listed, and the principal diagnosis is correct and properly identified. The hospital can list the secondary diagnoses in any sequence on the claim form because the GROUPER program will search the entire list to identify the appropriate DRG assignment.

- Principal Diagnosis -- Determine whether the principal diagnosis listed on the claim is the diagnosis which, after study, is determined to have occasioned the patient's admission to the hospital. The principal diagnosis (as evidenced by the physician's entries in the patient's medical record) (See 42 CFR 412.46) must match the principal diagnosis reported on the claim form. The principal diagnosis must be coded to the highest level of specificity. For example, a diagnosis from Chapter 16 of the ICD-9-CM Coding Manual, "Symptoms, Signs, and Ill-defined Conditions," may not be used as the principal diagnosis when the underlying cause of the patient's condition is known.
- Inappropriate Diagnoses -- Exclude diagnoses relating to an earlier episode that have no bearing on the current hospital stay. Delete any incorrect diagnoses and revise the DRG assignment as necessary.

C. Procedures -- Ensure that the hospital has reported all procedures affecting the DRG assignment on the claim. The claim form provides space to list six procedures. If there are more procedures performed than can be listed on the claim, verify that those reported include all procedures that affect DRG assignment, and that they are coded accurately.

You are not required to place additional procedures on the claim as long as all procedures affecting the DRG assignment are listed on the claim. If the hospital reported the maximum six procedures and you need to add one that affects DRG assignment, delete a code that has no effect and insert the new code.

D. Guidelines for DRG Validation Review -- Apply the following guidelines when conducting DRG validation review:

- Your validation of the claim confirms the principal diagnosis, secondary diagnoses, procedures, and the discharge status. The patient's age and sex need not be verified because these items are verified by the intermediary's edits before your DRG validation. If you find an error in discharge status or make corrections to the diagnosis or procedure information that affect the DRG, report the necessary information to the intermediary;
- Individuals with training and experience in ICD-9-CM coding are to review issues that involve technical coding changes or professional coding judgment;
- Do not make changes that do not require referral to a physician reviewer (e.g., technical coding changes) when the change has no effect on DRG assignment;
- Do not add diagnosis and procedure information to a claim when the addition would have no effect on the DRG assignment;
- Do not notify the involved hospital or physician of errors identified during the DRG validation process when the errors have no effect on DRG assignment;
- Refer to a physician reviewer issues that involve changes to diagnosis or procedure narrative descriptions or codes only when resolution of an issue requires a physician's medical judgment and the related change would affect DRG assignment;
- Do not refer a coding issue to a physician reviewer when the resulting change would have no effect on DRG assignment. Instead, take no action on the suspected coding error because a conclusion cannot be reached without a physician's involvement;
- When a correction that would affect DRG assignment requires the professional judgment of a physician reviewer and the case involves care provided by a health care practitioner other than a physician, ensure that the physician reviewer consults with a peer of the affected practitioner before making a determination;
- Before making a correction that affects DRG assignment, notify the involved provider and the patient's attending physician (or other attending health care practitioner), and provide an opportunity for discussion as specified in §4530. When a case is also questioned for both DRG changes and quality concerns, do not send notices at separate times. Notices are to be sent to comply with the quality review completion timeframes (See Exhibit 4-1A);

- After satisfying the requirement to offer an opportunity for discussion, notify the involved parties of the changes you are making to diagnostic and procedural information, as instructed in §§7100-7115; and
- Process any request for a re-review according to instructions contained in §7300. A provider or practitioner dissatisfied with the QIO's change that results in a lower payment may request a re-review to the QIO.

NOTE: Inclusion of physicians in the DRG validation process is consistent with the intent of the acknowledgment statement required by 42 CFR 412.46, which is to make physicians accountable for their role in the payment process. The physician could be partially responsible for the incorrect DRG; thus, it is useful to notify him or her of this matter. Further, it may be useful for the QIO to hear the physician's viewpoint prior to changing the DRG assignment.

4200 - Introduction - (Rev. 2, 07-11-03)

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

- Outlier review (See NOTE in §4210);
- Limitation on liability determinations;
- Readmission review; and
- Transfer review.

4210 - Outlier Review - (Rev. 2, 07-11-03)

You are authorized to perform outlier review as specified at §1886(d)(5)(A)(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 (See 42 CFR 476.1). Outlier review is not performed for M+CO cases or in PPS waived/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:

- 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;
- 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 non-covered 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. Non-covered 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));
- 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; and
- 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), Chapter 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, you change the DRG assignment. Perform all reviews (admission, quality, invasive procedure, coverage, DRG validation, documentation, and discharge) for cost outlier cases whether or not you confirm the case as an outlier.

For cost outlier cases, the hospital must provide a copy of the itemized bill and medical records for your review. The itemized bill must be sufficiently detailed for you to identify each item or service billed. If, after you complete the DRG validation, 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:

- Not duplicative or erroneously billed;
- Actually furnished; and
- Ordered by the physician.

When reviewing cost outlier cases, be alert to certain items such as combined billing. CMS 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).

When you have a hospital that bills a flat per diem rate (i.e., an all inclusive rate hospital) and, therefore, does not have itemized charges, contact the Regional Office RO to verify that the hospital does, in fact, bill on an all-inclusive rate basis and does not have individual charge data available. Once verified, the cost outlier review requirements that follow apply for the all-inclusive rate hospitals:

- Review for medical necessity and appropriateness of the admission;

- Review for medical necessity and appropriateness of each day of the stay for cost outlier cases from these hospitals;
- Deny non-covered days and carve the per diem charges out of the outlier payment;
- Send notices of such denials to the beneficiary, hospital, physician, intermediary, and carrier (if appropriate); and
- Apply limitation on liability provisions to admission denials and denials of days, where appropriate (See §4230 below).

Deny as non-covered care services that are duplicative or erroneously billed, not furnished, and/or not ordered by the physician. These denials do not constitute initial determinations requiring notice to beneficiary, and are not subject to the limitation on liability and reconsideration provisions. Send a notice explaining such denials of costs to the hospital, intermediary, and carrier, if appropriate.

C. Day and Cost Outlier Relationship -- When the intermediary identifies a claim (case) as both a day outlier and a cost outlier, the PRICER (the intermediary's computer program) selects the higher payment amount. In cost outlier cases, after the intermediary notifies the hospital of the adjustment, the hospital has the option of declining the cost outlier. However, if your review has resulted in denied costs that reduce the total cost below the cost outlier threshold, and the claim (case) is above the day outlier threshold, send the adjustment request to the intermediary. The intermediary will process the adjustment and either pays the provider or holds back money on another claim.

4230 - Limitation on Liability Determinations - (Rev. 2, 07-11-03)

The statutory authority for applying the limitation on liability provision applicable to physician's liability is contained in §§1842(l) and (m) of the Act. §1879 of the Act contains the statutory authority for applying the beneficiary's and provider's limitation on liability provisions. When you determine that care provided a Medicare beneficiary is non-covered because such care is not medically reasonable and necessary (See §1862(a)(1) of the Act), or is custodial in nature (See §1862(a)(9) of the Act), determine whether or not the beneficiary and/or the provider/practitioner is liable for payment of the non-covered care.

A. Denials Covered by the Limitation on Liability Provisions -- The limitation on liability provision only applies to those denials based on:

- §1862(a)(1) or (9) of the Act (items/services are not medically reasonable or necessary, or expenses are for custodial care);
- §1814(a)(2)(C) of the Act (home health services - patient is not homebound); or

- §1835(a)(2)(A) of the Act (home health services - patient does not or did not need skilled nursing care on an intermittent basis).

The following examples illustrate types of denials where payment cannot be made under the limitation on liability provision because these cases are not §§1862(a)(1), 1862(a)(9), 1814(a)(2)(C), or 1835(a)(2)(A) denials (These examples are not all inclusive):

- Denials made pursuant to §1886(f)(2) of the Act, where a provider has circumvented PPS through unnecessary admissions and readmissions;
- Reduction of payment based on a change in DRG assignment;
- Cost outlier items and services that were duplicative billed, not furnished, or not ordered by a physician;
- Physician charges included on the hospital bill. The physician charges are to be included on a separate Part B billing;
- Services/items denied when requested medical records are not received;
- Services payable under State or Federal workmen's compensation;
- Charges for convenience items or services; and
- Provider billing errors.

NOTE: When you review a case that involves non-covered 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 (See §4125).

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, he or she 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 non-coverage (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 non-covered is found at 42 CFR 411.406. Determine the provider's liability whenever your denial is based on medical necessity, appropriateness, 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 non-coverage and, therefore, is held liable for the denied services/items (no payment will be made under the Medicare Program) 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;
- 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;
- The provider or practitioner could have been expected to have known that the services/items were excluded from coverage based on receipt of CMS notices, manual issuances, bulletins, or other written guides or directives from intermediaries/carriers or QIOs, including notification of QIO 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 non-covered 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);

- 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 (See 42 CFR 476.78(b)(6)(ii)); or
- 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 non-covered. 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 Non-coverage (HINN) Is Involved -- After the hospital issues a notice of non-coverage, 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.

- 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.

- Admission HINN -- Determine liability as follows:

- HINN Issued on the Day of Admission -- The beneficiary or his/her representative is liable for customary charges for all services furnished after the admission HINN is received. However, to hold a beneficiary or his/her representative liable for charges on the day of admission, the hospital must issue the admission HINN no later than 3:00 PM on the day of admission. If the hospital does not meet these requirements, the beneficiary or his/her representative is protected from liability until the day following receipt of the admission HINN (e.g., a HINN issued for an admission after 3:00 PM or a late evening admission).

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

- HINN Issued After the Day of Admission -- The beneficiary or his/her representative is liable for customary charges for all services furnished beginning the day following the date of receipt of the admission HINN.
- Continued-stay HINN -- Determine liability as follows:
- HINN Issued With the Concurrence of the Attending Physician Where the Beneficiary or His/Her Representative Requests QIO Review by Noon of the First Working Day After the Day He/She Receives the Continued-stay HINN and He/She Meets the Conditions of §1879(a)(2) -- The beneficiary's or his/her representative's liability begins at noon of the day following the date of notification of your determination. The hospital is held financially liable for costs incurred from the date of the continued-stay HINN, because it knew that services were non-covered (as demonstrated by issuance of the HINN).

NOTE: If the hospital does not provide the medical records by close of business of the first working day after the date that the beneficiary or his/her representative receives the continued-stay HINN, the beneficiary's or his/her representative's liability does not begin until noon of the day following the date of notification of your determination.

A provider is considered to have knowledge that services are non-covered as of the date it issues the continued-stay HINN to the beneficiary.

- HINN Issued With the Concurrence of the QIO, or With the Concurrence of the Attending Physician Where the Beneficiary or His/Her Representative Does Not Request QIO Review by Noon of the First Working Day After the Day He/She Received the Continued-stay HINN, and Beneficiary or His/Her Representative Meets the Conditions of §1879(a)(2) -- Determine liability as follows:
 - For short-term/acute care hospitals paid under PPS or in waived States, the beneficiary or his/her representative is liable for

customary charges for services furnished beginning the third day following the date of receipt of the continued-stay HINN;

- For hospitals paid on reasonable cost basis, the beneficiary or his/her representative is liable for customary charges for services furnished beginning the day following the date of receipt of the continued-stay HINN; or
- For swing bed situations (i.e., continued-stay HINN issued to a beneficiary when his/her level of care changes from acute to SNF or NF, or from SNF to NF), the beneficiary or his/her representative is liable for customary charges for services furnished beginning the day following the date of receipt of the continued-stay HINN.

NOTE: If the beneficiary leaves the facility on the day following the date of receipt of the continued-stay HINN, the beneficiary or his/her representative is liable, with respect to days before the day the beneficiary leaves the hospital, only for applicable deductible and coinsurance amounts and for charges for convenience items or services normally not covered by Medicare.

E. Application of Grace Days -- The statutory authority for applying grace days is contained in §1154(a)(2)(B) of the Act. When you determine that the stay in either a PPS or non-PPS hospital is no longer covered, you may approve up to a maximum of two grace days for the purpose of post-discharge planning.

You may apply grace days under the following conditions:

- The beneficiary is still in the hospital (i.e., you are performing concurrent review); and
- Both the provider and the beneficiary are found not liable for the denied services (i.e., a HINN is not involved). Therefore, Medicare payment may be made for the denied services under §1879 of the Act.

Apply grace days based on the date of your denial notice, not based on the date of non-coverage.

EXAMPLE: You determine that the services are no longer covered under Medicare beginning 1/22. The denial notice is dated 1/23. You may approve payment for either one or two days after the date of the denial notice. Therefore, the beneficiary would be liable beginning 1/25 or 1/26, based on whether one or two grace days are applied.

NOTE: Grace days do not apply to situations involving HINNs. A provider must be unaware of non-coverage and the issuance of a HINN demonstrates otherwise.

F. Indemnification -- The statutory authority for indemnification of the beneficiary is specified in §1879(b) of the Act. When the conditions specified in 42 CFR 411.402 are met, the beneficiary can be indemnified (i.e., reimbursed) for payment of denied services.

- Determining Indemnification for Payment of Denied Services/Items -- When you determine that the beneficiary is not liable and that the provider and/or practitioner is liable for the denied services (i.e., Medicare will not make payment), the beneficiary is indemnified as follows:
 - For denials of services furnished prior to January 1, 1989, the beneficiary is indemnified for the denied services, including any deductible and coinsurance amounts (The beneficiary remains liable for payment of any convenience services and items);
 - For denials of services furnished on or after January 1, 1989 through December 31, 1989, the beneficiary is indemnified for the denied services, including any deductible amounts (The beneficiary remains liable for payment of any convenience services and items); and
 - For denials of services furnished on or after January 1, 1990, the beneficiary is indemnified for the denied services, including any deductible and coinsurance amounts (The beneficiary remains liable for payment of any convenience services and items).

NOTE: Deductible does not apply to SNF swing bed denials.

When you determine that both the beneficiary and the provider and/or practitioner are not liable for the denied services, indemnification does not apply since Medicare will make payment under §1879 of the Act. The beneficiary remains liable for payment of any applicable deductible, coinsurance, and convenience services and items.

- 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 - (Rev. 2, 07-11-03)

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 QIOs -- 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 QIO.

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 - (Rev. 2, 07-11-03)

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 QIOs, follow instructions in §4240.B.

4255 - Circumvention of Prospective Payment System (PPS) - (Rev. 2, 07-11-03)

A. Background -- §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, multiple readmissions, or other inappropriate medical or other practices with respect to beneficiaries or billing for services (See §476.71(a)(8)). The Secretary may have you:

- Deny Part A payment with respect to inpatient hospital services with respect to the unnecessary admission or subsequent admission of the same individual; or
- 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.

§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)..." §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. QIO 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:

- 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.
- Readmission of Patient to Hospital for Care That Could Have Been Provided During First Admission -- This prohibited action occurs when a patient is readmitted to a hospital for care that, pursuant to professionally recognized standards of health care, could have been provided during the first admission. This action does not include circumstances in which it is not medically appropriate to provide the care during the first admission.
- Inappropriate Transfer of Patient From PPS Unit to PPS-excluded Unit in Same Hospital -- This prohibited action occurs when a patient is admitted to an acute care part of the hospital even though the medical record shows that the patient required care in a PPS-excluded psychiatric or rehabilitation unit within the same hospital, a bed in the PPS-excluded unit was available at the time of initial admission, and the patient is subsequently transferred to the PPS-excluded unit. This also applies to similar transfers from PPS units to beds in hospital-based SNFs and SNF swing beds. A transfer is considered an admission for purposes of payment under PPS (See 42 CFR 412.4).
- Inappropriate Transfer of Patient From PPS-excluded Unit to PPS Unit in Same Hospital -- This prohibited action occurs when a patient, who requires only the level of care being provided him/her in the PPS-excluded unit, is transferred to a PPS unit in the same hospital. A prohibited action also occurs when the transfer is from a PPS-excluded unit to a hospital-based SNF or swing bed.

D. Actions to be Taken by QIO -- Your review process must provide opportunities for feedback to and from the hospital and for correcting identified prohibited actions before a pattern develops. Work with the hospital to identify the most efficient and effective method to improve care or to correct any identified problems. You should make it clear

to the provider that there is a problem. Appropriate follow-up may include working with the provider and will always include monitoring provider activity. Working with the provider would be sufficient initially if there is no clear provider intent to circumvent PPS and if there is no evidence of imminent danger to the patient.

NOTE: If a single case of circumvention of PPS is identified with no other cases or other grounds for initial denials, you need to take the most appropriate action(s) to address this situation. A single episode of improper readmission or transfer would not support a circumvention of PPS finding absent some other evidence.

Refer the case with a brief summary of the issues to your Project Officer. If the prohibited action causes severe risk, or is a gross and flagrant violation, or fails in a substantial number of cases to comply that meets §1156(b) of the Act, refer to 42 CFR 1004.1(b) and §9005 for further instructions.

Enter the results of your review into the Standard Data Processing System (SDPS) as specified in your contract, the SDPS Database Administrator Guide, or other administrative directives, and into your database for pattern analysis. On an ongoing basis, analyze patterns of care involving quality concerns resulting from readmissions and transfers that may have significance beyond a single episode.

If the results of your pattern analyses clearly established that a hospital has been taking actions with the intent of circumventing PPS and that these actions resulted in unnecessary admissions, premature discharges and readmissions, or multiple readmissions of Medicare beneficiaries, you may:

- Deny the second admission and issue a denial notice to the hospital (See §§7100, 7440, and Exhibit 7-34);

NOTE: Initiate a corrective action plan to address the circumvention of PPS issues. If the hospital demonstrates a lack of interest in participating in a proposed improvement project addressing circumvention of PPS issues, you should try again to gain the hospital's participation by pointing out the potential benefits in eliminating prohibited actions.

- Initiate a sanction report and recommendation, based on a gross and flagrant violation of the responsible provider's or physician's Medicare obligations, if the prohibited action caused a patient's death, presented an imminent danger to the health, safety, or well-being of a Medicare beneficiary, placed the beneficiary unnecessarily in high-risk situations, or resulted in permanent damage of a major physical function (See Chapter 9); or
- Refer the cases included in a pattern to the Regional Office of the Inspector General (OIG) for potential termination of the provider agreement under §1866(b) of the Act and 42 CFR 489.21(e) (including cases where there is evidence of

intent and the hospital refuses to cooperate/participate in corrective activities, or the corrective action plan fails to resolve these payment issues).

If you suspect that fraud or an abusive practice is involved, consult with your RO Project Officer and the OIG Regional Office. Refer individual cases to OIG for further investigation when necessary. Examples of such practices include a hospital submitting two separate claims for a given patient, as if the patient were readmitted to the hospital but you find that the patient was discharged only once from the hospital, or you identify two hospitals as having an unexplained pattern of Medicare transfers between them.

4260 - Onsite Review - (Rev. 2, 07-11-03)

§1154(a)(15) of the Social Security Act (the Act) requires you to perform significant onsite review activities, including onsite review in at least 20 percent of the rural hospitals in your review area. Onsite QIO activities include, but are not limited to:

- Providing information and engaging in discussion with hospitals to aid them in improving performance;
- Examining medical records for project data collection or case review;
- Supporting continuous quality improvement activity; or
- Presenting findings from program integrity projects.

Regularly assess these activities to determine the efficiency and effectiveness of your methods, which may include onsite visitation, videoconferences, teleconferences, regional meetings, or any other formats that are mutually acceptable to you and the hospitals to achieve the desired ends.

NOTE: Rural hospitals are hospitals located outside of a Metropolitan Statistical Area or New England County Metropolitan Area, as defined by the Executive Office of Management and Budget.

4300 - Introduction - (Rev. 2, 07-11-03)

Integrated case review is the process used to review all categories of care (e.g., the three categories of review: quality review, utilization review (See §4410), and DRG validation; or when applicable, two categories of review: utilization review and DRG validation) when conducting Fee-For-Service (FFS) and Medicare + Choice (M+C) case review. Integrated case review begins with the receipt of the medical record. The PRAF is a review tool designed to integrate case review and promote a seamless medical review process as a case proceeds from one review level to another. Complete the PRAF whenever a case is referred for physician review.

4305 - Non-physician Review - (Rev. 2, 07-11-03)

A. First Screening Review -- The non-physician reviewer performs an initial screening review of the case to determine:

- If the documentation in the medical record is adequate for you to make a medical review determination (i.e., all necessary reports and notes are physically present and legible); and
- If the case requires referral to a physician reviewer.

The non-physician reviewer uses the following screening instruments, as applicable, for each case:

- Admission criteria;
- Discharge screens;
- Invasive procedure criteria;
- QIO-developed quality screens;
- CMS coverage guidelines;
- Published CMS criteria (e.g., rehabilitation criteria in the Medicare Intermediary Manual (MIM));
- DRG validation guidelines;
- Coding guidelines;
- QIO-developed documentation guidelines; and
- Other screens, criteria, and guidelines (e.g., practice guidelines that are well accepted by the medical community) as supplied by you.

In all cases, in addition to screening instruments, the non-physician reviewer applies his/her own professional expertise to identify potential concerns for referral to a physician reviewer.

If the medical record passes the first non-physician screening review, enter the data into your system for pattern analysis activities and close the case.

If the non-physician reviewer determines that a case should be referred for physician review, he/she initiates the PRAF and refers the case (See Exhibit 4-1).

If the non-physician reviewer cannot decide whether to refer the case to a physician reviewer because a component of the medical record is missing or illegible, request the appropriate component from the facility and record a documentation error as specified in §4520.D.

NOTE: Decisions that do not require clinical judgment to resolve (e.g., technical coding errors) are not referred to a physician reviewer.

B. Second Screening Review -- The non-physician reviewer performs second screening review when missing or illegible medical record components are subsequently provided by the facility/plan. If the medical record passes the second non-physician screening review, enter the data into your system for pattern analysis activities and close the case. If, even with the additional information, the case does not pass all screens, criteria, and application of the non-physician reviewer's professional expertise, the non-physician reviewer initiates the PRAF and refers the case for physician review.

If the facility does not provide the requested information, technically deny the case as specified in §4520.D and enter the case into your system for pattern analysis activities. Reopen the case as specified in §7102 if the information is supplied at a later date.

4310 - First Level Physician Review - (Rev. 2, 07-11-03)

Perform first level physician review for every case where the non-physician reviewer has identified a potential concern requiring a clinical decision. The physician reviewer reviews the PRAF and the complete medical record to determine:

- If the potential concerns identified and referred by the non-physician reviewer are valid; and
- If review of the medical record demonstrates potential concerns not identified by the non-physician reviewer.

The first level physician reviewer completes the PRAF for first level physician review (PRAF 1) (See Exhibit 4-1).

If the first level physician reviewer determines that all concerns identified by the non-physician reviewer are resolved and does not identify additional potential concerns, enter the data from first level physician review into your system for pattern analysis activities and close the case.

If the first level physician reviewer determines that a potential concern exists, provide the appropriate parties an opportunity to discuss the case (See §4530). In the case of potential quality concerns, the first level physician may make a preliminary identification of the source(s) of the concerns using the source legend of the PRAF. Send preliminary notices to the involved physician(s) and to the provider.

Provide the physician review results (including the physician reviewer case decision abstract and rationale from PRAF 1) of each first level physician review to the non-physician reviewer who made the referral (You may also choose to supply this information to your non-physician reviewers from additional levels of physician review as part of your quality improvement process).

NOTE: A gross and flagrant violation may be identified at any level of physician review. When the physician reviewer identifies a potential gross and flagrant violation, follow the procedures for development of a case with a potential gross and flagrant violation (See §9000)

4312 - Action Following Opportunity for Discussion - (Rev. 2, 07-11-03)

A. Response Received to Opportunity to Discuss -- When the involved physician(s) and/or provider respond to your opportunity for discussion, refer the case to a second level physician reviewer.

B. No Response Received to Opportunity to Discuss -- When neither the involved physician(s) nor provider respond to your opportunity for discussion, you may choose not to perform second level physician review. Make a determination based on the available information at the time of the first physician review. Send final notices of your determination to the provider and to all physicians who received a preliminary notice, regardless of the outcome of the determination.

In the case of quality concerns, if the preliminary sources of quality concerns were identified by the first level physician reviewer, you may assign those sources without further physician review. If the preliminary sources of quality concerns were not identified by the first level physician reviewer and are unclear, then the case is referred for a second level physician review.

4315 - Second Level Physician Review - (Rev. 2, 07-11-03)

Always perform second level physician review when a potential concern has been identified by the first level physician reviewer and the involved physician(s) and/or provider have responded to the opportunity for discussion. The second level physician reviewer reviews the medical record, the PRAF, and any additional information received during the opportunity for discussion.

The degree to which the medical record must be reviewed a second time by a physician in these cases should be determined on a common sense basis by the physician reviewer. If the physician reviewer is very familiar with the medical record in question (i.e., he/she served as the first level physician reviewer), only minimal review (e.g., evaluation of how the response conforms to the information in the medical record) should be necessary. If the second level physician reviewer did not perform the first level review, a more thorough examination of the medical record is indicated. The second level physician

reviewer makes the final determination and completes the PRAF for second level physician review (PRAF 2) (See Exhibit 4-1).

Send final notices of your determination to the provider and to all physicians who received a preliminary notice, regardless of the outcome of the determination.

Enter the data from second level physician review into your system for pattern analysis activities and close the case.

4320 - Third Level Physician Review - (Rev. 2, 07-11-03)

Perform third level physician review when the involved physician(s) and/or provider request a reconsideration (for initial utilization denials) or a re-review (for confirmed DRG or quality concerns). The third level physician cannot be a physician who was originally involved in the first or second level review. The third level physician reviewer reviews the medical record, the PRAF, and any additional information received during the discussion period or later. The third level physician reviewer completes the PRAF for third level physician review (PRAF 3).

Send notices of the reconsideration/re-review determination of the third level physician reviewer to the provider and involved physician(s).

Enter the data from third level physician review into your system for pattern analysis activities and close the case.

4325 - Use of the Physician Reviewer Assessment Format (PRAF) - (Rev. 2, 07-11-03)

A. Purposes of the PRAF -- The PRAF has been designed to achieve two objectives:

- Standardize the structure of the review process to obtain more consistent, reliable review decisions; and
- Standardize data reporting to provide both you and CMS with more reliable data for pattern analysis, feedback, and improving care.

To achieve these objectives, it is crucial that the format be an integral part of the review of each case (i.e., each reviewer must assess the case according to the requirements of the PRAF). Attempting to collect PRAF data from cases not reviewed according to the PRAF structure does not fulfill the objectives of the PRAF.

The PRAF is a format, not a form. You may design a form other than the model PRAF. However, collect and report all of the information found on the model PRAF. Collect the information in such a way that the same linkages can be made as if you were using the model PRAF (e.g., final determinations can be linked to specific quality screen criterion failures, and category assignments can be linked to specific concerns) (See Exhibit 4-1).

B. Personnel Using the PRAF -- All non-physician and physician reviewers must use the PRAF, as appropriate.

- The Non-physician Reviewer -- Non-physician reviewers will identify potential concerns and initiate the PRAF by completing the:
 - Patient identifying information section(s);
 - Non-physician reviewer decision summary;
 - Non-physician reviewer identification; and
 - Case decision abstract and question/statement of concern. The non-physician reviewer may also write a case summary, depending on your protocol.

NOTE: You may assign personnel other than non-physician reviewers to complete the patient identifying information section(s).

- The First Level Physician Reviewer -- The first level physician reviewer determines if a potential concern(s) exists. Whether a potential concern raised by the non-physician reviewer is validated or invalidated, and/or if an additional concern(s) is independently identified by the first level physician reviewer, he/she must complete the:
 - Physician reviewer preliminary decision summary;
 - Physician reviewer identification; and
 - Physician reviewer case decision abstract and rationale.

NOTE: The first level physician reviewer checks the "Immediate Attention" box, when appropriate.

- The Second Level Physician Reviewer -- The second level physician reviewer determines if a confirmed concern(s) exists. Whether a potential concern is confirmed or not, he/she must complete the:
 - Physician reviewer initial/final decision summary;
 - Physician reviewer identification; and
 - Physician reviewer case decision abstract and rationale.

NOTE: The second level physician reviewer checks the "Immediate Attention" box, when appropriate.

- The Third Level Physician Reviewer (Reconsideration/Re-review) -- The third level physician reviewer determines if an initial utilization denial, a confirmed quality concern, or a QIO DRG validation should be upheld or reversed. Whether a determination is reversed or not, he/she must complete the:
 - Physician reviewer reconsideration/re-review decision summary;
 - Physician reviewer identification; and
 - Physician reviewer case decision abstract and rationale.

NOTE: The third level physician reviewer checks the "Immediate Attention" box, when appropriate.

C. Elements of the Model PRAF -- The PRAF is used to make review decisions for patients in any setting (e.g., inpatient hospital, physician office).

- Patient Identifier Information -- The patient identifier information provides administrative data for case identification. Enter patient identifier information at the top of the Decision Summary, the Non-physician Reviewer - Case Decision Abstract and Question/Statement of Concern, and the Physician Reviewer Case Decision Abstract and Rationale at all levels of review.
- Non-physician Reviewer Decision Summary -- In the non-physician reviewer decision summary, the non-physician reviewer identifies each concern by sequential number, notes which quality screen criterion each concern failed as appropriate, and assigns a suggested category to each concern. The non-physician reviewer's ability to clearly identify, distinguish, and categorize potential concerns is crucial to the development of further information on the PRAF. The non-physician reviewer enters his/her identification number and the date.
- Physician Reviewer Preliminary Decision Summary -- The first level physician reviewer enters the category of each concern identified by the non-physician reviewer in the sequential order assigned by the non-physician reviewer. If the physician reviewer believes that the non-physician reviewer's concern is not valid, he/she enters "0".

The first level physician reviewer may also add concerns he/she has identified independent of the non-physician reviewer. These are to be assigned sequential concern numbers and categorized by the physician reviewer.

The first level physician reviewer also enters the name(s) of the physician(s) who is to receive a preliminary notice for each concern. The physician reviewer must identify

those physicians who should receive preliminary notices. Send preliminary notices only to those physicians who can supply information necessary to address the concerns raised.

The first level physician reviewer enters his/her identification number and the date.

- Physician Reviewer Initial/Final Decision Summary -- The second level physician reviewer enters the category of each concern he/she reviews in sequential order (The category assignment may change after the opportunity for discussion). If the concern is not confirmed, the physician reviewer enters "0".

The second level physician reviewer enters the source(s) of any confirmed quality concerns in sequential order. The sources to be assigned are found on the source legend. For DRG or utilization concerns, the source is "0".

The second level physician reviewer also sequentially enters the name(s) of any physician(s) determined to be the source, or one of the sources, of a confirmed quality concern.

The second level physician reviewer enters his/her identification number and the date.

- Physician Reviewer Reconsideration/Re-review Decision Summary -- The third level physician reviewer enters the category of each concern he/she reviews in sequential order (The category assignment may change after the reconsideration/re-review). If the concern is not reconfirmed, the physician reviewer enters "0".

The third level physician reviewer enters the source(s) of any reconfirmed quality concerns in sequential order. The sources to be assigned are found on the source legend.

The third level physician reviewer also sequentially enters the name(s) of any physician(s) believed to be the source, or one of the sources, of a confirmed quality concern.

The third level physician reviewer enters his/her identification number and the date.

- Office Use Only -- Use this section to identify physicians who are to receive notices by Unique Physician Identification Number (UPIN) and to track the case as it moves through the physician review process.
- Immediate Attention -- A physician reviewer at any level of review may check the Immediate Attention box when he/she believes that you should pay special attention to the case under review (e.g., the physician reviewer believes that additional investigation should be undertaken).

When the box is checked, the physician reviewer must justify the need for special attention in the physician reviewer Case Decision Abstract and Rationale section of the

PRAF. Determine the appropriate way to process PRAFs marked for special attention (e.g., immediate review by the medical director).

- Non-physician Reviewer Case Decision Abstract and Question/Statement of Concern -- For each potential concern he/she has identified, the non-physician reviewer must define the concern clearly and concisely and provide clinical data from the medical record to support the identified potential concern. You may also require a non-physician reviewer case summary in this section.

The non-physician reviewer may sign this section (optional), but must enter his/her identification number and the date.

- Physician Reviewer Case Decision Abstract and Rationale -- Note whether the case decision abstract and rationale is for the preliminary, initial/final, or reconsideration/re-review determination.

First level physician reviewers are to address all potential concerns raised by the non-physician reviewer, as well as any independently identified concerns. Second level physician reviewers are to address all concerns for which the opportunity for discussion is provided. Third level physician reviewers are to address all concerns for which the reconsideration or re-review is requested. At each level, the physician reviewer must justify his/her decision clearly and concisely and provide clinical data from the medical record to support the decision. You may also require a physician reviewer case summary in this section. Second and third level physician reviewers are to include alternative courses of action that would have precluded the confirmed (or reconfirmed) concern.

Physician reviewers are to consider concerns from a systems perspective. It is seldom that a concern is the result of a single individual's action. For example, if the physician ordered an incorrect dose of medication and the medication was administered, the reviewing physician should consider the elements (e.g., nursing department, pharmacy) and the processes (e.g., poor communications) that failed to prevent the occurrence.

The physician reviewer may sign this section (optional), but must enter his/her identification number and the date.

- Categories for Classifying Concerns -- Categories are grouped as Utilization Categories (applicable to review of NODMARs), Prohibited Action Categories, Quality Categories, and DRG categories (Only the Quality Categories are used for managed care review except for review of NODMARs). Place each potential and confirmed concern in these categories. In general, assign one category to each concern. If a concern seems to fall into several categories, rethink the concern because it may be that several separate concerns are being combined. There may be several concerns within one clinical episode.

NOTE: There are a few DRG validation categories that are to be reported as such even though the case may not have been referred for physician review (e.g., D.14, D.15).

4400 - Introduction - (Rev. 2, 07-11-03)

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 Organization (M+CO) review under §§1154(a)(4) and 1852(e)(3) of the Act and 42 CFR 476.70 and 476.72.

For FFS cases, you are to review services provided by PPS providers located in your State or review area or by non-PPS providers in a waived/excluded area. For M+C cases, you are to review services provided by M+COs 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 (NODMAR), see Chapter 7). Where the M+COs immediate service area crosses State lines, your review responsibility extends across State lines also (i.e., review remains the responsibility of the QIO in the State in which the M+CO has its contract).

4405 - Review of Medicare Services - (Rev. 2, 07-11-03)

The objectives of case review are dependent on whether you are conducting FFS or M+CO review. Review FFS and M+C services paid 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 - (Rev. 2, 07-11-03)

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

- 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) and (a)(3)). 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+CO settings.

- 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+CO 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 of Participation (CoP) specified in 42 CFR, Part 482 (Conduct beneficiary complaint review only 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 beneficiary complaint 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 beneficiary complaint review).
 - 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 beneficiary complaint review only).
 - Hospitals -- Hospitals (including emergency services/departments) are acute care, general hospitals, and acute long-term care 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 (For PPS Hospitals and non-PPS hospitals in Maryland, conduct utilization and, when applicable, conduct quality review and beneficiary complaint review) (For psychiatric hospitals or rehabilitation hospitals, conduct beneficiary's request for immediate review of a HINN/NODMAR).

- 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 beneficiary complaint review only).
- 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 beneficiary complaint 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 beneficiary complaint review and beneficiary's request for immediate review of a HINN/NODMAR).
- 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 beneficiary complaint 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. CAH swing beds must meet the CoP specified in 42 CFR 485.645 (Conduct beneficiary complaint review only).
- Specialty Hospitals -- Examples of specialty hospitals are psychiatric and rehabilitation hospitals. Specialty hospitals must meet the CoP specified in 42 CFR, Part 482 (Conduct beneficiary complaint review and beneficiary's request for immediate review of a HINN/NODMAR).
- Community Mental Health Centers -- CMHCs deliver partial hospitalization services (specialized outpatient mental health services) to Medicare beneficiaries. CMHCs must meet the requirement for coverage specified in 42 CFR 410.110 (Conduct beneficiary complaint review only).

4500 - Introduction - (Rev. 2, 07-11-03)

Other Fee-For-Service (FFS) and Medicare + Choice Organization (M+CO) 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;
- Monitoring practitioners'/providers' improvement plans;
- Profiling case review results, and developing and implementing projects to address hospital admission and coding patterns;
- Monitoring hospital's physician acknowledgment statements; and
- Conducting internal quality control activities (See Chapter 13).

4510 - Using Screening Criteria - (Rev. 2, 07-11-03)

See §1154(a)(6) of the Act.

You are to establish written criteria or obtain national criteria for non-physician reviewer use when screening FFS and M+CO 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+CO review, use FFS criteria plus additional criteria unique to M+COs. Criteria must be reassessed regularly and updated as necessary to reflect current standards of practice. CMS does not require that you use a specific criteria set so long as the criteria you select meets the above requirements.

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 timeframes 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+COs within the State of newly established or revised criteria at least 30 calendar days prior to implementation. New QIO contractors must notify provider, physician, and M+COs of their medical criteria within 30 calendar days of their contract effective date. Provide copies of criteria to providers/practitioners/M+COs, upon request. Provide copies of criteria to carriers upon mutual agreement. Do not send copies of your criteria to CMS for approval, but you must have copies available for CMS' 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 Memorandum of Agreement (MOA) with providers, M+COs, 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 Chapter 3).

4520 - Requesting Medical Records/Reviewing Documentation - (Rev. 2, 07-11-03)

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)). Your review is performed outside the provider facility. 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 the medical record is not received by the 15th day, send a reminder notice to the provider or practitioner.

Under the Hospital Payment Monitoring Program (HPMP), 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. Hospitals are expected to deliver the requested medical records to the CDAC within 30 days from the date of the request. For these records, the CDACs mark a medical record as canceled (not received) 31 days from 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.

Allow the provider/M+CO 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+CO of the action you will take if the records are not furnished within the 30-day timeframe (See §4520.B).

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

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

B. Failure to Submit Medical Records -- When an inpatient hospital, Ambulatory Surgical/Surgery Center (ASC), or swing bed provider fails to submit the medical records for a FFS patient within the prescribed timeframes, issue a technical denial and record a documentation error (See §7101.B). 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 medical records (including from CDACs) not received 45 days from the date of the record request.

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 a M+CO 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 timeframes 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.

C. 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.

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

- Ambulatory Surgical/Surgery 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.
 - Rehabilitation hospitals are to meet the requirements specified in 42 CFR 482.24(c).
 - Critical Access Hospitals (CAHs) are to meet the requirements specified in 42 CFR 485.638(a)(4).
 - Skilled Nursing Facilities (SNFs) and SNF swing beds are to meet the requirements specified in 42 CFR 483.75(l)(5).
 - Community Mental Health Centers (CMHCs) are to meet the requirements specified in 42 CFR 424.24(e)(2).
- Establishing Documentation Guidelines -- QIOs 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 (CoP) in 42 CFR Subchapter G 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:

- 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 timeframes for comment periods.
- Involve Health Care Practitioners Other Than Physicians (HCPOTPs) for guidelines used in the review of services delivered by HCPOTPs.
- Collaborate with other QIOs, when appropriate.
- Notify provider, physician, and M+COs within the State at least 30 calendar days prior to implementation. New QIO contractors must notify provider, physician, and M+COs within 30 calendar days of their contract effective date.
- Provide a copy to providers/practitioners/M+COs upon request.

- Reassess regularly and update as necessary.

Specify in your MOA with providers/M+COs 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 Chapter 3).

D. 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+CO 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 timeframe, 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+CO 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 were referred.

QIO 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+CO in locating or reading the problematic section(s).

E. 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+CO/physician(s) prior to making a review determination.

F. 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+CO because a determination cannot be made on the basis of the medical record alone. A documentation error occurs when:

- The provider/M+CO 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.

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); and 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.

G. 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).

- 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.
- 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 timeframe, proceed with the review; or

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

H. 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:

- When a pattern seriously and repeatedly impedes review; or
- 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 - (Rev. 2, 07-11-03)

When you identify a potential utilization, DRG assignment, or quality concern, notify providers/practitioners/M+COs in writing of the opportunity for discussion. Give them

20 calendar days from the date of your notice for oral discussion with appropriate QIO 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+COs 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+COs.

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 QIO 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 QIO HCPOTP, if available, or with a QIO 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/Medicare + Choice Organizations (M+COs) -- Afford providers/M+COs an opportunity for discussion in accordance with the following guidelines:

- Afford providers/M+COs an opportunity to discuss the concern(s) with a QIO physician if the provider's/M+CO's representative is a physician. If the

provider's/M+CO's representative is a nurse or other staff person, use knowledgeable non-physician staff for the discussion, as appropriate.

- 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 case file accordingly. In this situation you will be unable to offer the provider an opportunity for discussion.
- M+COs may coordinate responses with the physician/provider and forward one combined response to you.

4540 - Adhering to Review Timeframes - (Rev. 2, 07-11-03)

A. Review Beginning/Completion Dates -- The timeframe for FFS and M+C retrospective review begins when you have adequate information to request medical records. For HPMP 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 timeframes specified in §4540.B. The review of a case ends with a completion date as follows:

- When a case is not referred for physician review, the review completion date is the date the review of the medical record is completed.
- 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.
- When an opportunity to discuss a case has been afforded the physician/provider/M+CO, 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+CO. 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 timeframes of review, you may accelerate your review in some areas and use the time gained in other areas.

B. Review Timeframes -- Use the Time of Review document provided with the Case Review Information System (CRIS) User's Guide to determine the review timeframes for each category of review (e.g., quality review, utilization review). The timeframe for retrospective review includes the 30 days a provider has to submit the medical record. If the requested medical record comes in earlier than 30 days, then the QIO gains the extra time to complete its review. The completion review timeframes vary for different review

categories. See Exhibit 4-1A for the timeframes applicable to each specific review category.

- Retrospective Review -- The timeframes for questioned cases include the 20-day opportunity for discussion requirement as specified in §4530. The time reduction for HPMP cases is based on the review start date defined as the date the medical record is received by the QIO. For HPMP cases, the QIO simply receives the records from the CDAC and begins the review unless time is needed for additional information (15 days). When requesting record information because a provider/M+CO submits an incomplete or partially illegible medical record, add 15 calendar days to the review timeframes specified below (See Exhibit 4-1A for the timeframes applicable to case review). In general, complete retrospective review within the timeframes:
 - 60 calendar days for an unquestioned case (30 days for HPMP cases);
 - 90 calendar days for a case questioned for DRG validity or by the physician reviewer for utilization (60 days for HPMP cases); or
 - 100 calendar days for a case questioned by the physician reviewer for quality of care (70 days for HPMP cases) (Excludes beneficiary complaints of quality of care review).

- Re-openings -- Complete review within the following timeframes:
 - 30 calendar days for an unquestioned case;
 - 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 - (Rev. 2, 07-11-03)

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+CO profiles to use as a data source in conducting your State analysis for use in your Hospital Payment Monitoring Program (See Chapter 11) and to identify possible interventions, including improvement 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+COs or by CMS. Reports disseminated to PPS and non-PPS providers/M+COs 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+CO's internal policies/procedures or a general problem that exists within the medical community. For example, the M+CO only permits enrollees to have a certain number of a particular diagnostic study within a given timeframe, 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+CO regarding its systems/guidelines governing the issue, including how the PPS or non-PPS provider/M+CO 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's/M+CO's 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+CO to correct any concerns. The intent is to see whether the problem derives from the PPS or non-PPS provider's/M+CO's internal directives or whether the directives are acceptable. However, the PPS or non-PPS provider/M+CO does not have the ability to monitor that its directives are being followed.

4560 - Maintaining Memoranda of Agreements (MOAs) - (Rev. 2, 07-11-03)

Maintain MOAs with providers, payers, M+COs, and State licensing/certification agencies as instructed in Chapter 3.

4570 - Prepayment Review System (PRS) Implementation - (Rev. 2, 07-11-03)

Your request to intermediaries and carriers to implement pre-procedure and prepayment review of a procedure, diagnosis, provider, or practitioner must conform to the negotiated Memoranda of Agreements (MOAs) between you and the payers outlining the conditions for necessary data exchange requirements (See Chapter 3).

4580 - Monitoring Hospitals' Physician Acknowledgement Statements - (Rev. 2, 07-11-03)

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, CMS may, as appropriate:

- Withhold Medicare payment in full or in part to the hospital until the hospital provides adequate assurances of compliance; or
- Terminate the hospital's provider agreement.

B. Monitoring Requirements -- At least annually, 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 annual monitoring requirement at one single time or more frequently during each contract year. Perform this activity offsite or onsite the hospital setting. To perform this activity, you must do the following:

- Be familiar with the hospitals' own internal procedures to secure the acknowledgment statements from physicians (See §4580.A). Ensure that each hospital, in your review area, is in compliance with the acknowledgment requirement;
- Inform providers in your review area about your monitoring activities;
- Request from the hospitals a list of all physicians with new admitting privileges for the year/period under review. The list should include the physician name, Unique Physician Identification Number (UPIN), the date admitting privileges were granted, the date acknowledgment was signed, and the date of the first claim submitted to the FI for that particular physician, when applicable. As needed, you may request copies of the signed acknowledgements for verification. Validate the information received from the hospital against the claims data. Validate all acknowledgements if there are 5 or less. For 6 or more acknowledgements, select a random sample of the listed physicians. If a deficiency was found on the sample validated, select and validate all or another random sample to ensure that a pattern does not exist. You must determine what constitutes a pattern based on the number of physicians' first claims submitted by the hospital before the physician signed the acknowledgement statements;
- Coordinate, as necessary, with the intermediary in your review area to facilitate action by the Fiscal Intermediary (FI) or you when needed. 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 of a hospital not obtaining appropriate acknowledgment(s) before billing;

- As needed, request an improvement plan to correct any deficiencies that are found;
- Report results into SDPS.

C. Reporting Requirements -- If you determine that corrective action is necessary (i.e., the deficiency affects payment under the PPS Program):

- Notify the intermediary of the deficiency for claim adjustment;
- Notify the hospital that it must correct the deficiency immediately. Concurrently, inform the appropriate CMS Associate Regional Administrator through your Project Officer; and
- If the problem continues, or a pattern of noncompliance is established, refer the case to the appropriate CMS Associate Regional Administrator for further action(s) through your Project Officer.

4590 - Reporting Requirements for Review Activities - (Rev. 2, 07-11-03)

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

B. QIO and Intermediary Information Exchange -- After completing case review, report to the intermediary and the provider, as specified in the SDPS Database Administrator Guide, any claims that need adjustment because of:

- A change in the DRG;
- Admission denied;
- Day outlier days denied (See NOTE in §4210);
- Cost outlier services denied;
- Non-PPS hospital or SNF swing bed days denied;
- Incorrect date for hospital to begin charging the beneficiary;
- Failure to provide medical documentation for review (See §4520.B);

- Partial or complete reversals of a previous QIO decision;
- Change in discharge status in a PPS hospital;
- Deemed admission denials or approvals;
- Readmission/transfer denied;
- Assistant-at-cataract denied; and
- Outpatient services denied.

4600 - Introduction - (Rev. 2, 07-11-03)

You must have access to a sufficient number of non-physician reviewers to screen medical records and physician reviewers to make QIO determinations for Fee-For-Service (FFS) and Medicare + Choice (M+C) cases under review as specified in your contract.

4610 - Non-physician Reviewers - (Rev. 2, 07-11-03)

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 - (Rev. 2, 07-11-03)

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 Department of Veterans Affairs (DVA) health care facility in your State, even though the physician's license to practice has been issued by a different State. If the M+CO'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, creates an unavoidable potential conflict of interest, or compromises 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 Medical Doctors) or by a specialty board under the auspices of the American Osteopathic Association (for Doctors of Osteopathy). Each prospective board-certified physician reviewer must provide evidence of that certification.

If use of the required reviewer is impractical, creates an unavoidable potential conflict of interest, or compromises 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, creates an unavoidable potential conflict of interest, or compromises 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+CO physicians when physician review of M+C services is required. A M+C physician is a physician who, as a regular part of his/her practice, provides care that is paid for by a M+CO. These physicians may be employed by a staff model M+CO 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, QIOs 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 (i.e., 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+CO 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+CO 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) - (Rev. 2, 07-11-03)

A HCPOTP is a person credentialed in a recognized health care discipline who provides the services of that discipline to patients (e.g., a nurse anesthetist). A 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 a HCPOTP peer before making the determination (See 42 CFR 476.102(a)(3)).

For services furnished by a 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 - (Rev. 2, 07-11-03)

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)(1) 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)).

QIOs must also be aware of potential conflicts of interest specific to M+CO review. For example:

- Only FFS physicians reviewing the quality of M+CO services;
- M+CO physicians reviewing care provided or arranged for by a M+CO from which these physicians receive financial benefit; or
- Physicians who perform services for one M+CO and review services of another M+CO that competes directly with their M+CO 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 - (Rev. 2, 07-11-03)

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 CMS' 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 CMS or other CMS contractors. To minimize expenses and maximize exchange of ideas, you are encouraged to collaborate with other QIOs, hospitals, M+COs, 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 CMS 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 CMS upon request. In developing training plans:

- Identify the needs of non-physician and physician reviewers, the goals and objectives of the training, the methodology to be used, and the training topics to be included;
- For each course, identify the cost, length of time in hours, location, audience, course description, and trainer credentials, regardless of whether the course is offered in-house, by a QIO consortium, or by a non-QIO source;
- Identify the methodology you will use to evaluate the effectiveness of the training.

NOTE: Training plans must ensure that investment in initial physician reviewer training is recovered. For example, you may decide not to pay physician reviewers during their initial training. Upon completion of the training, you could double the physicians' hourly rates of pay for review activity up to the approved number of hours spent in training.

B. Initial Training -- At a minimum, initial training should include:

- An overview of your review process, goals of your review, and the effect of individual case review determinations. Explain that a major purpose of review is to improve care through educational feedback and continuous quality improvement. Stress the educational focus of your actions when concerns are identified;
- An overview of the cooperative project process and disease-specific quality indicators;
- A review of relevant Medicare statutory and regulatory requirements, the QIO Manual, and the Statement of Work (SOW);
- A review of incentives that may affect care in both the FFS and M+CO settings;
- A review of the DRG validation process;
- A review of the norms and criteria you use for case review;
- An overview of types of medical record formats used by facilities in your area;

- Instruction on how to extract information necessary to make a determination from the medical record;
- Instruction on how to verify information found in one area of the medical record by using information from another part of the medical record;
- Instruction on coding guidelines and practices (for personnel responsible for coding decisions);
- Discussion of the role of the reviewer in determining whether care is inconsistent with principles on which there is substantial consensus (e.g., published specialty guidelines);
- Discussion of the need to base cooperative projects and determinations on widely supported analyses of scientific data, rather than on the beliefs of the reviewer, even if supported by anecdotal or other evidence;
- Discussion of the goal of achieving consistency in case review by having the reviewer be confident that other reviewers would agree with his/her interpretation based on the evidence and would reach a similar conclusion regarding the issue;
- Instruction on the process for performing project data collection, including when it is to be performed and its goal; and
- Instruction on how to discuss potential and confirmed concerns with the providers/practitioners/M+COs (for QIO physician reviewers and personnel who are expected to interact with providers/practitioners/M+COs).

C. Continuing Education -- In developing ongoing training, identify training needs from multiple sources such as:

- Internal quality control findings;
- Staff recommendations;
- Other QIOs;
- Providers/M+COs under review; and
- CMS and CMS contractors.

D. Continuing Medical Education (CME) and Continuing Education Units (CEUs)/Hours -- CME/CEU courses are necessary for clinical staff to be aware of changes in practice. Make reasonable efforts to secure CME/CEU credit for QIO-developed education programs. If unsuccessful, make other arrangements, where possible (e.g., arrange for a QIO consortium to offer CME/CEU courses, pay for

Medicare reviewers to attend courses offered by non-QIO sources). In either case, document your efforts.

4700 - Introduction - (Rev. 2, 07-11-03)

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 QIO 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 QIO 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 up-coding for DRG enhancement, consistent failure in effective discharge planning) should receive priority consideration.

4705 - Feedback to the Provider and Involved Physicians - (Rev. 2, 07-11-03)

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 - (Rev. 2, 07-11-03)

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 (e.g., 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 timeframe 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.

4715 - When an Action Plan Is Not Needed - (Rev. 2, 07-11-03)

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 that require action, forward the information to the QIO in the new State of practice. Provide your Project Officer with a copy of any concerns forwarded to another QIO.

4720 - Provider Implementation of an Action Plan - (Rev. 2, 07-11-03)

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

4725 - Additional Performance Improvement Activities - (Rev. 2, 07-11-03)

If a provider's action plan is not successful (i.e., the stated outcome has not been achieved) within the stated timeframe, 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 timeframe;
- 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 QIO-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 CMS RO (or to a State survey agency through the RO) for a facility investigation for compliance with the facility's Medicare provider agreement;
- 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);
- Referral to the Medicare carrier (for a physician with an identified pattern of utilization or other concerns, as appropriate); and/or

- Referral to the Office of the Inspector General (OIG) for possible sanction action (See §9000 for development of a sanction recommendation of a substantial violation in a substantial number of cases).

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:

- Be knowledgeable concerning the availability of specific Continuing Medical Education (CME) courses, and consider recommending attendance at courses that address the categories of concern;
- 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);
- Contact teaching institutions about their willingness and ability to provide mini-residency courses that address specific categories of concerns, and consider recommending attendance at such mini-residency courses to address appropriate behaviors of concern;
- Be knowledgeable concerning the rules regarding board certification examinations, and consider recommending taking (not necessarily passing) board certification exams; and
- 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).

4730 - Monitoring Performance Improvement Actions - (Rev. 2, 07-11-03)

Assess the impact of your performance improvement actions. Consider the nature of each action to determine the most efficient and effective means of assessing the impact of your activities. In the case of provider action plans, employ assessment techniques to enable you to make accurate decisions as to when a provider action plan can be modified

or discontinued. In the case of other actions (e.g., direct negotiation with a physician concerning educational activities), assess whether an action has been successful or whether another action (e.g., sanction) must be instituted.

Develop specific criteria for judging whether an action plan or other performance improvement action has succeeded. Tailor your assessment to your assessment criteria and the data available. You may determine that process (e.g., review/audit of a provider's modified quality assurance procedures) or outcome assessment (e.g., analysis of billing data from the provider for a DRG of concern), or both, may be the most appropriate method to determine the success of your actions. You may institute project data collection to monitor performance when other modalities will not satisfactorily collect the data you require to assess impact.

Your impact assessment techniques must be:

- Appropriate to the clinical and other issues involved;
- Objective;
- Cost-effective; and
- Reproducible.

When appropriate (e.g., an outcome measure has an extended timeframe), perform an interim impact assessment. Subject that assessment to subsequent validation (e.g., by pattern analysis or case review findings).

Share your assessment of the outcome of an individual provider's action plan with the provider. Also, share interim assessments, if performed. If a physician is involved, share your assessment with the physician.

NOTE: Released assessments must conform to all QIO confidentiality requirements. The identities of individual providers/practitioners must be protected (See §§10000-10090).

4735 - Timing Requirements for Performance Improvement Activities - (Rev. 2, 07-11-03)

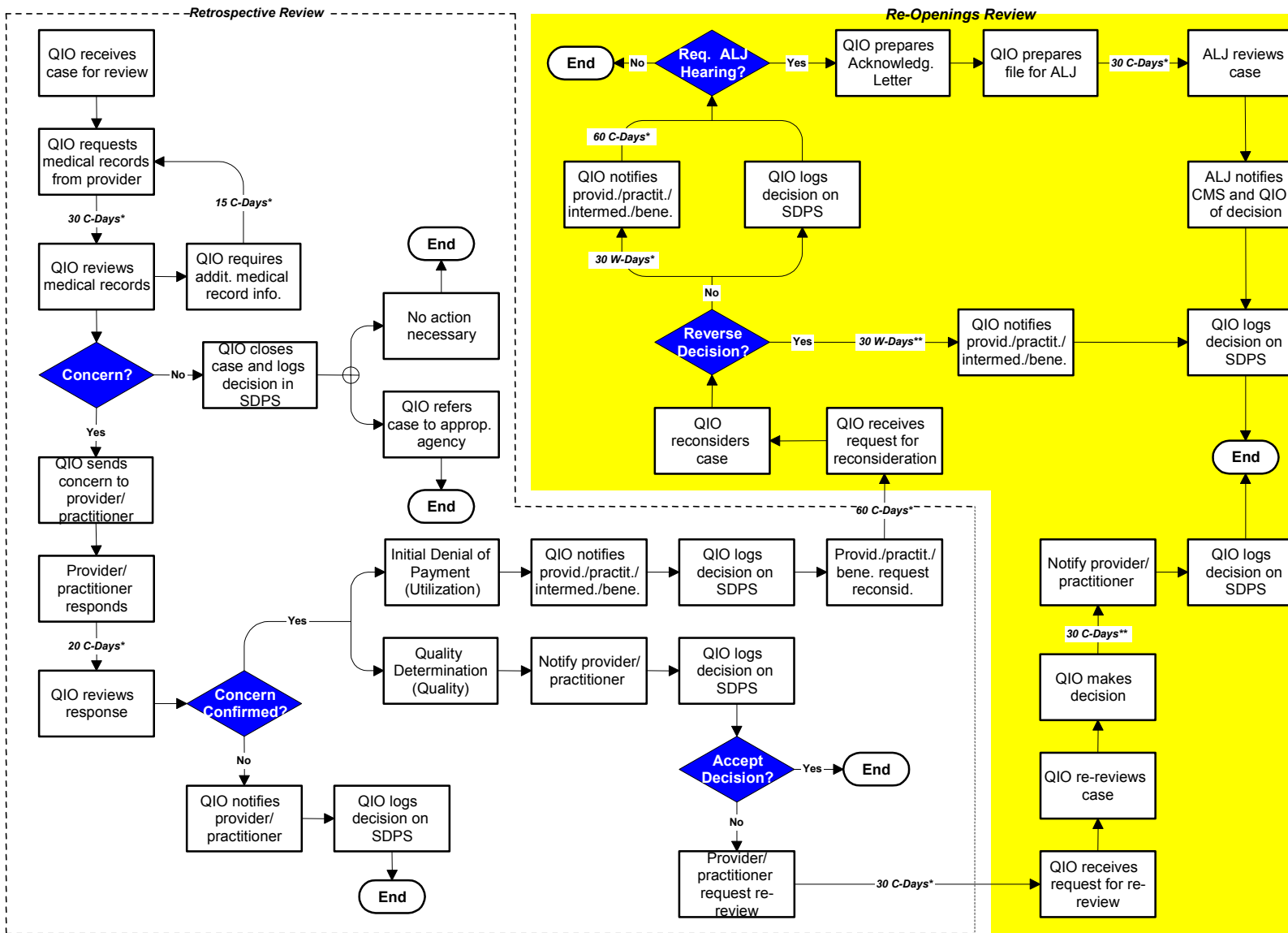
Request an action plan from a provider within 30 calendar days of the date you have determined an action plan is required. You may delay this request for a short period with good reason. However, it is expected that delays will be rare. Allow 30 calendar days for the provider to develop an action plan.

Be familiar with timeframes in which performance can reasonably be expected to improve. Use your assessment of the nature and magnitude of the pattern of concerns and your knowledge and experience of the nature of institutional change in general and

with specific providers to set appropriate timeframes for improvement. Do not allow providers or practitioners unreasonable periods of delay in developing or implementing action plans or in proceeding with other improvement activities (e.g., a mini-residency). Interpret unreasonable delays as refusal to cooperate and proceed accordingly.

Exhibit 4-1 - Standard Mandatory Case Review Process - (Rev. 2, 07-11-03)

STANDARD MANDATORY CASE REVIEW PROCESS



*C-Days = calendar days **W-Days = working days

Exhibit 4-1A - Standard Mandatory Case Review Process Timeframes - (Rev. 2, 07-11-03)

STANDARD MANDATORY CASE REVIEW PROCESS TIMEFRAMES

Retrospective Review

(FROM RECEIPT OF MEDICAL RECORDS)

(ADD 15 CALENDAR DAYS WHEN APPLICABLE)

Timeframes:

60 Calendar Days: Unquestioned Case
90 Calendar Days: Questioned Case (for DRG/validation)
100 Calendar Days: Questioned Case (for Quality of Care)

Re-Openings Review

(FROM RECEIPT OF REQUEST)

Timeframes:

30 Calendar Days: Unquestioned Case
50 Calendar Days: Questioned Case (for DRG/validation)
60 Calendar Days: Questioned Case (for Quality of Care)