(1) Payment will not be made under Medicare to an excluded practitioner or other person for services or items furnished or ordered during the period of exclusion;

(2) Payment will not be made under Medicare to any provider for services or items ordered by an excluded practitioner or other person when the order was a necessary precondition for payment under Medicare; and

(3) Assignment of a beneficiary's claim for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion will not be valid.

(b) *Exceptions.* Payment is available for services or items provided up to 30 days after the effective date of an exclusion for—

(1) Inpatient hosptial or skilled nursing services or items furnished to a beneficiary who was admitted before the effective date of the exclusion; and

(2) Home health services or items furnished under a plan established before the effective date of the exclusion.

(c) *Denial of payments to beneficiaries.* If a beneficiary submits claims for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion—

(1) HCFA pays the first claim submitted and immediately gives the beneficiary notice of the exclusion; and

(2) The beneficiary's right to payment extends to services or items furnished or ordered up to 15 days after the date on the notice.

(d) *Effective date of termination of provider agreement.* The effective date of termination of a Medicare provider agreement is determined in accordance with §§ 489.53 and 489.55 of this chapter.

§ 474.56 Reinstatement after exclusion.

Exclusion will remain in effect until—

(a) The OIG determines, in accordance with §§ 420.130 through 420.136 of this chapter, that the basis for the exclusion no longer exists and there is reasonable assurance that the problems will not recur, or

(b) The OIG's determination to exclude is reversed by a hearing decision.

Subpart G—Appeals

§ 474.58 Appeal rights.

(a) *Right to administrative review.*

(1) A practitioner or other person dissatisfied with an OIG determination or an exclusion that results from a determination not being made within 120 days is entitled to a hearing before an Administrative Law Judge and may also request a review of that decision by the Appeals Council in accordance with §§ 405.1530 through 405.1595 of this chapter.

(2) Due to the 120-day statutory requirement specified at § 474.42(e) of this part, the following limitations apply:

(i) The period for submitting additional information will be not be extended.

(ii) Any material received by the OIG after the 30-day period allowed, will not be considered and will not be subject to review by the Administrative Law Judge and the Appeals Council.

(3) OIG's determination continues in effect unless reversed by a hearing decision.

(b) *Right to judicial review.* Any practitioner or other person dissatisfied with a decision of the Appeals Council or an administrative law judge (if a request for Appeals Council review is denied), may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

D. Part 489 is amended as follows:

1. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, and 1395hh).

2. Section 489.55 is revised to read as follows:

§ 489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services furnished under a plan established before the effective date of termination.[1]

(Catalog of Federal Domestic Assistance Programs, No. 13.773, Medicare—Hospital Insurance and No. 13.774, Medicare—Supplementary Medical Insurance)

[1] For terminations before July 18, 1984, payment was available through the calendar year in which the termination was effective.

Dated: December 11, 1984.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

R.P. Kusserow,

Inspector General, Department of Health and Human Services.

Approved: January 28, 1985.

Margaret M. Heckler,

Secretary.

[FR Doc. 85-9001 Filed 4-11-85; 2:42 pm]

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42 CFR Parts 400 and 476

[HSQ-110-F]

Medicare Program; Acquisition, Protection, and Disclosure of Utilization and Quality Control Peer Review Organization (PRO) Information

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These regulations govern the acquisition, protection, and disclosure of information obtained or generated by Utilization and Quality Control Peer Review Organization (PROs). The Peer Review Improvement Act of 1982 authorizes PROs to acquire information necessary to fulfill their duties and functions, places limits on disclosure of PRO information, and establishes penalties for unauthorized disclosure. These regulations implement the PROs' statutory right of access to necessary information and set forth their responsibilities to assure that information once acquired is adequately safeguarded and disclosed only for proper purposes.

EFFECTIVE DATE: The regulations are effective May 17, 1985.

Sections 476.105, 476.116, and 476.134 of this rule contain information collection requirements with which the public is not required to comply until the Executive Office of Management and Budget (EOMB) approves these requirements. (See section VI. of the preamble for a discussion of information collection.)

FOR FURTHER INFORMATION CONTACT: Mary K. Terry, (301) 594-7910.

SUPPLEMENTARY INFORMATION:

I. Legislative History

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97-248)) amended Part B of Title XI of the Social Security Act (Act) to establish the Utilization and Quality

Control Peer Review Organization (PRO) program.

Congress originally enacted Part B of Title XI in 1972, establishing the Professional Standards Review Organization (PSRO) program. The purpose of the PSRO program was to assure that health care services and items for which payment may be made under the Medicare, Medicaid and Maternal and Child Health and Crippled Children's programs were medically necessary, conformed to appropriate professional standards and were delivered in the most efficient and economical manner possible. The 1982 legislation provided for PROs to assume PSRO responsibilities for the review of health care services funded under Title XVIII of the Act (Medicare) to determine whether those services are medically necessary, are furnished at the appropriate level of care, and are of a quality that meets professionally recognized standards. In addition, PROs will monitor and validate a sample of diagnostic and procedural information supplied by providers to fiscal intermediaries regarding prospective payments to hospitals. To carry out their responsibilities PROs, like PSROs, will acquire information from the medical records of patients and from other records maintained by health institutions, practitioners, and claims payment agencies. In addition, they will generate information regarding the quality and appropriateness of health care services. PROs will use this information to develop and review profiles (patterns of utilization and practice) and to assess the quality of care being furnished. PROs will then transmit their determinations to organizations responsible for making payments under the Act.

The PRO legislation contains several provisions affecting data collection and disclosure. Under section 1154(a)(7)(C) of the Act, PROs have the authority to examine pertinent records of any practitioner or provider of health care services for which the PRO has review responsibility. Section 1154(a)(9) of the Act requires that PROs "collect such information relevant to its functions, and keep and maintain such records, in such form as the Secretary may require to carry out the purposes of this part, and shall permit access to and use of any such information and records as the Secretary may require for such purposes, subject to the provisions of section 1160." The other relevant language in section 1154 authorizes PROs to exchange information with claims payment agencies, other PROs and other public or private review organizations as may be appropriate (section 1154(a)(10)). Section 1160 of the Act contains the majority of a PRO's statutory responsibilities concerning the disclosure of information. This section recognizes both the need to protect the interests of patients, health care practitioners and providers of health care in the confidentiality of their medical records and the need to disclose certain information.

II. Proposed Rule

On April 16, 1984 we published in the **Federal Register** a proposed rule that would implement that part of the PRO statute concerning acquisition, protection, and disclosure of PRO information (49 FR 14977). The major provisions of the proposed rule are as follows:

A. General Provisions

1. PRO information must be held in confidence and not be disclosed unless the disclosure is necessary to carry out the purposes of the PRO statute or is provided for by regulations published by the Secretary.

2. The proposal describes the procedures for disclosure by a PRO of information necessary to carry out the purposes of the statute, including notice requirements, limitations on redisclosure and penalties for unauthorized disclosure. It also specifies the applicability of certain other statutes and implementing regulations to PRO information.

B. PRO Access to Information

1. Under the proposal, PROs are permitted to require institutions or practitioners to provide to the PRO copies of records and information pertinent to health care services furnished in the PRO area to Medicare beneficiaries. If authorized by the institution of practitioner, PROs also have access to the records of other patients.

2. PROs are permitted to have access to records held by Medicare intermediaries or carriers and certain other information collected or generated by institutions, practitioners or other entities. Certain limitations on PRO data collection were also specified in the proposed regulations.

C. PRO Responsibilities

1. In the proposal, we delineate PRO responsibility for: maintaining the confidentiality of information in their possession, including the responsibilities of PRO officers and employees; training requirements, including those for persons with authorized access to confidential information; purging of personal identifiers; and data systems procedures.

2. A PRO would be required to place a public notice in a newspaper announcing the existence of its data system, the types of information acquired by the PRO, and the procedures by which each patient, practitioner, and institution may obtain information about themselves.

D. Disclosure of Nonconfidential Information

Diclosure of nonconfidential information would be required of PROs regardless of the source of the request. PROs may also disclose this information to anyone who they believe would be interested in the information.

E. Disclosure of Confidential Information

1. The proposal requires the disclosure of all information requested by the Department. The Department includes HCFA and other Departmental components that are responsible for assuring that funds for the PRO programs are expended in accordance with the law and regulations.

2. The April 16th document permits some disclosure of patient-identified information to a patient or his or her representative. If the patient's request is not made in connection with a denial decision, the proposed regulations require the PRO to allow the attending practitioner an opportunity to comment on the appropriateness of disclosing the information to the patient.

3. Under the proposed rule, disclosure of practitioner-identified information is permitted only to the individual practitioner, to the institution where the individual practices or, with the practitioner's consent, to any designated person, agency or organization.

4. PROs would be required to provide limited access to certain identifying information to Federal and State agencies, including fraud and abuse agencies and licensing and certification bodies and researchers, who have a significant need for information to carry out their recognized responsibilities or in order to avoid duplication in collecting and processing information. PRO information must be disclosed to public health agencies if the PRO determines the disclosure of the information is necessary to protect against and imminent danger to individuals or to the public health.

5. PRO deliberations must not be disclosed except to HCFA or the Office of the Inspector General (OIG). The reasons for PRO decisions may be disclosed.

6. The proposal would require disclosure of quality review studies with identifiers, but only on-site and only to: practitioners or institutions identified in the study; authorized personnel from the General Accounting Office; HCFA; accreditation, licensure, and certification bodies; Federal and State fraud and abuse agencies; and, under certain circumstances, a medical review board established under section 1881 of the Act which pertains to End Stage Renal Disease facilities.

7. PROs could disclose their interpretations of the quality of health care in a particular institution to the public.

8. PROs would be required to disclose sanction reports directly to the OIG, HCFA, and Federal and State fraud and abuse agencies.

9. In addition to PRO's authorization to disclose information at their discretion to carry out the purposes of the PRO statute, the proposal gives PROs discretion to disclose confidential information to research agencies and establishes criteria and guidelines for the PRO to use in exercising this discretion.

III. Public Comments

We received over 160 letters of comment in response to the proposed rule. Comments were received from hospitals, State and national medical associations, hospital councils, peer review organizations, members of Congress and other interested parties. The comments and our responses to those comments are set forth below:

A. General Provisions

1. *Definition of confidential information.*

Comment: One commenter stated that the definition of confidential information in § 476.101(b) of the proposed rule was inconsistent with the statute in the section 1160(b)(2) of the Act recognizes as confidential only statistical data that explicitly identify an individual. Therefore, data that implicitly identify an individual would be considered non-confidential.

Response: The PRO statute does not support such a distinction between explicit and implicit disclosure. We believe that permitting the disclosure of information that identifies an individual, even though not explicitly, would undermine the rationale of the statute. The statute does not preclude our prohibiting the disclosure of such information, and the intent of the statute is to limit the disclosure of information concerning identifiable individuals to specific situations, whether that identification is implicit or explicit.

2. *Distinction between confidential and non-confidential information.*

Comment: We received several comments regarding the distinction between confidential and non-confidential information. Some though that the regulations should adhere more closely to the statutory presumption that all PRO data should be held in confidence except under clearly defined circumstances.

Response: We are retaining the distinction between confidential and non-confidential information in order to permit the disclosure of information that does not identify an individual and to limit the release of patient- or practitioner-identified information to that required for PRO review or for other statutorily mandated reasons. Section 1160(a)(2) of the Act imposes on the Secretary the statutory obligation to identify in regulations the cases and circumstances under which PRO information may be disclosed.

3. *Notice requirements—15 days.*

Comment: Fifteen commenters believed that § 476.105 of the regulations should require PROs to give more than 15 calendar days notification to institutions before the disclosure of information about the institution that is not routinely prepared for PRO use.

Response: We agree and are changing the 15 calendar day notification requirement in § 476.105 to 30 calendar days. In addition, if the comments are received after the 30-day timeframe, the PRO is obligated to forward the comments to the recipient of the disclosed information.

We are revising § 476.105(a) to clarify that the PRO must notify an identified institution of the PRO's intention to disclose information, other than reports routinely submitted to HCFA (including Medicare fiscal agents) or reports submitted to or from PRO subcontractors or to or from an institution, about that institution.

4. *Exceptions to PRO notice requirements.*

Comment: Several commenters disagree with the exception to the notice requirements (§ 476.106) that PROs need not notify an institution of a disclosure if the disclosure is made in an investigation of fraud or abuse and the information is related to a potentially prosecutable offense. The commenters believe that practitioners and providers should be notified by the PRO when fraud or abuse is suspected in a potentially prosecutable offense.

Response: We understand the commenters concern; however, any such notification would serve only to impede the investigation of fraud or abuse. We believe this exception is required to protect the investigative process in pursuing cases involving fraud or abuse. We are modifying § 476.106 to require that all investigative agencies except the Office of the Inspector General and General Accounting Office (GAO), must specify in writing to the PRO that the information requested is related to a potentially prosecutable criminal offense.

5. *Limitations on redisclosure.*

Comment: One commenter requested that we clarify § 476.107, Limitations on redisclosure, to prevent the release of information that identifies individuals other than the individual who is releasing the information.

Response: This section permits a patient or practitioner to redisclose information about himself or herself and permits an institution to redisclose information about itself. We agree with the commenter that there is a potential in the section, as written, for information to be released that might identify other individuals. Therefore, we are modifying § 476.107(g) to state that information pertaining to a patient or practitioner may be redisclosed by those individuals provided it does not identify any other patient or practitioner.

Comment: One commenter requested that we modify § 476.107(h) to restrict redisclosure by an institution if the redisclosure would identify a practitioner.

Response: We believe this is a valid concern; therefore, we have modified § 476.107(h) to state that an institution may disclose information pertaining to itself provided the information does not identify an individual practitioner or patient.

Comment: Several commenters stated that the regulation does not adequately address the redisclosure of confidential information by public agencies.

Response: We believe we have sufficiently limited redisclosure by public agencies under § 476.107 (i) and (j) of the regulations. These paragraphs specify the instances when public agencies can redisclose information, such as in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency receiving the information. We also believe there is an overwhelming need to ensure that State and local public health officials are able to redisclose appropriate information where there is substantial risk to the public health. Therefore, we are permitting additional redisclosures by public health agencies in order to protect the interests of patients, practitioners and providers under section 1160(a)(2) of the Act. In addition,

we have modified paragraph (f) for clarification and are adding a paragraph (k) to permit redisclosure as necessary for the OIG and GAO to carry out their statutory responsibilities.

We do not believe any further changes are necessary to regulations. However, to be consistent with the statute we have deleted from § 476.107(i) the reference to Federal and State health planning agencies. Also, Federal and State health planning agencies do not receive confidential information under the PRO statute; therefore, they are not subject to the redisclosure limitations contained in § 476.107.

6. *Penalties for unauthorized disclosure.*

Comment: Several commenters believed that the penalties for unauthorized disclosure should be strengthened.

Response: Section 1160(c) of the statute provides for the penalties described in § 476.108 of the regulations; therefore, we are making no change to the regulations based on this comment. However, we are correcting a grammatical error in the second half of the sentence in § 476.108 to now read: ". . . be fined no more than $1000 *or* imprisoned for no more than 6 months, or both . . ." (emphasis added).

7. *Extent of an institution's right to privacy.*

Comment: Seventy-five commenters stated that because §§ 476.120(g) and 476.141 allow for disclosure of information that identifies a particular institution, there is a potential for misinterpretation and misuse of these data with no due process for institutions.

Response: Section 476.120(g) (redesignated as § 476.120(a)(7)) provides for disclosure of nonconfidential aggregate statistical information that does not identify individual patients, practitioners or reviewers and § 476.141 provides for the disclosure of PRO interpretations, and generalizations on the quality of care that identify a particular institution. We agree with the commenters and have made several changes to the regulations based on the ideas contained in those comments. The following changes will afford a provider the protection needed to avoid possible misinterpretation where the PRO releases data concerning that provider. We have specified that §§ 476.120(a)(7) and 476.141 are subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105 that require a PRO to notify an institution of its intent to disclose information about the institution that is not routinely prepared for PRO use, provide the institution with a copy of that information, and give the institution an opportunity to comment on the information. Further, as stated earlier in the comment on the 15-day notice requirement, we have amended that requirement to extend the time period for a provider to comment on disclosed information from 15 to 30 calendar days, thereby providing additional protection for hospitals.

We therefore believe that the final rule assures adequate protection of the rights and interests of institutions, because under these regulations the institution has the opportunity to provide explanatory statements regarding the data which the PRO is considering disclosing. For example, if the PRO's statistics relate to mortality, the hospital might include additional information such as case mix statistics, the severity of the illnesses treated, or the number and ages of its patients. If the PRO releases nosocomial infection rate data, the hospital could add information regarding special services susceptible to such infections, such as burn units. The PRO must attach these comments to the disclosed material. However, to alleviate some confusion, we have also revised the phrase "not routinely prepared for PRO use" to make reference instead to reports routinely submitted to HCFA (including Medicare fiscal agents) or reports submitted to or from PRO subcontractors or to or from an institution.

Comment: One commenter requested that we define the phrase "interpretations and generalizations on the quality of health care" as used in § 476.141.

Response: A PRO's "interpretations and generalizations on the quality of health care" means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO's review activities.

Comment: Thirty-nine commenters objected to the exclusion of information that identifies hospitals from the proposed definition of confidential information.

They believe that hospitals should be afforded the same protection as practitioners in terms of disclosure policies.

Response: Section 1160(a)(2) of the Act states that the Secretary shall provide by regulation for adequate protection of the interests of patients as well as for practitioners and providers. Public interest is served by providing access to certain PRO data by the public or by agencies that have public responsibilities to which PRO data are relevant. PROs deal with matters of great public concern—the provision and cost of health care.

They are, therefore, an important source of information to aid consumers and consumer organizations in reaching informed decisions about the types of health care services that are offered. Also, the policy of disclosure of provider-specific, but not practitioner-specific information is supported by recommendations in the congressionally mandated Institute of Medicine October 1981 study entitled "Access to Medical Review Data: Disclosure Policy For Professional Standards Review Organizations".

However, while we believe that disclosing provider information is appropriate and necessary to the public interest, we do not intend that such disclosure be misused. As stated in the previous comment, the regulations contain the requirement that the institution may submit comments on information to be disclosed and the PRO must attach these comments to the disclosed material. Also, the regulations contain the caveat that a PRO must not release nonconfidential information in instances where the identity of a patient, practitioner or reviewer; e.g., publishing the surgical mortality rates of a hospital that has only one surgeon, will be obvious to an individual with an understanding of the area.

B. PRO Access to Information

1. *Access to information from institutions and practitioners*

Comment: Section 476.111(b) of the proposed rule permits PROs to have access to and obtain information from records of non-Medicare patients, if access is authorized by the institution or practitioner. Fifty-two commenters believed that this section is ambiguous regarding PRO access to records of private-pay patients, and that the patient's consent should be required before a PRO is given access.

Response: We agree. We are adding a new § 476.111(b) to clarify that PROs may obtain specific non-Medicare patient records relating to review the PRO performs under non-Medicare contracts if authorized by those patients in accordance with State law. We are redesignating the proposed paragraph § 476.111(b) as paragraph (c) and modifying it to specify that PROs may have access to and obtain records of non-Medicare patients who are not covered under a private review contract held by the PRO only in connection with their quality review responsibilities and

only if authorized by the institution or practitioner.

Quality review is an integral and essential element of the PRO statute. Section 1154(a)(1)(B) of the Act specifies that any PRO must (in accordance with its contract with the Secretary) perform review to determine whether the quality of care provided to Medicare beneficiaries meets professionally recognized standards of health care. Furthermore, this PRO requirement represents the continuation of a peer review function mandated by Medicare statute over the past ten years. Also, in section 1154(a)(8), the Congress provides the same process for PROs as it had for earlier Medicare peer review for prescribing the way in which quality review would be performed by PROs, namely, regulations of the Secretary. The provisions of section 1154(a)(7)(D) and (a)(9) direst PROs, in a way similar to earlier peer review organizations, to inspect facilities and collect information necessary to carry out PRO review functions, including quality review. Section 1866(a)(1)(E) imposes a similar obligation on Medicare providers to release patient care data to PROs for review purposes including the conduct of Medicare quality review.

Taken together, these provisions give statutory authority to PROs to conduct quality review in the same manner as conducted by previous Medicare peer review organizations.

The quality review process consists of screening patient care information to identify and verify quality problems in addition to conducting quality review studies. A quality review study (QRS) is an assessment conducted by or for a PRO of a patient care problem for the purpose of improving the patient care of some of all providers or practitioners in the PRO area through peer analysis, intervention, and resolution of the problem and follow-up. Patient consent is not needed to access these records because unlike utilization review under private contracts, PRO quality review assesses the professional practice patterns of providers and practitioners.

While the identified problem must affect Medicare patients, it usually affects other patients as well, especially in the context of acute inpatient care. This is because quality problems relate to the way in which care is delivered (i.e., the behavior of a provider or practitioner). In some of these cases, a problem can be adequately addressed for Medicare patients only by addressing the problem for all patients in an acute care setting.

This means that in some quality review studies a PRO must review both Medicare and non-Medicare patient records in order to resolve the problem for Medicare patients. For example, a Medicare quality review study may seek to analyze and resolve a problem concerning the increase in the rate of post-operative infections in certain operations when prophylactic antibiotics were not used. However, for individual providers or specific practitioners, the frequency with which certain operations are performed on Medicare patients may be too low to draw reliable conclusions about the proper use of these antibiotics by that practitioner or in that provider on a timely basis (i.e., it may take a year of data collection for Medicare patients only). In contrast, the frequency with which these operations are performed on all patients may be adequate to permit timely and reliable assessment of the problem (i.e., within one to three months) and permit more rapid problem resolution for Medicare patients.

Also, physician and hospital-wide studies encourage general resolution of problems through the alteration of area practice patterns. This benefits both Medicare and non-Medicare patients and assures more substantive and longer lasting improvement in a problem than could have been achieved by focusing only on Medicare patients.

2. *Access to information of intermediaries and carriers.*

Comment: We received comments on various aspects of the provision set forth in § 476.112. Several commenters believed the regulation is vague as to what records and information (private or Medicare records) are available to the PRO. Several commenters requested that we add time periods for the transfer of information to the PRO. One commenter believed that the protection of confidential information transmitted by fiscal agents to PROs is not safeguarded through any clearly stated mechanism. Two commenters recommended patient consent before PROs could obtain access to patient records and information held by intermediaries or carriers. Regarding patient consent, one commenter believed that subsequent PRO disclosures of data could go beyond the intent of the individual who authorized the fiscal agent to obtain the data originally.

Response: We agree with commenters concerning the vagueness as to what records and information are available to the PRO under this provision. We are, therefore, modifying § 476.112 to specify that PROs can access only Medicare records or information held by intermediaries or carriers.

We do not believe it is necessary to specify in regulations time periods and safeguards for the transfer of information to the PRO because they will be covered in each PRO's agreement with a fiscal agent. The requirements for maintaining the confidentiality of information transferred to PROs are covered under § 476.115. Therefore, it is not necessary to add any additional safeguards in § 476.112.

Concerning the comments on patient consent, we do not believe it is necessary to obtain separate patient consent prior to accessing each record or piece of information, because patient consent is already given as a condition of payment under Medicare. For subsequent PRO disclosures that might go beyond the original intent of the authorizing individual, we believe the disclosure and redisclosure provisions contained in these regulations are sufficiently detailed and comprehensive to adequately protect the rights of individual patients. We are, therefore, making no changes to the regulations with regard to this issue.

3. *Access to information collected for PRO purposes.*

Comment: Several commenters believed that the provisions under § 476.113 requiring institutions to disclose to a PRO information collected for PRO purposes and information generated in quality review studies would allow a PRO access to internal hospital review and quality assurance decisions rather than only that information needed for a PRO's QRS.

Response: We agree that there is potential for PROs to have access to internal hospital review documents and do not believe it is proper to allow PROs such broad access to hospital records. Therefore, we are changing the definition of "quality review study" in § 476.101 to clarify that a QRS for purposes of these regulations means only a QRS conducted by or for a PRO. Thus, a PRO would not have access to a hospital's quality assurance information not collected for a PRO. We are also modifying this definition to conform to the definition of "quality review study" contained in § 466.1 of final regulations concerning a PRO's assumption of review published elsewhere in this issue of the **Federal Register.**

4. *Limitation on data collection.*

Comment: Two commenters thought that proposed § 476.114 should be expanded to include private patient data as well.

Response: The statutory bases for § 476.114, which are contained in sections 1154 (a)(7)(C) and (a)(9) of the Act, provide a PRO with access to information for the purposes of carrying

out its responsibilities under Title XI of the Act which, under circumstances described in § 476.111 may include non-Medicare patient information.

However, we are clarifying in § 476.114 that the reference to 44 U.S.C., Chapter 35 refers only to the PRO's collection of information as a Federal contractor.

C. PRO Responsibilities

1. *Requirements for maintaining confidentiality.*

Comment: The proposed § 476.115(d)(1) permits authorized access to confidential PRO information to an individual who "is undergoing or has completed a training program" in the proper handling of PRO information. We received two comments requesting that we delete the phrase "is undergoing".

Response: We agree with these commenters and are amending § 476.115(d) as requested. The training required to assure appropriate handling of confidential peer review data is generally accomplished within a short period. Therefore, it does not appear that requiring this training to be completed prior to permitting an individual to have access to this information would unduly burden a PRO.

Comment: One commenter suggested that training in the handling of confidential information should be a condition of PRO employment.

Response: We believe that the handling of confidential information is important. Therefore, § 476.115(c) requires that a PRO train participants of the PRO review system in the proper handling of confidential information, and § 476.115(d), as amended under these final regulations, does not permit an individual participating in the PRO review system on a routine or ongoing basis to have authorized access to confidential PRO information until that individual has completed a training program in the handling of PRO information. We believe that these provisions provide the necessary safeguards for the handling of confidential information without unduly restricting the PRO's abilities to hire staff.

Comment: One commenter believed that under § 476.115(e)(1) of the regulations PROs should be able to determine when it is appropriate to purge personal identifiers from PRO files rather than requiring them to wait for notification from HCFA.

Response: We do not believe that PROs should decide when identifiers are to be removed from confidential information because HCFA may require access to this information for longer periods than a PRO. Therefore, we are retaining this provision.

2. *Public notice of PRO information.*

Comment: Several commenters opposed the proposed requirements in § 476.116 concerning publication in the newspaper and notification to individual patients, practitioners, and institutions of the availability of PRO information because there is no statutory requirement for this notice and because they believe it could lead to PROs acting as clearinghouses for confidential information. Several commenters were also concerned about requiring notice to individuals and institutions under review, viewing this as cumbersome and resulting in unnecessary paperwork for the PRO.

Response: We agree with the commenters concerning publication of a newspaper notice and are amending § 476.116 of the regulations by deleting this requirement to avoid any possibility of inadvertently placing a clearinghouse function on a PRO. However, we are retaining the requirement that PROs notify patients, practitioners, and institutions under review concerning the type of information collected and its availability.

Although there is no specific statutory requirement for such notification, we believe these provisions are in keeping with recognized practices to assure that individuals are aware of information collected about them.

D. Disclosure of Confidential Information

1. To the Department.

Note.—A question was raised during the review of comments as to whether the requirement for disclosure to the Department under § 476.130 included the disclosure of patient records to Administrative Law Judges of the Social Security Administration. We wish to clarify that ALJs as part of the Department may request and obtain from the PROs these patient records.

Comment: Fifty-six commenters expressed concern that information or reports disclosed by the PRO to the Department would then be subject to redisclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552).

Response: We understand the commenter's concern. It is true that Federal agencies are subject to the provisions of the FOIA. However, the reports routinely submitted to HCFA do not identify patients or practitioners. Also, sensitive information such as quality review studies and PRO deliberations are accessible to the Department in very limited circumstances. Since the Department generally cannot request that this information be sent to it, this information cannot routinely be disclosed by the Department. Moreover, the FOIA protects personal privacy by exempting from compulsory disclosure information contained in "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy" (5 U.S.C. 552(b)(6)). Also, the Department's regulations protect individual privacy under 45 CFR 5.16 and 5.71. We have amended regulations located at § 476.130 to clarify that the Department's access to PRO information is limited by the disclosure provisions for PRO deliberations and quality review study information contained in §§ 476.139(a) and 476.140.

2. *Disclosure about patients.*

Comment: Several commenters requested that we modify the proposed § 476.132(b)(1) to apply the proposed 15-day physician notification period required when a request is not in connection with denial cases to denial cases as well.

Response: We do not believe this is necessary because the appeal and reconsideration process assures proper physician notice and opportunity to comment.

Comment: One commenter was concerned that, in determining whether released information would harm a mentally ill patient, the PRO should give more consideration to the medical opinion of psychiatrists.

Response: According to the proposed § 476.132(b)(2) [§ 476.132(a)(2) of these final regulations], the attending physician decides whether release of the requested information would harm the patient. If the attending physician feels that another specialist should be consulted, he or she may do so. For example, if a case involved a mentally-ill patient, the attending physician would be free to consult with a psychiatrist. However, the final decision to release the requested information will remain with the attending physician. We do not believe any change regarding this issue is warranted. However, we have changed the regulations to replace the term "physician" with "attending practitioner" in setting forth who can decide whether information would harm the patient.

Comment: The proposed rule in § 476.132 requires the PRO to provide patient information to the patient or to an individual designated by the PRO as the patient's representative if the patient is incompetent. One commenter wanted to know how "patient representative" is defined. Five others believe the PRO should rely on the hospital medical

record for determining who is responsible. One commenter questioned whether the PRO should decide who is competent. Finally, five commenters felt that the PRO has no authority for providing patients with their records.

Response: We are adding a definition of "patient representative" to the definition section of this subpart (§ 476.101(b)). "Patient representative" means an individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient, or an individual identified by the PRO in accordance with § 476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate. We are also modifying § 476.132(c)(3) to indicate that when a patient is unable to designate a representative, the PRO must first rely on the medical record to determine who is responsible. If the name of the responsible person is not recorded in the medical record, then the PRO may rely upon the attending practitioner for information. If the attending practitioner is unable to identify a responsible person, then the PRO must make a determination based on other reliable information. As to the determination of patient competency, we believe such a determination can be made by the PRO based on the documentation provided in the medical record. With regard to comments concerning patient records, the authority under which a PRO may provide patients with their records is inherent in its responsibilities under Title XI to provide patients with information relating to denial decisions and reconsiderations.

3. *Verification and amendment of PRO information.*

Comment: Several commenters wanted to know the types of information to be verified by the PRO for accuracy and also clarification of how the PRO will verify this information (§ 476.134). One commenter thought there was no recourse for the individual or institution if the PRO disagrees with a proposed amendment. Another commenter said that when the PRO disagrees with an amendment, the PRO should include the reasons given for the proposed amendment along with reasons for refusal.

Response: A description of the information to be verified and the methods by which PROs will verify its accuracy will be specified in the PRO contracts and in administrative guidelines. We do not believe it is appropriate to include these details in the regulations. We agree with the request that the reasons for the requested amendment be included along with the reasons for refusal. Section 476.134 of the regulations has been amended to require that a statement of the reasons for the request be included with the disclosed information as well as the reasons for refusal. We believe this will provide sufficient recourse for an individual or institution should a PRO disagree with a requested amendment.

4. *Disclosure necessary to perform review responsibilities.*

Comment: One commenter believed that HCFA should impose stringent restrictions concerning redisclosure of PRO information to subcontractors, consultants, and medical review boards.

Response: We believe that § 476.107, Limitations on redisclosure, assures adequate protection for the redisclosure of confidential information; therefore, we believe that no changes in the regulations are necessary.

5. *Disclosure to intermediaries and carriers.*

Comment: One commenter believed that there was no need for intermediaries and carriers to obtain copies of records from the PRO. The commenter believed that if they needed to review records, they should do so onsite at the PRO.

Response: We believe it is both necessary and appropriate for intermediaries and carriers to receive copies of records from PROs when they are making coverage determinations for payment of claims. However, we believe that the number of cases for which copies of records will be requested will be few.

6. *Optional disclosure of confidential information.*

Comment: Five commenters were concerned that the PRO may release confidential information without a request to do so, also indicating that section 1160(b) of the Act allows disclosure of information identified as necessary by fraud and abuse agencies, public health agencies, and licensing and certification agencies, but only upon request (with the exception of cases where there may be a substantial risk to the public health).

Response: While the statute states explicitly that disclosure by the PRO without request is allowed in cases involving substantial risk to the public health (section 1160(b)(1)(B)(ii)), section 1160(a)(2) of the Act authorizes the Secretary to issue regulations that permit additional disclosures to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care. We believe that PROs should be permitted to, and have an obligation to, disclose information to agencies without a request when the situation warrants. For example, whenever the PRO determines that a case may involve fraud or abuse, the case should be referred to fraud and abuse agencies to protect patients and Medicare funds.

Comment: One commenter stated that PROs may be liable for providing confidential information to fraud and abuse agencies, without a request, if, for example, the recipient agency determines that no illegal activities occurred (§ 476.137).

Response: It is our opinion that a PRO could not be held liable for such a disclosure so long as the disclosure is made in accordance with these regulations.

HCFA believes that regulations are not the proper vehicle for dealing with this type of litigation but that each suit must be dealt with on a case-by-case basis.

Comment: One commenter thought that disclosure to State governmental agencies should include disclosure to State agencies responsible for administering Title XIX (Medicaid) funds.

Response: Section 1160 of the Act does not address disclosure to State agencies administering Title XIX funds. However, HCFA will notify Medicaid State agencies concerning sanctions. Therefore, we are making no changes to this section of the regulations.

7. *Disclosure to the courts.*

Comment: Two commenters questioned whether proposed § 476.138(c) (now § 476.138(a)(3)) which states that patient records in the possession of a PRO are not subject to subpoena or discovery in a civil action conflicts with § 476.107(i) and (j) which permit certain redisclosures of confidential information.

Response: Section 1160(d) of the Act only provides protection from subpoena or discovery in a civil action for patient records in the possession of the PRO. Furthermore, section 1160(b) of the Act permits the redisclosure of such information by certain governmental agencies when the redisclosure is made in a judicial, administrative or other legal proceeding resulting from the agency's investigation. Therefore, no changes are being made to the regulations as a result of these comments.

Comment: One commenter recommended that "civil action" in the proposed §§ 476.138(c) (§476.138(a)(3) of these final regulations) and 476.140(d) be defined and that the definition include civil arbitration. The commenter requested this change because of a court decision which held that a State agency

chartered with responsibility for disciplinary sanctions could subpoena the confidential records of a medical review committee (a group exercising functions similar to those of PROs).

Response: We agree with the commenter. Congress precluded patient-identified records held by PROs from subpoena or discovery in civil actions. We, therefore, believe it would be within congressional intent to preclude patient-identified records from subpoena or discovery in a variety of civil actions, including administrative, judicial or arbitration proceedings.

We also believe that quality review study information with identifiers held by PROs should be protected in the same manner as other patient identified information because quality review study information is based on medical records and consists of patient identified information. Therefore, we are amending regulations at §§ 476.138(a)(3) and 476.140(d) (redesignated as (e)) to prohibit the disclosure of patient-identified records and quality review study information that identifies patients in a civil action, including an administrative, judicial or arbitration proceeding. These restrictions do not apply to the Department's administrative subpoena authority under the Social Security Act, the Inspector General's subpoena authority, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

8. *Disclosure of PRO deliberations and decisions.*

Comment: Two commenters stated that practitioners and providers should have access to PRO deliberations or at least to an indepth narrative of the deliberations, especially for sanctions. One commenter suggested adding that deliberations are not subject to subpoena or discovery in a civil action.

Response: In response to the first comment, the strict limitations on disclosure of PRO deliberations set forth at § 476.139 are necessary to encourage frank discussions among those involved. Also, a PRO may disclose the reasons for PRO decisions (see § 476.139(b)). In response to the second comment, there is no statutory basis for protecting PRO deliberations from subpoena or discovery in a civil action. Therefore, we are not changing the regulations.

Comment: One commenter questioned whether § 476.139 supersedes other sections of these regulations addressing disclosure of confidential information when the information involves PRO deliberations (§§ 476.132, 476.133, 476.137, and 476.138). Another stated that if the reasons for PRO decisions are disclosed, they should not identify practitioners or providers. Other commenters believed that the OIG and General Accounting Office (GAO) should have access to PRO deliberations other than just the deliberations included in sanction reports.

Response: With regard to the comment concerning PRO deliberations, § 476.139 is controlling over the disclosure requirements in other sections of the regulations. Each of the sections cited by the commenter have been amended to clarify this fact. Regarding the protection of practitioners and providers when the reasons for a PRO decision are disclosed, § 476.139(b) addresses this concern because it states that reasons for PRO decisions may be disclosed only if the opinions or judgments of a particular individual cannot be discerned. We are revising § 476.139(b) to clarify that opinions or judgments of a particular individual, patient, or practitioner cannot be discerned and are making a technical change to § 476.139(b) to revise the heading to "Reasons for PRO decisions", so that it more accurately describes the information contained in that paragraph.

Regarding the comment on OIG and GAO access to PRO deliberations, we agree and are changing § 476.139 to make clear that the OIG and GAO have access to PRO deliberations to carry out their statutory responsibilities. This change includes offsite access to provide for those very limited circumstances where offsite access would be essential to the carrying out of the Inspector General's responsibility to eliminate fraud, abuse and waste in HHS programs and the General Accounting Office's statutory responsibilities.

We have made several other changes to § 476.139 which are discussed more fully under section IV. Changes to the Regulations.

9. *Disclosure of quality review study information.*

Comment: A number of commenters were concerned that providers would have access to quality review studies containing identifiers of particular providers.

Response: We agree. As worded, § 476.140(b) would have permitted a PRO to disclose quality review study information to all institutions and practitioners involved in the study with all identifiers included. We are therefore amending this section to prevent disclosure of information identifying a particular institution or practitioner to other institutions or practitioners.

We are also making several technical changes to § 476.140 as specified in section IV., Changes to the Regulations.

Comment: Two commenters were concerned that there is no statutory basis for release of quality review studies to accreditation, licensure, and certification agencies.

Response: Section 1160(b)(1)(C) of the act requires the PROs, in accordance with procedures and safeguards established by the Secretary, to provide data and information which may identify specific providers and practitioners to these agencies.

10. *Practitioner-identified information.*

Comment: The proposed rule requested comments regarding the advisability of releasing practitioner-identified information.

Most commenters concur with our proposal for maintaining the confidentiality of practitioner-identified information. There is concern that the release of such data could be misinterpreted and misunderstood. Several other commenters concurred as well, but would also maintain the confidentiality of institution-identified information.

One commenter stated that our proposal to reveal practitioner-identified information was in violation of the statute and indicates the extent to which the proposed regulations favor public disclosure over the protection of individual privacy.

A number of commenters favor increased access to practitioner-identified information, believing that such information is necessary to assist employees and consumers in choosing physicians, to control costs, and to assist efforts aimed at increasing the quality of care.

Commenters also expressed concern that limiting the disclosure of practitioner-identified information may serve as a precedent for limiting disclosure of other information. One commenter would modify § 476.133(b) to allow a PRO, on its own initiative, to disclose to an institution, practitioner-identified information pertaining to a physician's practice or performance patterns in the institution.

There were also several comments on practitioner-identified information concerning § 476.130 (which calls for disclosure of information to the Department). Commenters stated that disclosure may hinder physician cooperation in the review process. One commenter indicated that blanket authorization for the PRO to release practitioner-identified information to the Department serves no purpose and should be limited to situations where a clear pattern of potential abuse is evident.

Response: While a number of commenters believe that general disclosure of practitioner-identified information is necessary to control health care costs and to assist consumers and others in health-related matters, we continue to believe that general disclosure is inappropriate. The potential is great for such information to be misinterpreted and misused. Public disclosure of PRO data about identified physicians could be misleading, perhaps with significant damage to reputations and practices. Releasing information that may damage the reputation of practitioners is particularly troublesome because even if the information is completely accurate, it may not fully describe all the factors relevant to a practitioner's practice. For example, mortality figures for coronary surgery may be higher for Surgeon A than for Surgeon B. However, this may be because Surgeon A is performing more complicated procedures or because Surgeon A's patients are on the average sicker than Surgeon B's patients. Furthermore, the general disclosure of practitioner-identified information could reduce the effectiveness of the peer review process under the PRO program. Also, as mentioned earlier, the Institute of Medicine report supported limitation on disclosure of practitioner-identified information. Therefore, as proposed, we would permit the disclosure of practitioner-identified information to the individual practitioner, to the institution where the individual practices, or, with the practitioner's consent, to any designated person, agency or organization. Practitioner-identified information may also be disclosed to recognized Federal and State agencies in certain situations (§§ 476.130, 476.137 and 476.138).

11. *Disclosure of sanction reports.*

Comment: One commenter said that the State Medicaid agency should be advised of any possible sanction in progress by a PRO against a Medicare provider because any abuse in Medicare could have possible implications for Medicaid.

Response: Because no decision has been reached concerning sanctions in progress, the information in the PRO's possession is subject to the same disclosure limitations as any other confidential information.

12. *Disclosure to research and statistical agencies.*

Comment: Twenty commenters objected to the proposed rule permitting PROs to disclose confidential information on its own initiative to research and statistical agencies, stating that there is no specific statutory basis for such action. Seven commenters believed that the PRO should have patient, and practitioner, and provider consent before releasing the information. Six said that because there is no protection from redisclosure after the information is released, patient practitioner identifiers should be deleted.

Response: The primary responsibility of a PRO is to review services provided under the Medicare program to assure that Medicare payment is made only for services that are medically necessary, delivered in the most appropriate setting, and meet professionally accepted standards of patient care quality. In order to accomplish this task, a PRO must perform preadmission review and review hospital admissions occuring within seven days of a previous discharge, every permanent cardiac pacemaker insertion, all transfers, a random sample of all Medicare admissions, day and cost outliers, and validate whether the diagnostic and procedural information reported by hospitals for DRG assignment is correct. PROs also have utilization and quality of care objectives that have to be met under the terms of their contract. The PROs, therefore, carry a heavy workload in order to fulfill their primary responsibilities.

A significant additional burden would be placed on PROs were they to routinely decide on which research or statistical agency requests for confidential information to honor.

Nevertheless, we did consider two approaches concerning PRO release of information to researchers and statisticians.

The first approach would be to require every PRO to release all PRO confidential information to a research agency upon request. The second approach would be to give the PRO the option of releasing confidential information. However, there are problems with both approaches; the mandatory method leaves the PRO with no control over the type of confidential information that may be released. The optional approach would result in inconsistent decisions among PROs as to what constitutes appropriate releases. This lack of uniformity would be unfair to patients, practitioners and researchers.

After careful consideration, we recognize that, while PRO confidential information may be helpful to some researchers, the preponderance of effects would have a significant adverse impact on PRO review. Therefore, we have decided to delete the proposed § 476.143 in its entirety.

We are redesignating proposed § 476.144 as § 476.143.

E. Cost of Duplicating Medical Records and Impact Analysis.

Comments: We received approximately 100 comments expressing concern over the costs of copying medical records requested by PROs under §§ 476.111(a) and 476.131 of the proposed regulations.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary including preadmission test records. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to the PRO.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of computation. Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of their being incurred and reported by hospitals for the years that represent the data bases for the prospective payment system.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs that in turn were reflected in Medicare cost reimbursement calculations. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any such increased costs. For example, in many cases, PROs' preadmission review activities will protect hospitals from retrospective denials. Thus, there will be trade-offs between a hospital's cost of providing medical records to PROs and a PRO's performance of review that, in many cases, may assist hospitals in avoiding unnecessary expenditures.

Comment: Five commenters stated that both a regulatory impact and a regulatory flexibility analysis were required in the NPRM, since the annual economic impact of these provisions meets the threshold criteria of Executive Order 12291 and the Regulatory Flexibility Act.

Response: We agree with the commenters that certain impacts (benefits, costs, and behavioral changes) will result from implementing this final

rule. However, we believe that our selection of policy alternatives in the implementation of the PRO program is responsive to Congressional intent and will result in net benefits to affected providers, practitioners, and beneficiaries.

Concerning their position that the annual economic impact will meet the threshold criteria of Executive Order 12291 or of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), we believe that the primary impact of this final rule will result from requiring hospitals to photocopy and send specific medical records under certain conditions (proposed §§ 476.111(a) and 476.131). In addition, as we remarked in our response to the previous comment, hospitals will experience benefits from PRO reviews, not just costs.

We estimate that in FY 1985 hospitals will incur about $9.8 million in additional operating expenses to photocopy records and mail them to PROs. This estimate assumes that PROs will perform retrospective offsite review on about 7 percent of the Medicare discharges in FY 1985. We estimate that the number of Medicare discharges, and thus the number of patient records to be reviewed offsite, will not increase significantly in FY 1986. Thus, the hospitals will incur no significant additional expenses above the FY 1985 estimated costs of $9.8 million. We estimate that these total costs will result in an average per hospital cost of less than $2,000 each year.

Because the photocopying provision, which is the provision that is most likely to have the greatest impact, does not meet any of the threshold requirements, we have determined that neither a regulatory impact or a regulatory flexibility analysis is required.

IV. Changes to the Regulations

Based on comments received and other considerations, we are making the following substantive changes to the proposed rules. We also have made technical changes to the proposed regulations in order to correct drafting and typographical errors and to clarify certain sections.

A. General Provisions

We are adding the definition of "Utilization and Quality Control Peer Review Organization (PRO)" to the definition section for 42 CFR Chapter IV located at § 400.200. We are adding this term because we make frequent references to it throughout 42 CFR Chapter IV.

In § 476.101(b) that includes the definitions for Part 476, we are making the following changes:

- We are modifying the definition of "abuse" to make it more consistent with the PRO sanction process.
- We are amending the definition of "confidential information". The phrase "Quality review study information which identifies patients" has been modified to read "Quality review studies which identify patients, practitioners or institutions".
- We are deleting the definition of "Medicare patient" because we believe that the term is self-explanatory.
- We are deleting the definition of "subcontracted institution" and adding a definition of "subcontractor" that is consistent with the definition contained in § 466.1 of the proposed regulations concerning a PRO's assumption of review that was published on July 17, 1984 (49 FR 29036).
- We are adding the definitions of "health care facility", "non-facility organization" and "patient representative".
- We are revising the definition of "practitioner" to conform to the definition contained in the proposed regulations concerning a PRO's assumption of review.
- We are adding language to the definition of "PRO deliberations" to further clarify its meaning.
- We are changing the definition of "quality review study" (QRS) to specify that a QRS for purposes of these regulations means only a QRS conducted by or for a PRO and to conform to the definition of QRS contained in § 466.1 of final regulations concerning a PRO's assumption of review published elsewhere in this issue of the **Federal Register.**
- We are adding definitions for "aggregate statistical data", "implicitly identify(ies)" and "PRO interpretations and generalizations on the quality of health care" to further clarify these terms.

These final rules amend the proposed regulations located at § 476.104 regarding the procedures for disclosure to clarify that the requirements for providing a notice of the disclosure specified in § 476.105 also apply. We are further revising § 476.104 to delete the requirement that information may not be redisclosed without written consent from the person or institution to which it pertains. This provision was not consistent with the proposed limits pertaining to redisclosure set forth in § 476.107.

In § 476.105 we are making the following changes:

- We are amending the notification requirement from 15 calendar days to 30 calendar days.
- We are clarifying the term "not routinely prepared for PRO use" contained in § 476.105(a).
- We are amending § 476.105(b)(2) to clarify that a PRO must notify a practitioner or institution of the PRO's intent to disclose information about that practitioner or institution except in cases involving fraud or abuse or an imminent danger to individuals or the public health. This revision is necessary to make § 476.105 conform to § 476.106.

These final rules amend proposed regulations located at § 476.106(b) to require that all investigative agencies, except the OIG and GAO, must specify in writing to the PRO that the information requested is related to a potentially prosecutable criminal offense.

We are amending regulations at § 476.107 by adding a paragraph (k) that would expand redisclosure as necessary for the Office of the Inspector General to carry out its statutory responsibilities. Paragraph (f) has also been amended to clarify that redisclosure is permissable as necessary for the GAO to carry out its statutory responsibilities. Regulations located at § 476.107 (g) and (h) are clarified to indicate that an institution, patient, or practitioner may disclose information pertaining to them provided that no other specific patient or practitioner is identified in that information. We are also amending § 476.107(i) to delete reference to Federal and State health planning agencies with respect to redisclosure of certain information.

We are amending regulations located at § 476.108 to correct a grammatical error with respect to the penalty for unauthorized disclosure of information.

B. PRO Access to Information

We are amending regulations located at § 476.111 to:

- Clarify that PROs may obtain specific non-Medicare patient records relating to review performed under non-Medicare contracts held by the PRO if authorized by those patients in accordance with State law; and
- Redesignate paragraph (b) as (c) and modify it to specify that a PRO may have access to and obtain records of non-Medicare patients who are not covered under a private review contract held by the PRO only in connection with its quality review responsibilities and only if authorized by the institution or practitioner.

The proposed regulations located at § 476.112 are amended to specify that PROs can only have access to Medicare records and information held by carriers or intermediaries.

We are clarifying in § 476.114 of the regulations that the requirements of 44 U.S.C. Chapter 35 only apply to a PRO's collection of information as a federal contractor.

C. PRO Responsibilities

Section § 476.115(d)(1) is amended to delete "is undergoing" from the reference to training programs. We further amended § 476.115 by revising paragraph (e) to clarify that patient records must also be purged of personal identifiers.

We are also amending regulations located at § 476.116 to delete the requirement for publication of notice in a newspaper of the availability of certain PRO information.

D. Disclosure of Nonconfidential Information

We are amending § 476.120 to clarify that the procedures for disclosure and notice of the disclosure specified in §§ 476.104 and 476.105 apply to the information subject to disclosure under § 476.120. We are also clarifying that the PRO must disclose certain aggregate statistical information to Federal or State health planning agencies.

E. Disclosure of Confidential Information

We are amending regulations at § 476.130 to specify that a PRO's disclosure of information to the Department is limited by §§ 476.139(a) and 476.140 of the regulations.

We are amending regulations located at § 476.132 to:

- Clarify that when patient identified information is disclosed to a specific patient or patient's representative, all other practitioner or patient identification must be removed;
- Clarify that the patient representative must be designated by the patient;
- Replace the term "physician" with "attending practitioner" in setting forth who can decide whether disclosure of information would harm the patient;
- Clarify that in the case of a disclosure request from a patient or the patient's representative regarding an initial denial determination, a PRO must release the information in accordance with the procedures for disclosure under § 473.28. The PRO is not required to notify the patient's practitioner of the request;
- Clarify that the regulations located at §§ 476.139(a) and 476.140 regarding the disclosure of PRO deliberations and quality review study information control over the disclosure provisions of § 476.132; and
- Establish the procedures by which a PRO determines who is responsible for a patient in cases in which the direct disclosure of information to a patient could harm the patient.

We are amending regulations located at § 476.133 to clarify that the disclosure of information about practitioners, reviewers and institutions under this section is also subject to requirements specified in other sections of these regulations. Additionally, we are specifying that the information disclosed by the PRO under this section concerning a particular practitioner or reviewer must not identify other individuals.

Regulations located at § 476.134 are amended to require that when a PRO disagrees with a request for amendment to PRO information, it must include with any disclosure of that information the reasons for the requested amendment as well as the reasons for refusal.

We are amending the regulations at §§ 476.136, 476.137 and 476.138 to specify that the provisions relating to the disclosure of PRO deliberations and quality review study information (§§ 476.139(a) and 476.140) control over the provisions for disclosure in §§ 476.136, 476.137 and 476.138.

We are further amending the regulations located at § 476.138 to clarify that, as provided in section 1160(b)(1)(C) of the Act, a PRO must disclose information to Federal and State agencies only to the extent required by the agency to carry out a function which is within the jurisdiction of the agency under Federal or State law. Also, we have revised the language at § 476.138(a)(3) (this was § 476.138(b) of the proposed regulations) referring to "imminent danger" to conform with section 1160(b)(1)(B) of the Act that refers to "a substantial risk to the public health".

We are amending regulations at §§ 476.138 and redesignating § 476.140(d) to (e) to preclude the use of a subpoena or other discovery methods in a variety of civil actions, including administrative, judicial or arbitration proceedings in order to obtain patient-identified records from a PRO. The restriction does not apply to the Department's administrative subpoena authority under the Social Security Act, the Inspector General's subpoena authority, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

We are amending regulations at § 476.139 to make several changes. First, § 476.139 is revised to insure that the opinions or judgments of a particular patient or practitioner cannot be identified. Second, we are amending § 476.139 of the regulations to specify that the OIG and GAO have access to PRO deliberations to carry out their statutory responsibilities including offsite access for those very limited circumstances where such access is essential. PRO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim. We believe this is necessary so as not to inhibit the frank and open discussions between peer reviewers when they are discussing a beneficiary's case. We have also clarified the regulations to specify that a PRO must disclose, if requested, in connection with the administrative hearing or review of a beneficiary's claim, the reasons for PRO decisions. The PRO must include the detailed facts, findings and conclusions that support the PRO's determination. The PRO must insure that the opinions or judgments of a particular individual or practitioner cannot be identified through the materials that are disclosed.

We are amending regulations at § 476.140(a)(1) to make the language consistent with that in § 476.107 (f), (i) and (j) regarding the responsibilities of various Federal, State and local agencies and to make it consistent with the changes made by the new paragraph (b) discussed below. We are also revising § 476.140 (a)(2) and (3) to limit further the onsite review of quality review studies. We are redesignating the proposed § 476.140 (b) to (c) and amending it to clarify that PROs may disclose certain quality review information offsite and to prevent the disclosure of quality review study information which identifies a particular institution or practitioner to other institutions or practitioners. Paragraphs (c) and (d) are redesignated as (d) and (e) respectively. In addition, a new paragraph (b) is being added to require PRO disclosure, both onsite and offsite, of quality review study information to the OIG and GAO as necessary to carry out their statutory responsibilities.

We are amending § 476.141 to clarify that the procedures for disclosure and notice of the disclosure specified in §§ 476.104 and 476.105 apply to the information disclosed under § 476.141.

We are amending regulations to delete § 476.143 in its entirety and to redesignate the proposed § 476.144 as § 476.143.

V. Impact Analysis

Executive Order (E.O.) 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual effect on

the economy of $100 million or more, cause a major increase in costs or prices, or meet other threshold criteria that are specified in section 1(b) of the Executive Order. In addition, the Regulatory Flexibility Act, Pub. L. 96–354, requires us to prepare and publish a regulatory flexibility analysis for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities. Under both the Executive Order and the Regulatory Flexibility Act, such analyses must, when prepared, show that the agency issuing the regulations has examined alternatives that might minimize an unnecessary burden or otherwise ensure that the regulations are cost-effective.

A. Executive Order 12291

In section III. E. of the preamble, we respond to 100 commenters concerning the potential cost of duplicating and sending patient records to a PRO. In that section we also address comments about the absence of an initial regulatory impact analyses in the proposed rule. We believe that our earlier determination that an E.O. 12291 impact analysis was not required was correct and that our responses in section III. E. fully address the questions raised by the commenters.

In response to other public comments, we have made changes to some of the provisions contained in the proposed rule. We believe that these changes will simplify and clarify our intended policies; and, that, taken as a whole, this rule will not result in an annual economic impact of $100 million annually, or that meets the threshold criteria of section 1(b) of the Executive Order. Thus, a final regulatory impact analysis is not required. It is our contention that these changes will, in fact, be beneficial to the PROs, providers, practitioners and beneficiaries by providing clarity in our policies and procedures that govern the acquisition, protection and disclosure of information obtained or generated by a PRO.

Regulatory Flexibility Act

As noted in the Executive Order discussion, we have responded to comments concerning the potential impact on providers resulting from these provisions. In Section III. E. we state most hospitals will incur some additional cost in duplicating patient records and information. However, for the reasons noted in that section of our response, we believe that the increase in cost resulting from these changes will not be significant, on average, for a substantial number of providers.

Also, for the purposes of this final rule, we have examined the changes noted in this preamble and conclude that the impact of these changes will also not be significant. These changes are primarily clarifications of our policies and procedures and, as such, will not result in additional costs and, in fact, should be beneficial to providers, practitioners, PROs and beneficiaries. Therefore, we have determined, and the Secretary certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), that this final rule, taken as a whole, will not result in a significant impact on a substantial number of small entities.

VI. Information Collection Requirements

Sections 476.105, 476.116, and 476.134 of this rule contain information collection requirements. They are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). The public is not required to comply with these requirements until OMB approves them under the Paperwork Reduction Act of 1980. Comments on these requirements should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, D.C., Attention: Fay Iudicello. A notice will be published in the **Federal Register** when approval is obtained.

List of Subjects

42 CFR Part 400

Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare.

42 CFR Part 476

Health care, Health professions, Health records, Privacy, Professional Standards Review Organizations (PSRO); and Utilization and Quality Control Peer Review Organizations (PROs).

42 CFR Chapter IV is amended as set forth below:

A. The table of contents is amended by revising the title of Part 476 in Subchapter D to read as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

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SUBCHAPTER D—PEER REVIEW ORGANIZATIONS

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PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

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PART 400—INTRODUCTION; DEFINITIONS

The authority citation for Part 400 reads as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

B. In Part 400, § 400.200 is amended by adding, in alphabetical order, the definition of "Utilization and Quality Control Peer Review Organization (PRO)" to read as follows:

§ 400.200 General definitions.

* * * * *

"Utilization and Quality Control Peer Review Organization" (PRO) means an organziation that has a contract with HCFA to review, under Part B of Title XI of the Act, the health care services or items furnished or proposed to be furnished to Medicare beneficiaries.

C. Part 476 is amended as set forth below:

1. The title of Part 476 is revised to read as follows:

PART 476—ACQUISITION, PROTECTION, AND DISCLOSURE OF PEER REVIEW INFORMATION

2. The table of contents is amended to reflect the establishment of a new Subpart A—"Professional Standards Review Organizations", to include current §§ 476.1–476.4. The table of contents is further amended by adding a new Subpart B and revising the authority citation to read as follows:

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

General Provisions

Sec.

476.101 Scope and definitions.
476.102 Statutory bases for acquisition and maintenance of information.
476.103 Statutory bases for disclosure of information.
476.104 Procedures for disclosure by a PRO.
476.105 Notice of disclosures made by a PRO.
476.106 Exceptions to PRO notice requirements.
476.107 Limitations on redisclosure.
476.108 Penalties for unauthorized disclosure.
476.109 Applicability of other statutes and regulations.

PRO Access to Information

476.111 PRO access to records and information of institutions and practitioners.

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476.112 PRO access to records and information of intermediaries and carriers.
476.113 PRO access to information collected for PRO purposes.
476.114 Limitations on data collection.

PRO Responsibilities

476.115 Requirements for maintaining confidentiality.
476.116 Notice to individuals and institutions under review.

Disclosure of Nonconfidential Information

476.120 Information subject to disclosure.
476.121 Optional disclosure of nonconfidential information.

Disclosure of Confidential Information

476.130 Disclosure to the Department.
476.131 Access to medical records for the monitoring of PROs.
476.132 Disclosure of information about patients.
476.133 Disclosure of information about practitioners, reviewers and institutions.
476.134 Verification and amendment of PRO information.
476.135 Disclosure necessary to perform review responsibilities.
476.136 Disclosure to intermediaries and carriers.
476.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare program.
476.138 Disclosure for other specified purposes.
476.139 Disclosure of PRO deliberations and decisions.
476.140 Disclosure of quality review study inforation.
476.141 Disclosure of PRO interpretations on the quality of health care.
476.142 Disclosure of sanction reports.
476.143 PRO involvement in shared health data systems.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302). Subpart A is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subpart B is also issued under secs. 1154(a), 1156(a) and 1160 of the Social Security Act, 42 U.S.C. 1320c-3(a), 1320c-5(a), and 1320c-9.

3. A new Subpart B is added to read as follows:

Subpart B—Utilization and Quality Control Peer Review Organizations (PROs)

General Provisions

§ 476.101 Scope and definitions.

(a) *Scope.* This subpart sets forth the policies and procedures governing—

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Peer Review Organization (PRO) (or the review component of a PRO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a PRO to comply with its responsibilities under the Act.

(b) *Definitions.* As used in this part:

"Abuse" means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

"Aggregate statistical data" means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

"Confidential information" means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) PRO deliberations.

"Health care facility" or "facility" means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

"Implicitly identify(ies)" means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.

"Non-facility organization" means a corporate entity that: (1) Is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the PRO area.

"Patient representative" means—(1) An individual designated by the patient, in writing, as authorized to request and receive PRO information that would otherwise be disclosable to that patient; or (2) and individual identified by the PRO in accordance with § 476.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

"Practitioner" means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

"PRO deliberations" means discussions or communications (within a PRO or between a PRO and a PRO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding PRO review responsibilities and appeals from PRO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

"PRO information" means any data or information collected, acquired or generated by a PRO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

"PRO interpretations and generalizations on the quality of health care" means an assessment of the quality of care furnished by an individual provider or group of providers based on the PRO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the PRO's review activities.

"PRO review system" means the PRO and those organizations and individuals who either assist the PRO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The PRO and its officers, members and employees;

(2) PRO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) PRO reviewers and supporting staff; and

(5) Data support organizations.

"Public information" means information which has been disclosed to the public.

"Quality review study" means an assessment, conducted by or for a PRO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

"Quality review study information" means all documentation related to the quality review study process.

"Reviewer" means review coordinator, physician, or other person authorized to perform PRO review functions.

"Sanction report" means a report filed pursuant to section 1156 of the Act and Part 474 of this chapter documenting the PROs determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

"Shared health data system" means an agency or other entity authorized by Federal or State law that is used by the PRO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

"Subcontractor" means a facility or a non-facility organization under contract

with a PRO to perform PRO review functions.

§ 476.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires PROs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires PROs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by PROs.

§ 476.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires PROs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other PROs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that PRO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical institution or other basis.

§ 476.104 Procedures for disclosure by a PRO.

(a) *Notice to accompany disclosure.* (1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 476.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 476.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under § 476.107 that limits redisclosure.

(b) *PRO interpretations.* A PRO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) *Fees.* A PRO may charge a fee to cover the cost of providing information authorized under this subpart. These fees may not exceed the amount necessary to recover the cost to the PRO for providing the information.

(d) *Format for disclosure of public information.* A PRO is required to disclose public information (§ 476.120(a)(6)) only in the form in which it is acquired by the PRO or in the form in which it is maintained for PRO use.

(e) *Medicare provider number.* A PRO must include the provider identification number assigned by Medicare program on information that HCFA requests.

§ 476.105 Notice of disclosures may be made by a PRO.

(a) *Notification of the disclosure of nonconfidential information.* Except as permitted under § 476.106, at least 30 calender days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to HCFA or Medicare fiscal intermediaries, or to or from PRO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the PRO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A PRO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and expections to the requirements for disclosure specified under § 476.132.

(2) A PRO must notify a practitioner or institution of the PRO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§ 476.137 and 476.138) except for cases specified in § 476.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the PRO discloses the identifying information. The PRO must forward with the information any commentsd submitted by the practitioner or institution in response to the PRO notice if received before disclosure, or forwarded separately if received after disclosure.

§ 476.106 Exceptions to PRO notice requirements.

(a) *Imminent danger to individuals or public health.* When the PRO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in § 476.105 may be sent simultaniously with the disclosure.

(b) *Fraud or Abuse.* The notification requirement in § 476.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

§ 476.107 Limitations on redisclosure.

Persons or organizations that obtain confidential PRO information must not further disclose the information to any other person or organization except—

(a) As directed by the PRO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by HCFA to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for HCFA to carry out its responsibilities for appeals under section 1155 of the Act or for HCFA to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the PRO from another source and the receiver of the information is authorized under its own authorities to acquire the

information directly from the source, the receiver may disclose the information in accordance with the source's redisclosure rules;

(f) As necessary for the General Accounting Office to carry out its statutory responsibilities;

(g) Information pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner;

(h) An institution may disclose information pertaining to itself provided it does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by HCFA may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry its statutory responsibilities.

§ 476.108 Penalties for unauthorized disclosure.

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than $1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

§ 476.109 Applicability of other statutes and regulations.

The provisions of 21 U.S.S. 1175 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR Part 2, are applicable to PRO information.

PRO Access to Information

§ 476.111 PRO access to records and information of institutions and practitioners.

(a) A PRO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the PRO area. The PRO may require the institution or practitioner to provide copies of such records or information to the PRO.

(b) A PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a PRO may have access to and obtain information from, the records of non-Medicare patients who are not covered under a private review contract held by a PRO if authorized by the institution or practitioner.

§ 476.112 PRO access to records and information of intermediaries and carriers.

A PRO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the PRO determines that the records or information are necessary to carry out PRO review responsibilities.

§ 476.113 PRO access to information collected for PRO purposes.

(a) Institutions and other entities must disclose to the PRO information collected by them for PRO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the PRO.

§ 476.114 Limitation on data collection.

A PRO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

PRO Responsibilities

§ 476.115 Requirements for maintaining confidentiality.

(a) *Responsibilities of PRO officers and employees.* The PRO must provide reasonable physical security measures to prevent unauthorized access to PRO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each PRO must instruct its officers and employees and health care institution employees participating in PRO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of PRO information.

(b) *Responsible individuals within the PRO.* The PRO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the PRO review system. That individual must notify HCFA of any violations of these regulations.

(c) *Training requirements.* The PRO must train participants of the PRO review system in the proper handling of confidential information.

(d) *Authorized access.* An individual participating in the PRO review system on a routine or ongoing basis must not have authorized access to confidential PRO information unless that individual—

(1) Has completed a training program in the handling of PRO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

(e) *Purging of personal identifiers.* (1) the PRO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by HCFA that those identifiers are no longer necessary.

(2) The PRO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the PRO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

(f) *Data system procedures.* The PRO must assure that organizations and consultants providing data services to the PRO have established procedures for maintaining the confidentiality of PRO information in accordance with requirements defined by the PRO and consistent with procedures established under this part.

§ 476.116 Notice to individuals and institutions under review.

The PRO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(a) The title and address of the person responsible for maintenance of PRO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of PRO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

Disclosure of Nonconfidential Information

§ 476.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure

specified in §§ 476.104 and 476.105, the PRO must disclose (a) Nonconfidential information to any person upon request, including—

(1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;

(2) Winning technical proposals for contracts from the Department, and winning technical proposals for subcontracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the PRO and institutions or between a PRO and the Medicare intermediary or Medicare carrier;

(4) Routine reports submitted by the PRO to HCFA to the extent that they do not contain confidential information.

(5) Summaries of the proceedings of PRO regular and other meetings of the governing body and general membership except for those portions of the summaries involving PRO deliberations, which are confidential information and subject to the provisions of § 476.139;

(6) Public information in its possession;

(7) Aggregate statiscal information that does not implicitly or explicity identify individual patients, practitioners or reviewers;

(8) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

§ 476.121 Optional disclosure of nonconfidential information.

A PRO may, on its own initiative, subject to the notification requirements in § 476.105, furnish the information available under § 476.120 to any person, agency, or organization.

Disclosure of Confidential Information

§ 476.130 Disclosure to the Department.

Except as limited by §§ 476.139(a) and 476.140 of this subpart, PROs must disclose all information requested by the Department to it in the manner and form required.

§ 476.131 Access to medical records for the monitoring of PROs.

HCFA or any person, organization or agency authorized by the Department or Federal statute to monitor a PRO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

§ 476.132 Disclosure of information about patients.

(a) *General requirements for disclosure.*

Except as specified in paragraph (b) of this section, a PRO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient's representative if—

(i) The patient or the patient's representative requests the information in writing;

(ii) The request by a patient's representative includes the designation, by the patient, of the representative; and

(iii) All other patients and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the PRO provides the requested information. If the attending practitioner states that the released information could harm the patient, the PRO must act in accordance with paragraph (c)(2) of this section. The PRO must make disclosure to the patient or patient's representative within 30 calendar days of receipt of the request.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the PRO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.28.

(2) A PRO must disclose information regarding PRO deliberation only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

(c) *Manner of disclosure.* (1) The PRO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the PRO must disclose the information to the patient's designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the PRO must disclose the information to a person whom the PRO determines is responsible for the patient.

The PRO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the PRO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the PRO must make a determination based on other reliable information.

§ 476.133 Disclosure of information about practitioners, reviewers and institutions.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) *Disclosure to the identified individual or institution.* A PRO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) *Disclosure to others.* (i) A PRO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) A PRO must disclose to Federal and State agencies that are responsbile for the investigation of fraud and abuse of the Medicare program and for licensing and certification, upon request, information that displays practice or performance patterns of a practitioner or institution, in accordance with the procedures for disclosure specified in §§ 476.137 and 476.138.

(iii) A PRO may disclose to any person, agency or organization, information on a particular practitioner or reviewer with the consent of that practitioner or reviewer provided that the information does not identify other individuals.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the PRO must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A PRO must disclose information regarding PRO deliberations only as specified in § 476.139(a).

(3) A PRO must disclose quality review study information only as specified in § 476.140.

§ 476.134 Verification and amendment of PRO information.

(a) A PRO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the PRO.

(b) If the PRO agrees with the request for amendment, the PRO must correct the information in its possession. If the information being amended has already been disclosed, the PRO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the PRO disagrees with the request for amendment, a notation of the request reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

§ 476.135 Disclosure necessary to perform review responsibilities.

(a) *Disclosure to conduct review.* The PRO must disclose or arrange for disclosure of information to individuals and institutions within the PRO review system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) *Disclosure to consultants and subcontractors.* The PRO must disclose to consultants or subcontractors the information they need to provide specified services to the PRO.

(c) *Disclosure to other PRO and medical review boards.* The PRO must disclose—

(1) To another PRO, information on patients and practitioners who are subject to review by the other PRO; and

(2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving or furnishing end stage renal disease services.

§ 476.136 Disclosure to intermediaries and carriers.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, a PRO must disclose to intermediaries and carriers PRO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services, furnished in the manner and form agreed to by the PRO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) PRO information about a particular patient or practitioner if the PRO and the intermediary or carrier (or HCFA if the PRO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) *Optional disclosure.* The PRO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

§ 476.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare program.

(a) *Required disclosure.* Except as specified in §§ 476.139(a) and 476.140 relating to disclosure of PRO deliberations and quality review study information, the PRO must disclose confidential information relevant to an investigation of fraud or abuse of the Medicare program, including PRO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare program that—

(1) Identifies the name and title of the individual initiating the request,

(2) Identifies the physician or institution about which information is requested, and

(3) States affirmatively that the institution or practitioer is currently under investigation for fraud or abuse of the Medicare program and that the information is needed in furtherance of that investigation.

(b) *Optional disclosure.* The PRO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare program, without a request.

§ 476.138 Disclosure for other specified purposes.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the PRO.

(1) *Disclosure to licensing and certification bodies.* (i) A PRO must disclose confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including PRO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the PRO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A PRO may provide the information specified in paragraph (a)(1)(i) of this section to the State or Federal licensing body without request.

(2) *Disclosure to State and local public health officials.* A PRO must disclose PRO information to State and local public health officials whenever the PRO determines that the disclosure of the information is necessary to protect against a substantial risk to the public health.

(3) *Disclosure to the courts.* Patient identified records in the possession of a PRO, are not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding.

(b) *Exceptions.* (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A PRO must disclose information regarding PRO deliberations and quality review study information only as specified in §§ 476.139(a) and 476.140.

§ 476.139 Disclosure of PRO deliberations and decisions.

(a) *PRO deliberations.* (1) A PRO must not disclose its deliberations except to—

(i) HCFA, at the PRO office or at a subcontracted organization;

(ii) HCFA, to the extent that the deliberations are incorporated in sanction and appeals reports; or

(iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) PRO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim.

(b) *Reasons for PRO decisions.* (1) A PRO may disclose to those who have access to PRO information under other provisions of this subpart, the reasons for PRO decisions pertaining to that information provided that the opinions or judgements of a particular individual or practitioner cannot be identified.

(2) A PRO must disclose, if requested in connection with the administrative hearing or review of a beneficiary's claim, the reasons for PRO decisions. The PRO must include the detailed facts, findings and conclusions supporting the PRO's determination. The PRO must insure that the opinions or judgements of a particular individual or practitioner cannot be identified through the materials that are disclosed.

§ 476.140 Disclosure of quality review study information.

(a) A PRO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; HCFA; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

(b) A PRO must disclose quality review study information with identifiers of patients, practitioners or institutions to the Office of the Inspector General and the General Accounting Office as necessary to carry out statutory responsibilities.

(c) A PRO may disclose information offsite from a particular quality review study to any institution or practitioner involved in that study, provided the disclosed information is limited to that institution or practitioner.

(d) An institution or group of practitioners may redisclose quality review study information, if the information is limited to health care services they provided.

(e) Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding. This restriction does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

§ 476.141 Disclosure of PRO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 476.104 and 476.105, a PRO may disclose to the public PRO interpretations and generalizations on the quality of health care that identify a particular institution.

§ 476.142 Disclosure of sanction reports.

(a) The PRO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to HCFA.

(b) The PRO must upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with § 476.137.

(c) HCFA will disclose sanction determinations in accordance with Part 474 of this chapter.

§ 476.143 PRO involvement in shared health data systems.

(a) *Information collected by a PRO.* Except as prohibited in paragraph (b) of this section, information collected by a PRO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) *PRO participation.* A PRO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the PRO from complying with the rules of this part.

(c) *Disclosure of PRO information obtained by a shared health data system.* PRO information must not be disclosed by the shared health data system unless—

(1) The source from which the PRO acquired the information consents to or requests disclosure; or

(2) The PRO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.

(Catalog of Federal Domestic Assistance Program Nos. 13.773 Medicare—Hospital Insurance; 13.774 Medicare—Supplementary Medical Insurance)

Dated: December 17, 1984.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: January 28, 1985.

Margaret M. Heckler,

Secretary.

[FR Doc. 85-9002 Filed 4-11-85; 2:43 pm]

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42 CFR Part 473

[HSQ-111-F]

Medicare Program; Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: These regulations implement that portion of the Peer Review Improvement Act of 1982 that provides for reconsiderations and appeals of Utilization and Quality Control Peer Review Organization (PRO) initial determinations. We are establishing procedures for a PRO to reconsider both its initial denial determinations regarding the medical necessity, reasonableness and appropriateness of health care services furnished or proposed to be furnished to a Medicare beneficiary in a health care institution and the application of the limitation of liability provision. We are also including in this final rule procedures for administrative appeals to the Department following a PRO reconsidered determination and judicial review following administrative appeals.

In addition, these regulations establish procedures for review of a PRO change in the diagnostic and procedural coding information that results in assignment of a discharge to a different diagnosis related group (DRG). This pertains to the review of claims for services furnished in hospitals reimbursed by Medicare under the prospective payment system.

EFFECTIVE DATE: May 17, 1985. Sections 473.18, 473.34 473.36 and 473.42 of this rule contain information collection requirements with which the public is not required to comply until the Executive Office of Management and Budget (EOMB) approves these requirements. (See section V. of this preamble for a discussion of information collection.)

FOR FURTHER INFORMATION CONTACT:
Mary Kay Terry, (301) 594–7910.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Pub. L. 97–248) amended Part B of Title XI of the Social Security Act (the Act) to establish the Utilization and Quality Control Peer Review Organization (PRO) program. This program, when fully implemented, will replace the existing Professional Standards Review Organization (PSRO) program. Initially, PROs have assumed responsibility for the review of hospital inpatient health care services for which payment may be made by Medicare. A PRO determines whether those services are reasonable and medically necessary, are of a quality that meets professionally recognized standards, and whether services and items provided on an inpatient basis could be effectively provided more economically on an outpatient basis or in a different type of inpatient facility.

Title VI of the Social Security Amendments of 1983, Pub. L. 98–21, added another review function. Under the new section 1886(d) of the Act, Medicare payment for hospital inpatient operating costs is based on a fixed amount, determined in advance for each case, according to a diagnosis-related code (DRG), which will be assigned to a case. Section 1866(a)(1)(F) of the Act requires PRO review of the validity of the diagnostic and procedural information supplied by the hospital and used by the intermediary to assign the DRG.

On July 17, 1984, we published a notice of proposed rulemaking (NPRM) (49 FR 29041) concerning reconsiderations and appeals of PRO determinations under section 1155 of the Act, which was added by the Peer Review Improvement of 1982. The proposal elicited 47 letters from the public. The provisions of the NPRM, the comments received and the changes in response to those comments, as well as additional changes made for clarity, are discussed below. Additional details of our proposal and the rationale for the proposed policies are contained in the preamble to the NPRM.

It should be noted that the provisions of this final rule may be revised later to bring them into conformance with planned amendments to the rules implementing section 1879 of the Act, which concerns the limitation on liability when Medicare claims are disallowed because the services or items were excluded from coverage as not medically reasonable and necessary or as custodial care. Proposed amendments are being developed and will be published for comment.

II. Provisions of the Proposed Rule

In the July 17, 1984 NPRM, we proposed that a party to an initial PRO determination who is dissatisfied with the determination is entitled to a PRO reconsideration of whether the services that were furnished (or proposed to be furnished)—

- Are medically necessary and reasonable, given the diagnosis and circumstances under which they were or would be furnished; and
- Were furnished in an appropriate setting.

If a PRO has determined that liability will not be waived under section 1879 of the Act for a noncovered furnished service, only the provider, practitioners or beneficiary who is liable would be entitled to a reconsideration of the determination. In addition, when it is established that the beneficiary (who is liable) is not pursuing his or her appeal rights, a provider or practitioner would be entitled to a reconsideration under section 1879 of the Act.

We proposed procedures and time limits for—

- Submitting reconsideration requests;
- Providing the parties with an opportunity to review all medical information upon which the initial determination was based and to submit additional information to be considered by the PRO in making its reconsidered determination; and
- Making the reconsidered determination and notifying the parties.

In addition, we proposed qualifications for organizations and individuals who perform the reconsideration of an initial determination so that the reconsideration would be fair.

We also proposed to use the current Part A procedures under 42 CFR Part 405, Subpart G for administrative appeals and judicial review. However, some modifications were made to reflect the fact that under section 1155 of the Act the amount in controversy necessary for a beneficiary to receive a hearing is $200 and $2,000 for a judicial review. However, these amounts do not apply to hearings under section 1879 of the Act, for which the amount in controversy is $100 for a hearing and (for Part A only) $1,000 for a judicial review. (There is no judicial review of determinations of Part B claims under section 1879 of the Act.)

III. Analysis and Response to Comments

We received 47 letters from individuals and organizations. These commenters included hospitals, associations representing hospitals, a State agency concerned with the elderly, an association representing the elderly, two legal advocates for the elderly, organizations representing physicians, an organization representing nurses, an organization representing medical colleges, professional standards review organizations (PSROs), an organization representing PSROs, and two Medicare fiscal intermediaries. The main issues in the letters that we received and our responses to them are discussed below.

A. HCFA Should Prepare Special Information for the Beneficiary That Explains Reconsideration and Appeals

Comment: Two commenters think that a beneficiary will have difficulty in understanding the reconsideration and appeals process. Therefore, the commenters urge HFCA to prepare a brochure that describes the reconsideration and appeals process for a beneficiary to receive at the time of a hospital admission.

Response: We believe that it is of utmost importance that beneficiaries be fully informed of the PRO review process, especially PRO determinations that affect payment. We agree that a beneficiary should receive a description of the reconsideration and appeals process, but believe that the best time for receipt of this information will be at the time of receipt of the initial denial notice. Therefore, under § 466.94 (contained in another final rule published in this issue of the **Federal Register**, Utilization and Quality Control Peer Review Organization (PRO): Assumption of Responsibilities and Medicare Review Functions and Coordination of Medicaid with Peer Review Organization (PRO Review)), we are requiring that a PRO include this information in the beneficiary's initial denial notice. The denial notice must include a statement informing each party or the party's representative—

(1) Of the right to reconsideration;

(2) When and how to request a reconsideration; and

(3) The locations for filing the request.

Information regarding hearings will be supplied with notices of reconsidered determinations.

Also, hospitals are not precluded from making this information available at the time of a beneficiary's admission.

B. PRO Review of Changes in Procedural or Diagnostic Information That Result in a DRG Change

Comment: One commenter requested clarification of the proposed § 473.18(d), which lets the PRO decide whether to review its changes to diagnostic and procedural coding supplied by the hospital that resulted in a DRG change based upon DRG validation.

Response: We agree that this was unclear and have modified proposed § 473.18(d) (now § 473.15). At the request of a provider or a practitioner, the PRO will review a DRG change resulting from a DRG validation that changed the diagnostic or procedural information and caused lower payment. This review by the PRO is under section 1866(a)(1)(F) of the Act, and that section does not provide for further review; that is, the review of the DRG coding change is final and is not subject to a further hearing.

C. Provide for Reconsideration and Appeal of Denial of Grace Days

Comment: Several commenters believe that denial of grace days should be appealable because they may affect the health care of beneficiaries if not enough time is allowed for post-discharge arrangements. In contrast, another commenter said that the final rule should state that the PRO decision regarding the number of grace days available to a beneficiary is not subject to a reconsideration.

Response: The granting of grace days is purely discretionary and not an initial denial determination that would be subject to a reconsideration. Section 1154(a)(2) of the Act specifies that PROs are to make initial determinations based upon review described at sections 1154(a)(1)(A) and 1154(a)(1)(C) of the Act. Initial determinations under section 1154 (a)(1)(A) of the Act involve the issue of whether the services were reasonable and medically necessary or constituted custodial care. Section 1154(a)(1)(C) of the Act involves the issue of whether services proposed to be furnished would be delivered in the most appropriate setting.

Under section 1154(a)(2) of the Act, these determinations are conclusive for Medicare payment purposes, with four exceptions. One of these exceptions is that a PRO may extend payment for not more than two days when it finds that post-discharge planning is necessary and that the provider did not know that payment for these days would not otherwise be made (section 1154(a)(2)(B) of the Act.) This PRO function is therefore different from the determinations based on sections 1154(a)(1)(A) and 1154(a)(1)(C) of the Act because, when a PRO allows "grace days" under section 1154(a)(2)(B) of the Act, it does not do so based on medical necessity, reasonableness, or appropriateness of the care in question. Further, section 1154(a)(2)(C) of the Act makes clear that only a determination under sections 1154(a)(1) (A) or (C) is subject to the hearing provisions in section 1155. Section 1154(a)(2)(C) of the Act applies to "such determination", clearly referring only to the determinations made under sections 1154(a)(1) (A) or (C) of the Act. The awarding of "grace days" under section 1154(a)(2)(B) of the Act is not a determination under section 1154(a)(1) (A) or (C). Section 1154(a)(2)(C) of the Act thus clearly contemplates that the awarding of "grace days" was not the type of PRO activity that was intended to be subject to the hearing and review provisions in section 1155 of the Act.

We agree that this final rule should state that the granting of grace days is not subject to reconsideration, and § 473.14(c)(1) contains this information.

D. No Reconsideration or Appeal Should be Allowed if There are no Direct Medicare Payment Issues in Dispute

1. *Comment:* One commenter wants our final rule to continue the current procedures that allow the *beneficiary* to pursue an appeal based on the coverage issues even if payment is made under the limitation of liability provisions in section 1879 of the Act because no supplemental insurance policy will pay the portion not covered by Medicare if the PRO has issued a denial involving medical necessity. Another commenter questions whether Congress intended, in providing in section 1155 of the Act for a reconsideration, that a *party* merely be "dissatisfied" with a PRO denial even if there are no payment consequences to that party.

Response: We agree with the first comment. We will continue to allow a beneficiary to obtain a reconsideration or hearing of a coverage issue in dispute even if we have paid for the denied service under the limitation of liability provisions of section 1879 of the Act.

With regard to the second comment, any party, including providers, practitioners, or beneficiaries who are dissatisfied with an initial denial determination, has access to a PRO reconsideration. However, section 1155 of the Act further provides for a hearing only for the beneficiary, and only when the reconsideration is adverse to the beneficiary. As noted above in the first comment, a determination of noncoverage on grounds that medical necessity was lacking may be adverse even if we make payment for the noncovered services under section 1879 of the Act. A determination of that kind may also preclude future payments under section 1879 of the Act for a similar service, since the beneficiary is on notice of the noncoverage.

2. *Comment:* In addition, some commenters believe that providers or practitioners should be given the right to a reconsideration even if they are not liable for payment under the limitation of liability provision.

Response: We agree with this comment. Section 473.16 governs reconsideration rights under the PRO program, not the limitation of liability provisions. Therefore, providers or practitioners may obtain a reconsideration on the issues of medical necessity, reasonableness of care, and appropriateness of the setting.

E. PRO Criteria

Comment: One commenter suggested that practitioners be allowed to appeal the PRO criteria and review process that the practitioner considers to be unreasonable and detrimental to patient care or which may affect the general public interest.

Response: We believe that PRO criteria should be developed with local peer participation to assure that they are reasonable or not detrimental. Section 1154(a)(6) of the Act requires that a PRO develop professionally deeveloped norms of care, diagnosis and treatment critiera (as defined in Part 466) based on local patterns of medical practice. Such criteria are developed by physician members of the PRO. We believe that this is the appropriate process for raising questions concerning PRO criteria. These criteria are used by a PRO for the purpose of screening cases for possible unnecessary, unreasonable or inappropriate care.

If any questionable case is identified using these criteria, a peer physician or surgeon associated with the PRO will contact or attempt to contact the physician to discuss the case further. A denial may be issued only after this discussion or attempt and only if the peer physician concludes that the proposed procedure is not reasonable or medically necessary, or could, with adequate safety, be provided on an outpatient basis.

F. Justification for Reconsideration Requests

Comment: Three PSROs recommend that a provider or practitioner be required to supply a detailed justification with each reconsideration

request to prevent a frivolous request that may result in unnecessarily burdening a PRO staff and causing excessive delay in completing other reconsiderations.

Response: Under section 1155 of the Act, a beneficiary, provider, or practitioner who is dissatisfied with a PRO determination is entitled to a reconsideration by the PRO that made the initial determination.

To afford a practitioner and a provider adequate opportunity for this statutorily required reconsideration, we believe that a provider or practitioner should be required only to submit the request for reconsideration timely and in writing. Any additional restrictions would be inconsistent with the intention of the statute. However, the PRO will reconsider its determination based on the record, which includes the same record on which the initial determination was based and additional information submitted along with a reconsideration request.

G. Where to File a Request for Reconsideration

Comment: Several commenters object to the proposed § 473.20(a)(2), which allows a beneficiary to file a request for a reconsideration with a PRO representative at a hospital. The commenters believe that, because these representatives will be present only a few days each month, the hospital will be burdened with the costs of handling the requests. Another commenter recommends that a provider and practitioner be allowed to use the same filing locations as a beneficiary.

Response: We agree that the proposed provision that allows a beneficiary to file a request for a reconsideration with a PRO representative at the hospital may place an unreasonable burden on the hospital. Therefore, we are revising that section (now § 473.18) and omitting that provision from the final rule. However, we are retaining the other locations available to a beneficiary for filing for a reconsideration.

With regard to the second comment, it is appropriate that beneficiaries, because of their relative lack of familiarity with the health care system as compared with practitioners and providers, be given the broadest opportunity to initiate a reconsideration; whereas practitioners and providers are thoroughly familiar with requesting reconsiderations and should have no problem in making a request to the PRO or its subcontractor who made the initial determination.

H. Time Period for Request of Review of Preadmission Denial

Comment: One commenter suggested that the proposed § 473.28(b) (now § 473.20) be revised to allow a party more than three days to request a reconsideration for a preadmission denial. This commenter believes that three days is not enough time to permit the provider, practitioner and beneficiary to file a request and prepare documentation that would be sufficient to support a reconsideration.

Response: This three day rule for requesting a reconsideration is to obtain expedited PRO reconsideration. It does not replace a party's right to request a reconsideration within the usual 60 day time period. We have clarified that the three day time period applies to receiving an expedited reconsideration. The short timeframe is necessary to avoid delay in obtaining proper hospital treatment if the initial denial determination is reversed and the admission is found to be necessary. Therefore, a late request for an expedited reconsideration will not be granted. If a party so wishes, it may take up to 60 days to request a reconsideration. However, we note that the filing date and reconsideration date are not necessarily the same. In most cases, we expect that the reconsideration will not be held until the third day after the request is received by the PRO. This time is available to a claimant to prepare and submit additional documentation.

I. Provider and Attending Practitioner Notification When Beneficiary Requests a Reconsideration

Comment: One commenter recommends that we require the PRO to notify the provider and attending practitioner whenever a beneficiary requests a reconsideration.

Response: We assume that the commenter recommended this notification to allow the provider the opportunity to represent the beneficiary. Because the provider cannot represent the beneficiary in a reconsideration, this additional notification would serve no purpose. (See response to comment U of this section: Provider representation of beneficiary). The provider and practitioner are notified of the reconsidered determination. Therefore, we will not make this requested change.

J. Proving That a Beneficiary Will Not Seek Reconsideration of an Initial Determination

1. *Comment:* Two commenters think that we should establish specific criteria to explain how the provider or practitioner can establish that a beneficiary who is liable is not going to pursue his or her right to a reconsideration of the initial determination. In addition, some commenters believe that a provider or practitioner should be given the right to a reconsideration even if it is not liable for payment due to the limitation of liability provision in section 1879 of the Act.

Response: These comments reflect some confusion. In § 473.18(a) of the NPRM (now § 473.16(a)), we clearly stated that a provider or practitioner has a right to reconsideration of a PRO determination as to reasonableness, medical necessity, and appropriateness. This is not dependent on whether the beneficiary also asks for reconsideration. Section 473.16(a) repeats this provision (although it has been redrafted for clarity). The commenters were probably reacting to § 473.18(c) of the NPRM, which described appeal rights not under section 1155 of the Act (the PRO statute), but rather under the limitation of liability provisions in section 1879(d) of the Act. That provision clearly states that a provider or practitioner may appeal a determination under section 1879 of the Act only after we determine that the beneficiary will not exercise his or her appeal rights. We cannot change this statutory limitation. However, to clarify the regulation, we are removing most of the references to section 1879 procedures from Subpart B of 42 CFR Part 473. Instead, in § 473.14(c), we refer the reader to the regulations containing the procedures for appealing Medicare determinations made by HCFA and its fiscal intermediaries and carriers, including thise under section 1879 of the Act.

K. PRO Release of Medical Records

Comment: Thirteen commenters recommended that the proposed § 473.32 (now § 473.24) be revised to prohibit the PRO from releasing to the beneficiary the material upon which the initial determination was based. They stated that it is inappropriate for the PRO to release the patient's medical record without the provider's consent.

Response: This final rule addresses PRO information used in reaching a decision and the need of individuals to verify that that information is correct.

However, we recognize that there must be safeguards to which PROs must adhere to assure that certain sensitive patient information will not be released. We plan to publish those rules in a future issue of the **Federal Register.** They will be located in Part 476 of this

chapter, which contains the Department's rules concerning Acquisition, Disclosure, and Protection of PRO information. Once information is in possession of a PRO, it belongs to that PRO and it would be inappropriate to require that a PRO obtain approval before releasing its own information to a beneficiary. We have clarified the proposed § 473.32 (now § 473.24(a)) and § 476.132(b)(1) to require a PRO to provide the beneficiary only with the information that was used to support the initial denial determination.

L. Identify PRO Reviewers and Make Public PRO Deliberations

Comment: Several commenters stated that PROs should furnish the identity of reviewers and the record of the initial determination deliberation to the parties to aid in their understanding and appeal of an adverse determination.

Response: As stated earlier, parties to a reconsideration should be given the information that formed the basis of the determination. The PRO will release information about the facts and reasons supporting its decision so that the parties will be fully informed about the determination. Also, we agree that the identity of a reviewer can be released if the reviewer agrees. However, we are prohibiting a PRO from releasing the record of the PRO deliberations because we believe that release of this information would inhibit frank and thorough discussion among the reviewers.

M. Charges for PRO Photocopying

Comment: Five commenters object to the requirement that a provider is not allowed to charge a PRO for photocopying of information that is submitted to a PRO for a reconsideration and is not reimbursed by HCFA for such costs.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary including preadmission test records. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to the PRO.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of computation. Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of their being incurred and reported by hospitals for the years that represent the data bases for the prospective payment system. These bases include all allowable administrative costs of a hospital, including many that are not specifically incurred for Medicare purposes.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs that in turn were reflected in Medicare cost reimbursement calculations. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any possible increased costs. For example, in many cases, PROs' preadmission review activities will protect hospitals from retrospective denials. Thus, there will be trade-offs between a hospital's cost of providing medical records to PROs and PRO's performance of review that may assist hospitals in avoiding unnecessary expenditures.

N. Incentive for PRO To Affirm Its Initial Determination

Comment: Two commenters feel that due process will be compromised because a PRO has a strong incentive to affirm the initial determination during the reconsideration process because the PRO contract has specified targets and because we would allow the individual who makes the initial determination to also reconsider that determination.

Response: PRO objectives are targets for reducing unnecessary or inappropriate care, not rigid quotas. While PROs have negotiated specific contract objectives, we recognize that there are circumstances under which the objectives may need to be modified. For example, quality objectives would be modified if data developed during the course of the contract demonstrate that the problem targeted is more severe than previously thought, or if the PRO identifies a different problem of greater importance. Utilization objectives would be modified for demographic shifts (for example, an influx of Medicare beneficiaries into the PRO service area), for the effects of new technology, etc.

We agree with the second part of the comment that the individual who makes the reconsidered determination should not be the individual who made the initial denial determination. Therefore, we have revised the proposed § 473.24 (now § 473.28), Qualifications of a reconsideration reviewer, accordingly.

O. Who Should Make the Reconsidered Determination

1. *Comment:* One commenter wants to know the circumstances in which we would allow a physician to reconsider an initial denial determination involving services provided by a dentist.

Response: We believe it is the intent of the statute that the most effective method of peer review is for doctors of medicine to review doctors of medicine, doctors of osteopathy to review doctors of osteopathy, and doctors of dentistry to review doctors of dentistry. We have, however, made an exception to this rule in § 466.98 (published in another final rule elsewhere in this issue of the Federal Register), in situations where a PRO determines that peer practitioners are not available to perform peer review effectively. For example, if there is a shortage of peers which hinders adequate and timely review, a doctor of medicine or doctor of osteopathy may make initial denial determinations involving services provided by a doctor of medicine, doctor of osteopathy, or doctor of dentistry.

2. *Comment:* Several commenters believe that we should require that the reconsideration reviewer be a specialist in the type of services under review. Furthermore, commenters believe that the individual who reviews the change in DRG coding should have experience and proficiency in ICD–9–CM coding and DRG assignment.

Response: We agree that a reconsideration reviewer should be a specialist in the type of services under review except where meeting this requirement would compromise the effectiveness or efficiency of PRO review. For example, if the only specialist available to reconsider a case is located at the opposite side of the state, we would not require that the specialist travel an excessive distance to hold the reconsideration or for the party to travel an excessive distance to reach the reconsideration reviewer.

We also agree that the individual who reviews changes in DRG coding must be qualified through training and experience to review ICD–9–CM coding. In addition, we are providing that the individual who reviews changes in DRG procedural or diagnostic information must be a physician. These provisions are located in the regulations at § 473.15.

Q. Scope of Information To Be Considered During Reconsideration

Comment: Three commenters believe that proposed § 473.34, Evidence to be considered by the reconsideration reviewer, is too restrictive and should

be revised to allow oral testimony by the parties, declarations from medical witnesses and submission of rebuttal evidence upon completion of the initial presentation to the reconsideration reviewer. In addition, one commenter suggests that if we decide to prohibit a reconsideration hearing, we should not limit the scope of written evidentiary materials that may be submitted, as long as they pertain to the issues under review.

Response: Nothing in the proposed § 473.34 (now § 473.30) restricts the types of additional evidence that may be submitted by a party. We believe that the use of "additional evidence submitted by a party" as contained in § 473.30 is very broad and permits the PRO to consider declarations from medical witnesses and submission of rebuttal evidence. However, the types of issus raised do not generally lend themselves to oral testimony; rather they lend themselves to a review of documentation. Should a PRO choose to accept oral testimony, we will spell out procedures the PRO must follow in accepting such testimony in the PRO administrative guidelines. We anticipate, however, that the need for oral evidence should be rare. Therefore, we are making no substantive changes to § 473.30 of this final rule.

R. Timely Completion of Reconsidered Determination

Comment: Eighteen commenters suggested that proposed § 473.42(b) (now § 473.32(b)) require that a reconsideration requested by a provider or practitioner be performed in a timely manner; that is, within 30 days of the receipt of the reconsideration request. The commenters are concerned that payment decisions for providers and practitioners may be deferred indefinitely.

Response: We agree, and § 473.32 provides that a PRO must complete its reconsideration and send written notice within 30 working days after receipt of a request for reconsideration from a provider or practitioner.

S. Issue Notice of Reconsidered Determination Within a Specific Time Period

Comment: Two commenters suggest that rather than requiring the PRO to provide "prompt" written notice of its reconsidered determination to the intermediary or carrier, as appropriate (proposed § 473.44(b)), we should require that this notice be issued within a specific time period.

Response: We agree; therefore, we are revising proposed § 473.44(b) (now § 473.34(b)) to require that the PRO provide written notification of its reconsidered determination to the intermediary or carrier, as appropriate, within 30 days of the determination. We are also requiring that the PRO make this notification of the reconsidered determination only if the initial denial determination is modified or reversed.

T. Access to Record of PRO Reconsidered Determination

Comment: One commenter thinks that the proposed rule does not adequately explain who has access to the record of a PRO reconsideration.

Response: As indicated in the proposed rule, section 1160 of the Act sets forth the statutory rules that govern access and disclosure of the record of a PRO reconsideration. As noted earlier, we plan to publish the final rule implementing that section, Acquisition, Protection, and Disclosure of Utilization and Quality Control Peer Review Organization (PRO) Information in a future issue of the **Federal Register**. The regulations will be placed in Part 476 of this chapter.

U. Provider Representation of Beneficiary

Comment: Ten commenters believe that providers should be allowed to represent beneficiaries in hearings regarding medical necessity issues.

Response: We are not accepting this suggestion. We believe that it would be inappropriate to permit a provider to represent a beneficiary in appealing claims under Medicare because, under section 1879 of the Act, liability for the Medicare claim may be assigned to the beneficiary, physician, or other attending practitioner that furnished the service. Therefore, allowing a provider to represent a beneficiary whose claim has been denied could result in a conflict of interest. As to PRO appeals, section 1155 of the Act was clearly designed to permit hearings only for beneficiaries and not for providers, physicians, and other practitioners. Allowing a provider to represent a beneficiary would permit an alternative avenue of provider appeal rights clearly not authorized under section 1155 or 1879 of the Act and not in accordance with Congressional intent. We have not addressed this issue in the regulations text, because we will continue current Medicare policy, as provided in section 3789C of the Part A Intermediary Manual (page 3–262.14, revision 1079). Extant Medicare policy is that a provider may not represent a beneficiary in appealing claims denied under Part A of Medicare.

V. Time Period for Beneficiary to Request a Hearing

Comment: Two commenters believe that there should be a time limit on how long the beneficiary has to decide not to request a hearing in order that a provider or practitioner be able to file timely, if the liability of the beneficiary is at issue.

Response: Under § 473.42(b) (proposed at § 473.28), the beneficiary has 60 days from receipt of the notice of the PRO reconsidered determination to request a hearing.

Providers and practitioners may protect their right to a administrative hearing under section 1879 of the Act by submitting their request during this same 60 day period.

W. Hearing Issues for a Provider and Practitioner

Comment: Twenty-three commenters stated that proposed § 473.50(c) should not limit a provider and practitioner to a hearing based only on the issues of knowledge under Medicare's limitation of liability provision. These commenters believe that providers and practitioners will be denied their right to due process of law because the provider and practitioner are entitled only to a reconsideration, and are prohibited from obtaining a hearing on medical necessity, reasonableness, and appropriateness of the setting in which services were furnished. Furthermore, the commenters state that since the implementation of a prospective payment system covering inpatient hospital services, limitation of liability and coverage issues are tied so closely together that the provider and practitioner should be able to obtain a hearing on both issues.

Response: This limitation is imposed by section 1155 of the Act, which states that where the reconsideration is adverse a hearing is available only to the beneficiary. However, section 1879 of the Act entitles a provider and practitioner to an adminstrative hearing of a determination that finds them financially liable for a furnished service, because they knew or should have known that the service would not be covered, but only if the beneficiary is not going to exercise his or her right of appeal.

Also, we believe that due process is quite adequately afforded a provider and practitioner by the rules published today. Under §466.93, opportunity to discuss proposed initial denial determination, the provider or practitioner is provided with an opportunity to discuss the proposed

initial denial determination with the PRO physician before it is issued, including the nature of the patient's need for health care services and all factors that preclude treatment of the patient as an outpatient or in an alternative level of inpatient care. Then, after the issuance of a denial, the provider or practitioner can again present its side of the argument in a reconsideration, including relevant information not previously made available to the PRO. These procedures for peer review and provider appeals were consistently applied in the PSRO program, which preceded the PRO program.

X. Time Period to Request a Hearing and Date of Request for a Hearing

Comment: One commenter thinks that—(1) The timing of the request for a hearing under proposed § 473.54(b) should run from the date the reconsidered determination notice was received; and (2) The date of the request for an administrative hearing should be the date postmarked on the request.

Reponse: We agree. We are changing § 473.42(b) to include these provisions. Also, we are revising proposed § 473.28 (now § 473.20) to be consistent with Medicare appeals procedures. The regulations now state that a request for a reconsideration or hearing must be filed within 60 days after the date of receipt of the notice of the initial denial determination or the reconsidered determination, respectively. Receipt is presumed to be five days after the date of the notice. Further, we are deleting proposed § 473.24(a)(7). Section 473.24(a)(7) referred to nonreceipt of notice as a good cause for late filing. The time limit for receipt only begins with the receipt of a notice; therefore, nonreceipt is a separate issue from good cause for late filing.

Regarding the second comment, a request for a reconsideration or a hearing will be considered timely if the postmark date of the request is within the period for timely filing. We have added this to §§ 473.20 and 473.42.

Y. Amount in Dispute Necessary for Obtaining a Hearing

Comment: Two commenters want to know why we require that $200 be in dispute to permit some hearings while only $100 need be in dispute to permit other hearings.

Response: Section 1155 of the Act requires that at least $200 must be in controversy for a beneficiary to obtain a hearing by an ALJ after a PRO reconsidered determination. However, limitation of liability determinations are made under section 1879 of the Act, not title XI. Section 1869(b) of the Act permits a beneficiary to seek a hearing by an ALJ of a reconsidered limitation of liability determination under Part A where the amount in controversy is $100 or more, and section 1879(d) of the Act gives a provider or practitioner the same appeal rights a beneficiary has to appeal a limitation of liability determination when the beneficiary does not exercise appeal rights.

Z. Reopening a Reconsidered Determination for Fraud or Similar Abusive Practice

Comment: One commenter is concerned that the proposed § 473.60 (now § 473.48) extends reopenings to include reconsiderations obtained through similar abusive practice that does not support a formal finding of fraud. This commenter is afraid that this gives the PRO wide discretionary authority to reopen a reconsidered determination at any time depending upon the PRO's subjective definition of similar abusive practice.

Response: Many practices that do not involve a fraudulent act nevertheless result in unnecessary and wasteful expenditure of Medicare funds. In order to increase efficiency of the Medicare program, we believe it is appropriate to permit reopenings at any time such practices are discovered.

IV. Changes to the NPRM

Based on the comments received and other considerations, we are making the following changes to the proposed rule. We have also made technical changes to the proposed regulations to correct drafting errors and to simplify and clarify certain sections:

A. Changes Based on Public Comments

- We have added a new § 473.14(c)(1) to state that the granting of grace days is not subject to reconsideration.
- We have changed proposed § 473.16(d) (now § 473.15) to require a PRO to review changes as a result of a DRG validation that caused an assignment of a different DRG, if the review is requested by a provider or practitioner.
- In § 473.15(a)(3), we require the individual who reviews changes in DRG procedural or diagnostic information to be a physician, and we require the individual who reviews changes in DRG coding to be qualified through training and experience with ICD–9–CM coding.
- We have changed proposed § 473.20 (now § 473.18) to prohibit a beneficiary from requesting a reconsideration from a PRO representative at the health care facility because this may place an unreasonable burden on the hospital.
- The proposed § 473.28 (now § 473.20) now explains that a beneficiary has three days in which to request an expedited reconsideration of a preadmission denial or the normal 60 day period to request a regular reconsideration of a preadmission denial.
- Also, under § 473.20, a request for a reconsideration must be filed within 60 days after receipt of the notice of the initial determination, and we presume receipt to occur five days after the date of the notice. In addition, a request for a reconsideration is considered filed on the day it is postmarked.
- Proposed § 473.24 (now § 473.28) has been revised to prohibit the individual who made the initial denial determination from also making the reconsidered determination.
- Under proposed § 473.32 (now § 473.24) the PRO has to provide the parties only with the information that was used to support the initial denial determination.
- Proposed § 473.42 (now § 473.32) has been revised to require a PRO to complete its reconsideration and send written notice within 30 working days after receipt of a request for reconsideration from a provider or practitioner.
- Proposed § 473.44 (now § 473.34) has been revised to require that the PRO provide written notification of its reconsidered determination to the intermediary or carrier, as appropriate, within 30 days of the determination, if the initial denial determination has been modified or reversed.
- Proposed § 473.54 (now § 473.42) restates Medicare policy that a request for a hearing must be filed within 60 days after receipt of the notice of the reconsidered determination and that we presume receipt to occur five days after the date of the notice. In addition a request for a hearing is considered filed on the day it is postmarked.

B. Technical Changes

- We have reorganized the regulations text. Many procedures have been rewritten for clarity and are in regulations sections that are different from the proposed sections.
- We now refer to initial determinations that may be appealed on the issues of reasonableness or medical necessity of the services or appropriateness of the inpatient setting as initial denial determinations. We now refer to a review of a DRG coding change rather than a reconsideration of a DRG coding change so that it will be clear that no additional appeal is available.

• We have removed most references to the limitation of liability determinations under section 1879 of the Act and have specified that the rules under 42 CFR Part 405, Subparts, G or H, for reconsiderations and appeals of limitation of liability determinations in the Medicare program are applicable instead of the procedures in this rule.

• In proposed § 473.60 (now § 473.44) Determining the amount in controversy, we now indicate that the dismissal of a request for an ALJ hearing occurs when the ALJ determines that the amount in controversy is less than $200. In the proposal, we did not clearly indicate when the dismissal occurs.

V. Impact Analysis

A. Executive Order 12291

We have determined that these final regulations are not likely to result in an annual economic effect of $100 million or more, or meet other threshold criteria of section 1(b) of the Executive Order. Executive Order 12291 requires that a regulatory impact analysis be performed on any major rule. A "major rule" is defined as one which will:

• Result in annual effect on the national economy of $100 million or more;

• Result in a major increase in costs or prices for consumers, any industries, any government agencies, or any geographic regions; or

• Have significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or import markets.

This final rule is one of several efforts to promote a more efficient peer review program. Specifically, we streamlined the PRO reconsideration process primarily by not prescribing the details of that process. Our experience has shown that due to our stringent review instructions, the PSRO reconsideration process has taken the form of an evidentiary hearing. This is a relatively costly process as it can involve various professionals and numerous staff hours to complete the reconsideration review. PROs now have the option of conducting the reconsideration through oral presentations and a review of documentation, or through a review of documentation only.

We believe that this final rule will allow for administrative ease through the deletion of the requirement for professional consultation at the administrative hearing level and by having PROs make all limitation of liability determinations associated with their initial denials. These changes will be less costly to the program, and may result in some negligible savings.

At this time, we can not estimate precisely the increase or decrease in the number of reconsiderations, administrative appeals and judicial reviews that will occur in fiscal year 1985. We do not believe that this final rule will either encourage or discourage appeals. Since we assume that there will not be a significant incremental change in the number of reconsiderations and appeals, we conclude that this final rule is not likely to result in an annual economic effect that will meet any of the threshold criteria of the Order.

B. Regulatory Flexibility Act

The Secretary certifies under 5 U.S.C. 605(b), enacted by the Regulatory Flexibility Act of 1980, Pub. L. 96–354, that these regulations will not have a significant economic impact on a substantial number of small entities. The reason for this certification is that although the regulations will reduce the costs of the peer review reconsideration and appeals process, we do not expect the reduction to be significant.

We do not believe that providers will be significantly affected by these regulations because the total number of peer review reconsidered determinations and appeals currently average less than one reconsideration or appeal per provider per year. As noted above, we do not expect a significant incremental change in the number of reconsiderations and appeals in future fiscal years. Therefore, providers will not incur significant additional costs because of these provisions.

C. Paperwork Reduction Act of 1980

Sections 473.18, 473.34, 473.36 and 473.42 of this final rule impose information collection requirements on the public. They are subject to review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504–3507). We are seeking OMB approval of these requirements under section 3507 of that Act. When we obtain OMB approval, we will publish a notice in the **Federal Register.** The public need not comply with those sections of the regulations until OMB approval is obtained. Comments on these requirements should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., Washington, D.C., Attn: Fay Iudicello.

VI. List of Subjects in 42 CFR Part 473

Administrative practice and procedure, Health care, Health professions, Professional standards review organizations (PSRO), Reconsiderations, Utilization and quality control, Peer review organizations (PRO).

42 CFR Part 473 is amended as set forth below:

A. The table of contents for Chapter IV, Subchapter D is amended by revising the title of Part 473 to read as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Part

* * * * *

Subchapter D—Peer Review Organizations

* * * * *

473 Reconsiderations and Appeals.

* * * * *

B. 42 CFR Part 473 is amended as follows:

1. The title of Part 473 is revised to read as follows:

PART 473—RECONSIDERATIONS AND APPEALS

2. The table of contents is amended to reflect the establishment of a new Subpart A to encompass §§ 473.1—473.6 and the addition of a new Subpart B; and to revise the authority citation to read as follows:

Subpart A—PSRO Reconsiderations and Appeals

Sec.

473.1 Applicability.
473.2 Right to reconsideration review and hearing.
473.3 Utilization of procedures under Title XVIII, Part A, hearing procedures.
473.4 Professional consultation.
473.5 Determining amount in controversy in case of proposed services.
473.6 Right of judicial review.

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

473.10 Scope.
473.12 Statutory basis.
473.14 Applicability.
473.15 PRO review of changes resulting from DRG validation.
473.16 Right to reconsideration.
473.18 Location for submitting requests for reconsideration.
473.20 Time limits for requesting reconsideration.
473.22 Good cause for late filing of a request for a reconsideration or hearing.
473.24 Opportunity for a party to obtain and submit information.
473.26 Delegation of the reconsideration function.
473.28 Qualifications of a reconsideration reviewer.

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart A is also issued under sec. 150 of Pub. L. 97–248, 42 U.S.C. 1320c note. Subpart B is also issued under sections 1154(a), 1155, 1866(a), 1871, and 1879 of the Social Security Act, 42 U.S.C. 1320c–3(a), 1320c–4, 1395cc(a), 1395hh, and 1395pp.

3. A new Subpart B is added to read as follows:

Subpart B—Utilization and Quality Control Peer Review Organization (PRO) Reconsiderations and Appeals

§ 473.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Peer Review Organization (PRO) or its subcontractor or initial determinations concerning services furnished or proposed to be furnished under Medicare;

(b) Hearings and judicial review of reconsidered determinations; and

(c) PRO review of a change in diagnostic and procedural coding information.

§ 473.12 Statutory basis.

(a) Under section 1155 of the Act—

(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with a PRO initial denial determination made under the provisions of section 1154 of the Act, that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting, is entitled to a reconsideration by the PRO that made the initial denial determination;

(2) A Medicare beneficiary is entitled to a hearing by an administrative law judge (ALJ) if $200 or more is still in controversy after a reconsidered determination; and

(3) A Medicare beneficiary is entitled to judicial review of a final determination of the Department if $2,000 or more is still in controversy.

(b) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the Medicare program must maintain an agreement with a PRO under which the PRO will review the validity of diagnostic information furnished by the hospital.

§ 473.14 Applicability.

(a) *Basic provision.* This subpart applies to reconsiderations and hearings of a PRO initial denial determination involving the following issues:

(1) Reasonableness of services.

(2) Medical necessity services.

(3) Appropriateness of the inpatient setting in which services were furnished or are proposed to be furnished.

(b) *Concurrent appeal.* A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) *Nonapplicability of rules to related determinations.* (1) A PRO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in Part 405, Subpart G of this chapter for determinations under Medicare Part A, and Part 405, Subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or HCFA mean initial and reconsidered determinations made by a PRO.

§ 473.15 PRO review of changes resulting from DRG validation.

(a) *General rules.* (1) A provider or practitioner dissatisfied with a change to the diagnostic or procedural coding information made by a PRO as a result of DRG validation under section 1866(a)(1)(F) of the Act is entitled to a review of that change if—

(i) The change caused an assignment of a different DRG; and

(ii) Resulted in a lower payment.

(2) A beneficiary may obtain a review of a PRO DRG coding change only if that change results in noncoverage of a furnished service.

(3) The individual who reviews changes in DRG procedural or diagnostic information must be a physician, and the individual who reviews changes in DRG coding must be qualified through training and experience with ICD–9–CM coding.

(b) *Procedures.* Procedures described in §§ 476.18–473–36, 473.38(b), and 473.48 (a) and (c) for a PRO reconsideration or reopening also apply to PRO review of a DRG coding change.

(c) *Finality of review.* No additional review or appeal for matters governed by paragraph (a) of this section is available.

§ 473.16 Right to reconsideration.

A beneficiary, provider or practitioner who is dissatisfied with a PRO initial denial determination on one of the issues specified in § 473.14(a) has a right to a reconsideration of that determination by the PRO that made the initial denial determination.

§ 473.18 Location for submitting requests for reconsideration.

(a) *Beneficiaries.* Except as povided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to obtain a reconsideration must submit a written request to one of the following:

(1) The PRO or the PRO subcontractor that made the initial determination.

(2) An SSA District Office.

(3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.

(b) *Others.* A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the PRO or PRO subcontractor that made the initial determination.

(c) *Expedited reconsideration.* A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the PRO.

§ 473.20 Time limits for requesting reconsideration.

(a) *Basic rules.* (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under § 473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of an initial determination.

(2) The date of receipt of the notice of the initial determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

(b) *Late filing of request.* A PRO will accept a request filed after 60 days after receipt of the notice of the initial determination if the PRO finds under the criteria set forth in § 473.22 that there was good cause for the party's failure to file a timely request.

(c) *Request for expedited reconsideration.* A request for an expedited reconsideration under

§ 473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§ 473.22 Good cause for late filing of a request for a reconsideration or hearing.

(a) *General Rule.* In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the PRO or ALJ, respectively, must consider the following:

(1) What circumstances kept the party from making the request on time.

(2) Whether an action by the PRO misled the party.

(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.

(b) *Examples.* Examples of circumstances in which good cause may exist include, but are not limited to, the following:

(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.

(2) There was a death or serious illness in a party's immediate family.

(3) Important records were accidentally destoryed or damaged by fire or other cause.

(4) A party made a diligent effort but could not find or obtain necessary relevent information within the appropriate time period.

(5) A party requested additional information to further explain the determination within the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for an Appeals Council hearing).

(6) The PRO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.

(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.

(8) Other unusual or unavoidable circumstances exist that—

(i) Show that a party could not have known of the need to file timely; or

(ii) Prevented a party from filing timely.

§ 473.24 Opportunity for a party to obtain and submit information.

(a) Subject to the rules concerning disclosure of PRO information in section 1160 of the Act, at the request of a provider, practitioner or beneficiary, the PRO must provide an opportunity for examination of the material upon which the initial denial determination was based. The PRO may not furnish a provider, practitioner or beneficiary with—

(1) A record of the PRO deliberation; or

(2) The identity of the PRO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.

(b) The PRO may require the requester to pay a reasonable fee for the reproduction of the material requested.

(c) The PRO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§ 473.26 Delegation of the reconsideration function.

A PRO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a PRO subcontractor.

§ 473.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

(a) Qualified under § 466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of PRO review.

§ 473.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on—

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§ 473.32 Time limits for issuance of the reconsidered determination.

(a) *Beneficiaries.* If a beneficiary files a timely request for reconsideration of an initial denial determination, the PRO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—

(1) Within three working days after the PRO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the PRO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the PRO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the PRO receives the request for reconsideration.

(3) Within 30 working days after the PRO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) *Providers or practitioners.* If the provider or practitioners files a request for reconsideration of an initial determination, the PRO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§ 473.34 Notice of a reconsidered determination.

(a) *Notice to parties.* A written notice of a PRO reconsidered determination must contain the following:

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

(3) A statement explaining the Medicare payment consequences of the reconsidered determination.

(4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.

(b) *Notice to payers.* (1) A PRO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 473.36 Record of reconsideration.

(a) *PRO requirements.* A PRO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the

notice of the PRO's reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) *Contents of the record.* The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) *Confidentiality.* The record of a PRO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 473.38 Finality of a reconsidered determination.

A PRO reconsidered determination is final and binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with § 473.40 and a final rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with § 473.48

§ 473.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a PRO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) *Subject matter.* A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services;

(3) Appropriateness of the setting in which the services were furnished.

(c) *Governing provisions.* The provisions of Subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of Part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in that Subpart G to initial and reconsidered determinations made by an intermediary, carrier, or HCFA should be read to mean initial and reconsidered determinations made by a PRO.

§ 473.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 473.40 must submit a written request to one of the following:

(1) The office of the PRO or PRO subcontractor that made the initial determination.

(2) A SSA District Office.

(3) An office of the Office of Hearings and Appeals of SSA.

(4) An office of the Railroad Retirement Board, in the case of a beneficiary who is a railroad retiree.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 days of receipt of the notice of the PRO reconsidered determination, unless the time is extended for good cause as provided in § 473.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

§ 473.44 Determining the amount in controversy for a hearing.

(a) After a party has submitted a request for a hearing, the ALJ determines the amount in controversy in accordance with § 405.740 of this chapter.

(b) If the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, notifies the parties to the hearing that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties to the hearing and the PRO that the PRO reconsidered determination is conclusive for Medicare payment purposes.

§ 473.46 Appeals Council and judicial review.

(a) The circumstances under which the Appeals Council of the Social Security Administration will review an ALJ hearing decision or dismissal are specified in 20 CFR 404.970. Cases the Appeals Council will review.

(b) If $2,000 or more is in controversy, a party may obtain judicial review of an Appeals Council decision, or an ALJ hearing decision if a request for review by the Appeals Council was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Appeals Council decision or denial.

§ 473.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) *PRO reopenings—(1) General rule.* A PRO or PRO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in § 473.15, that is otherwise final, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) *Extension of time limit.* A PRO or PRO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in § 473.15, that is otherwise final, after one year but within four years of the date of the determination or review if—

(i) The PRO receives new material evidence;

(ii) The PRO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

(b) *ALJ and Appeals Council Reopening—Applicable procedures.* The ALJ or the Appeals Council, whichever made the final decision, may reopen and revise the decision in accordance with the procedures set forth in § 405.750(b) of this chapter, which concerns reopenings and revisions under Subpart G of Part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Appeals Council may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare—Hospital Insurance; No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: December 6, 1984.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: January 28, 1985.

Margaret M. Heckler,

Secretary.

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