

# **federal register**

**MONDAY, JANUARY 24, 1977**

**PART II**



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**DEPARTMENT OF  
HEALTH,  
EDUCATION, AND  
WELFARE**

**Public Health Service**



**PROFESSIONAL  
STANDARDS REVIEW  
ORGANIZATIONS**

**DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFARE**

Public Health Service

[ 42 CFR Part 101 ]

**CONDITIONAL PROFESSIONAL  
STANDARDS REVIEW ORGANIZATIONS**

**Assumption of Review Responsibility**

Notice is hereby given that the Assistant Secretary for Health of the Department of Health, Education, and Welfare, with the approval of the Secretary of Health, Education, and Welfare, proposes to add a new Subpart D to Part 101 of Title 42, Code of Federal Regulations.

Sections 1152(a) and 1154 of the Social Security Act authorize the Secretary to designate qualified organizations as Professional Standards Review Organizations (PSROs) for a conditional period not to exceed two years. Section 1154(b) of the Act authorizes the Secretary to require a conditional PSRO to perform such duties and functions during the conditional period of that PSRO, as he determines the organization is capable of performing. The purpose of the proposed Subpart D is to implement section 1154(b) of the Act by requiring all conditional PSROs to assume review responsibility on a gradually increasing basis during the conditional period. Such review responsibility will include the authority to make review determinations which, with respect to the provision of health care services subject to PSRO review, will be conditions for the payment or denial of claims under Medicare and Medicaid, as specified in new Subpart E of Part 101. However, pursuant to section 1158(a) of the Act, PSRO determinations will be advisory for the purposes of payment for Title V Maternal and Child Health and Crippled Children's programs funds.

Conditional PSROs will assume review responsibility only with regard to the issues of medical necessity, quality and level of care which are specified in clauses (A), (B) and (C) of section 1155(a) (1) of the Act and only in those health care institutions where they have assumed review responsibility in accord with a timetable for phasing-in review responsibility which will be approved by the Secretary. These regulations will apply to assumption of PSRO review in all such health care institutions. Each PSRO's formal plan and the comments of Medicare and Medicaid fiscal agents, as well as other relevant factors concerning the PSRO, will be evaluated by the Secretary to determine if the PSRO is capable of performing these functions prior to approving its assumption of such responsibilities.

The Secretary's decision to have conditional PSROs assume review responsibility is consistent with section 1154(b) of the Act and with the legislative history of the PSRO statute which states: Medicare and Medicaid claims paying agencies would be expected to abide by final decisions of the PSRO during this trial period. Placing reliance on the PSRO deci-

sion during the trial period is necessary to permit accurate appraisal of the effectiveness with which the conditionally approved PSRO could be expected to exercise the review function in the absence of concurrent review by others (Sen. Rpt. 92-1230, 92 Cong., 2d Sess., p. 261 (1972))

Sections 101.402 and 101.406 of the proposed Subpart D provide for a determination of capability by the Secretary at the time of conditional designation, approval of the PSRO's phase-in timetable, and certain notification requirements designed to inform health care institutions, appropriate administrative agencies and the public of the schedule for assumption of review responsibility by PSROs. The PSRO is to develop administrative procedures under section 101.405 necessary for coordinating PSRO activities with those of Medicaid and Title V State agencies, Medicare fiscal agents and health care institutions. Such administrative procedures may be incorporated in memoranda of understanding or agreements, at the option of the fiscal agents and institutions, within the time period specified in § 101.405. However, in the case of review functions which are to be delegated to health care institutions pursuant to section 1155(e) of the Social Security Act, the institution is required to enter into an agreement with the PSRO regarding the delegated review functions and procedures before the institution may begin review under the authority of the PSRO. If no agreement is reached in this case, the PSRO is required to begin review in accordance with applicable regulations of this Part. Regulations which set forth in detail the delegation of review process will be issued in proposed form in the near future.

The proposed regulations also provide for monitoring of PSRO activities (§ 101.409), and for reevaluation of the PSRO's capability to exercise review responsibility (§ 101.410). Medicare intermediaries will be routinely assisting the Secretary, at the request of the Secretary, by monitoring PSRO review and through the performance of other related functions. However, because of the strong financial interest which the States have in assuring that an effective review system exists because of the expenditure of State funds under Title XIX of the Social Security Act, provision is made under § 101.409 for a temporary suspension of PSRO authority by the Secretary, pending a full reevaluation of PSRO capability, where the State provides reasonable documentation that PSRO determinations, and not other factors, have had a detrimental impact either on State Medicaid expenditures or on the quality of care received by Medicaid patients. If such a temporary suspension of PSRO authority is in effect, the PSRO's determinations will be only advisory to Medicaid State agencies and Medicare fiscal agents for purposes of claims payment. However, in order to prevent the need for reestablishing utilization review committees, which would be an unnecessary and costly duplication of review during a period of only temporary suspension of PSRO authority, the provisions of Title

XIX and Title XVIII relating to utilization review and control, physician certifications, and State agency surveys and certifications, will be deemed to be satisfied by such advisory review by the PSRO during the period of suspension.

Interested persons are invited to submit written comments, suggestions or objections concerning Subpart D to the Director, Bureau of Quality Assurance, Health Services Administration, Room 16A-55, 5600 Fishers Lane, Rockville, Maryland 20852, on or before March 25, 1977. All comments received in timely response to this Notice will be considered and will be available for public inspection in the above-named office during regular business hours.

It is proposed to make Subpart D effective upon republication in the FEDERAL REGISTER.

The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: November 18, 1976.

THEODORE COOPER,  
Assistant Secretary for Health.

Approved: January 11, 1977.

MARJORIE LYNCH,  
Acting Secretary.

**Subpart D—Assumption of Review Responsibility  
by Conditional PSROs**

Sec.	Definitions.
101.401	Definitions.
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101.410	Reevaluation of capability.

**AUTHORITY:** Secs. 1152(a), 1154(b), 1155(a) (1), (2), 1164, 1165, Social Security Act, 86 Stat. 1430, 1432, 1433, 1442, 1443, (42 U.S.C. 1430c-1(a), 3(b), 4(a) (1), (2), 13, and 14); sec. 1102 of the Social Security Act, 49 Stat. 647 as amended (42 U.S.C. 1302)

**Subpart D—Assumption of Review  
Responsibility by Conditional PSROs**

**§ 101.401 Definitions.**

As used in this subpart: (a) "Act" means the Social Security Act, as amended (42 U.S.C. Chapter 7).

(b) "Conditional PSRO" means a Professional Standards Review Organization designated on a conditional basis pursuant to sections 1152(a) and 1154 of the Act.

(c) "Formal plan" means the plan submitted to the Secretary prior to designation of a conditional PSRO, detailing the tasks necessary for the orderly assumption and implementation of the responsibilities of such conditional PSRO, including a phase-in timetable.

(d) "Review responsibility" means (1) the responsibility of a PSRO to perform

duties and functions prescribed under Title XI, Part B of the Act and the regulations of this part in accord with the phase-in timetable approved by the Secretary and (2) the authority of a PSRO to make determinations in specified health care institutions under sections 1155(a) (1) and (2) of the Act which, with respect to issues arising under sections 1155(a) (1) and (2) of the Act, are conclusive under the Act, pursuant to section 1158 of the Act and Subpart E of this Part.

(e) "Health care institution" 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 the Act.

(f) "Medicaid State agency" means an agency which is established or designated under section 1902(a)(5) of the Act to administer a State plan to provide medical assistance under Title XIX of the Act.

(g) "Medicare fiscal agents" means intermediaries which are parties to agreements entered into by the Secretary pursuant to section 1816 of the Act and carriers which are parties to contracts entered into by the Secretary pursuant to section 1842 of the Act.

(h) "Phase-in timetable" means a schedule, contained in the PSRO's formal plan and updated as necessary, specifying the estimated times when a conditional PSRO will assume review responsibilities in particular health care institutions, whether such review is to be performed by the conditional PSRO or by a health care institution under delegation from the PSRO pursuant to section 1155(e) of the Act.

(i) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.

(j) "State survey agency" means an agency performing provider surveys under section 1864(a) of the Act.

(k) "Title V State agency" means an agency which is established or designated pursuant to section 505(a)(2) of the Act to administer the State plan under Title V of the Act.

#### § 101.402 Evaluation of capability.

At that time that the Secretary reviews each formal plan to determine whether to designate an organization as a conditional PSRO, the Secretary will evaluate the capability of such organization to exercise review responsibility. Such evaluation will be based upon the following criteria:

(a) The formal plan submitted by the organization to the Secretary;

(b) Comments and recommendations submitted by the appropriate Medicaid and Title V State agencies and Medicare fiscal agents pursuant to the request of the Secretary which will be made at the time he receives a formal plan for conditional designation; and

(c) Other relevant factors, as determined by the Secretary.

#### § 101.403 Notification of designation and capability.

Notification to an organization of the determination of the Secretary as to whether it is designated as a conditional PSRO will be made in writing and will include notification of the Secretary's determination of its capability to exercise review responsibility pursuant to its approved formal plan.

#### § 101.404 Assumption of review responsibility according to timetable.

A conditional PSRO which has been found by the Secretary to be capable of exercising review responsibility and has been so notified pursuant to § 101.403, shall assume review responsibility in particular health care institutions in accordance with such notification (whether review is to be performed by the PSRO or under delegation from the PSRO by a review committee pursuant to section 1155(e)), in accordance with its approved phase-in timetable and the requirements of this subpart.

#### § 101.405 Establishment of administrative procedures.

(a) *Procedures for State Medicaid and Title V State agencies and Medicare fiscal agents*—(1) *Development*. Each conditional PSRO, at least 90 days prior to the earliest date in the conditional PSRO's phase-in timetable for assumption of review functions in any health care institution, shall (i) develop proposed administrative procedures for correlation of PSRO activities with those of Medicaid and Title V State agencies and Medicare fiscal agents, and (ii) provide copies of such administrative procedures to the Secretary for review and comment and to the appropriate Medicaid and Title V State agencies, Medicare fiscal agents and State survey agency for review and comment.

(2) *Content*. The administrative procedures developed by a PSRO under paragraph (a)(1) of this section shall include:

(i) Procedures for informing such agencies and agents of PSRO approval or disapproval of health care services and items;

(ii) Other matters, consistent with Title XI, Part B of the Act, which the PSRO deems necessary for correlation of PSRO activities with those of such agencies and agents.

(3) *Procedures for comment and Memoranda of Understanding*. (i) A Medicaid or Title V State agency or Medicare fiscal agent may comment upon the administrative procedures developed by a conditional PSRO under paragraph (a)(1) of this section within 30 days after receipt of such procedures. The PSRO shall consider any such timely comments and make such modifications to its administrative procedures as the conditional PSRO deems appropriate and shall forward a copy of such revised procedures to the appropriate State agencies and fiscal agents.

(ii) If a Medicaid or Title V State agency or Medicare fiscal agent wishes to incorporate the PSRO's administra-

tive procedures into the form of a written memorandum of understanding with the conditional PSRO, the agency or agent shall so notify the PSRO. In such case, the PSRO and the agency or agent shall negotiate in good faith in an effort to reach written agreement on the PSRO's administrative procedures.

(4) *Approval of Secretary*. Each conditional PSRO, at least 30 days prior to the date in its phase-in timetable for its first assumption of review functions shall submit copies of its administrative procedures (modified as appropriate) or a written memorandum of understanding to the Secretary for approval. The appropriate Medicaid and Title V State agencies and Medicare fiscal agents may submit comments on the administrative procedures to the Secretary for his consideration, not less than 10 days prior to the date scheduled for the first assumption of review functions. If the Secretary does not disapprove the administrative procedures or the memorandum of understanding prior to the date in such phase-in timetable for the first assumption of review functions, then the PSRO shall utilize such administrative procedures or memorandum of understanding. If the Secretary disapproves the administrative procedures or the memorandum of understanding either prior to or after such date, the Secretary shall so notify the PSRO, and the appropriate Medicaid and Title V State agencies and Medicare fiscal agents, stating the reasons therefor, and will require the conditional PSRO to revise its administrative procedures or modify its phase-in timetable or both in accordance with a timetable specified by the Secretary.

(5) *Modification*. The administrative procedures developed under paragraphs (a)(1) through (a)(4) of this section may be modified, with the approval of the Secretary, either: (i) By a revised memorandum of understanding between the conditional PSRO and the appropriate Medicaid or Title V State agencies or Medicare fiscal agents; or (ii) by the conditional PSRO after providing such agencies or agents the opportunity for comment.

(6) *Previously approved procedures*. Paragraphs (a)(1) through (a)(4) of this section shall not apply in the event that, prior to the adoption of this regulation, a conditional PSRO (i) has already assumed review responsibility in accordance with a phase-in timetable approved by the Secretary in a health care institution and (ii) is utilizing administrative procedures (including memoranda of understanding) between the conditional PSRO and the appropriate Medicaid and Title V State agencies and Medicare fiscal agents which have been approved by the Secretary. However, such previously adopted procedures may be revised by the PSRO at any time in accord with paragraphs (a)(1) through (a)(5) of this section.

(7) *Current procedures available*. A copy of each set of current administrative procedures (including memoranda of understanding) utilized by the conditional PSRO under this section shall be

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maintained by the conditional PSRO on file and be available for public inspection in its principal business office.

(b) *Procedures for health care institutions.*—(1) *Development of procedures and other requirements prior to initiation of PSRO review.* Prior to the initiation of review in any health care institution, each PSRO shall, in accordance with applicable regulations of this part:

(i) Notify such institution in a timely manner of the procedures and requirements for delegation of review functions pursuant to section 1155(e) of the Act and the factors and process which the PSRO will utilize for evaluating the capability of the institutional review committee to perform review functions. An example of the notification letter, including the written evaluation factors, shall be submitted to the Secretary for his approval prior to use;

(ii) Evaluate the capability of a health care institution which seeks to obtain a delegation of PSRO review functions; and

(iii) Develop models of procedures for the coordination of PSRO and institutional administrative and review activities in (A) institutions to which all review functions have been delegated, (B) institutions in which review activities are apportioned between the PSRO and the institutions, and (C) institutions in which the PSRO performs all the review functions. Copies of the models of procedures shall be submitted to the Secretary for his approval at least 90 days prior to the earliest date in the PSRO's phase-in timetable for the first assumption of review functions. Each PSRO shall provide copies of its approved administrative and review procedures to all area health care institutions at least 60 days prior to the earliest date when the PSRO is to assume review activities in any institution under the approved phase-in timetable.

(2) *Consultation with nondelegated institutions.* At least 45 days before the conditional PSRO assumes review responsibility in any institution to which it does not propose to delegate any of its review functions, the conditional PSRO shall provide such institution an opportunity for consultation regarding the approved administrative and review procedures. After consideration of any comments made during consultation, the PSRO shall make such modifications in the administrative and review procedures as the PSRO deems appropriate for that institution, and may incorporate such procedures in a written agreement with the institution. However, such modifications or agreements shall not be inconsistent with the model approved by the Secretary pursuant to paragraph (b) (1) of this section and shall include provisions for administrative resolution of disputes and such other provisions as are required in the applicable regulations of this part.

(3) *Agreements with delegated institutions.* Where a conditional PSRO proposes to delegate all or part of its review functions to a health care institution, the PSRO and the institution, prior to such

delegation, shall enter into an agreement incorporating procedures for coordination of conditional PSRO and institutional administrative and review activities which are not inconsistent with the procedures in the model approved by the Secretary. Such agreement shall include provisions for administrative resolution of disputes and such other provisions as are required in the applicable regulations of this Part. Where such agreement cannot be accomplished, the PSRO shall initiate review in the institution by the date for the assumption of review functions in the institution by the PSRO.

(4) *Modification.* The administrative procedures developed under paragraphs (b) (1) through (b) (3) of this section may be modified, with the approval of the Secretary, either by a revised agreement between the conditional PSRO and the institution, or by the PSRO after providing the institution with an opportunity for comment.

(5) *Previously approved procedures.* Paragraphs (b) (1) through (b) (4) of this section shall not apply to administrative and review procedures (including agreements) utilized by conditional PSROs in health care institutions which were approved by the Secretary prior to the effective date of this subpart. However, such previously adopted procedures may be revised by the PSRO at any time in accord with subparagraphs (b) (1) through (b) (4) of this section.

#### § 101.406 Notification prior to assumption of review responsibility.

(a) *Notice to health care institutions and public of designation and timetable.* Each conditional PSRO which has been approved under § 101.403 shall, within 30 days of such notification, provide a copy of its approved phase-in timetable to each health care institution listed in its phase-in timetable and publish a notice in at least one local newspaper of general circulation in the PSRO area indicating (1) that the conditional PSRO has been found capable by the Secretary to exercise review responsibility, as defined in this subpart, in designated health care institutions in the PSRO area, (2) that the conditional PSRO will assume review responsibility according to a phase-in timetable approved by the Secretary, which is available for public inspection in the principal business office of the conditional PSRO, and (3) that the conditional PSRO will publish the exact dates upon which it will assume review responsibility in particular institutions pursuant to paragraph (c) of this section.

(b) *Fiscal and survey agency notices.* The Secretary will notify the appropriate Medicaid, State survey and Title V State agencies, and the Medicare fiscal agents of (1) the PSRO's approved phase-in timetable at the time of designation of such PSRO and (2) any revision in the approved timetable at the time the PSRO notifies the Secretary of such revisions in accordance with § 101.407.

(c) *Notices of exact date of assumption of responsibility.* At least 30 days prior

to assumption of review responsibility in any health care institution, whether such review is to be performed by the PSRO or by an institutional review committee, each conditional PSRO shall (1) publish a notice in at least one local newspaper of general circulation in the PSRO area of the date on which the conditional PSRO will assume review responsibility and (2) notify the health care institution and the Secretary of such date. The Secretary will in turn notify the appropriate Medicaid and Title V State agencies and Medicare fiscal agents when it receives notification from each PSRO pursuant to this paragraph.

(d) *Notice required for previously designated PSROs.* Conditional PSROs designated prior to the effective date of this subpart shall, to the extent they have not already complied with the requirements of paragraph (a) of this section, within 30 days after the effective date of this Subpart, notify health care institutions and the public in accordance with paragraph (a) (1) of this section that they have been found capable by the Secretary. Such notices shall also state that the conditional PSRO has assumed review responsibility in accordance with a phase-in timetable approved by the Secretary, which is available for public inspection in the principal business office of the PSRO.

(e) *Notice of delay in assumption of responsibility.* (1) If a conditional PSRO does not assure review responsibility in accord with the notice given in paragraph (c) of this section, it shall, prior to the date prescribed therein, notify the health care institution involved, the appropriate Medicaid and Title V State agencies and Medicare fiscal agents and the Secretary that it is unable to assume responsibility at such time and state the reasons for its inability to do so. The provisions of Titles XVIII and XIX of the Act specified in Subpart F of this part shall continue to be applicable with respect to such institution until such time as the PSRO assumes review responsibility in the institution.

(2) Where the Secretary has been notified pursuant to paragraph (e) (1) of this section, he will take such action as he deems necessary, which may include, but is not limited to, revision of the phase-in timetable pursuant to § 101.407, monitoring arrangements under § 101.409, or, reevaluation of the capability of the PSRO under § 101.410.

#### § 101.407 Revision of phase-in timetable.

(a) Where a conditional PSRO anticipates a delay of more than 90 days in meeting the estimated date for the assumption of review responsibility in any health care institution, the conditional PSRO shall, prior to such estimated date, notify the Secretary of such anticipated delay and request a revision in the approved phase-in timetable for such conditional PSRO.

(b) The Secretary may, at any time after designation, revise the approved phase-in timetable of any conditional PSRO, in accordance with a request

under paragraph (a) of this section or on the basis of his reevaluation of the capability of the conditional PSRO in accordance with § 101.410.

**§ 101.408 Public inspection of timetable.**

Each conditional PSRO shall maintain its current approved phase-in timetable on file for public inspection at the principal business office of the conditional PSRO during regular business hours.

**§ 101.409 Monitoring.**

(a) The Secretary may arrange to have Medicare fiscal agents or Medicaid or Title V State agencies assist him in monitoring the activities of a conditional PSRO. Where such arrangements are made, the conditional PSRO shall take all necessary and appropriate actions to facilitate such monitoring activities.

(b) Where a Medicare fiscal agent or a Medicaid or Title V State agency finds, in the course of monitoring a conditional PSRO, that problems appear to exist in the effectiveness of conditional PSRO review, the fiscal agent or agency shall so notify the conditional PSRO and meet with the conditional PSRO to discuss methods for improving the effectiveness of conditional PSRO review. The Medicare fiscal agent or Medicaid or Title V State agency shall promptly notify the Secretary of any serious problems regarding the effectiveness of conditional PSRO review, and shall further notify the Secretary of the results of its meeting with the conditional PSRO to resolve such problems. The Secretary will consider such information in evaluating the need for a reevaluation of the conditional PSRO's capability pursuant to § 101.410, or other appropriate action.

(c) Where, pursuant to paragraph (b) of this section, a Medicaid State agency and conditional PSRO have not been successful in resolving any problems regarding the appropriateness of PSRO review, the State may file a written complaint with the Secretary requesting either corrective action by the Secretary or, where the State believes the problems have a serious impact upon the administration of the State Medicaid program, a temporary suspension of the conditional PSRO's authority to make determinations which are conclusive for purposes of payment under the Act. Pending a reevaluation of the conditional PSRO's capability pursuant to § 101.410, the Secretary will temporarily suspend such PSRO authority in full or in part as he deems appropriate when the Secretary determines that the State has provided reasonable documentation that the PSRO's review determinations, and not other factors, have caused either of the following:

(1) A detrimental impact on State Medicaid expenditures; or

(2) A detrimental impact on the quality of care received by Medicaid patients. Where a conditional PSRO's authority is temporarily suspended by the Secretary, the PSRO shall continue its review ac-

tivities. During such period of suspension, the PSRO's determinations shall not be conclusive for purposes of payment under the Act but shall be only advisory to Medicaid State agencies and Medicare fiscal agents, and the provisions of Titles XVIII and XIX of the Act, relating to utilization review and control, physician certifications, and State agency surveys and certifications, shall be deemed to be satisfied.

**§ 101.410 Reevaluation of capability.**

(a) *Reevaluation factors.* The Secretary may at any time, pursuant to section 1154(b) of the Act, reevaluate the capability of a conditional PSRO to exercise review responsibility. Such reevaluation will be based upon:

(1) The progress of the PSRO in carrying out its formal plan;

(2) Any comments or recommendations submitted by Medicaid or Title V State agencies or Medicare fiscal agents; and

(3) Other relevant factors as determined by the Secretary.

(b) *Notice of tentative determination and intended action.* If, after such reevaluation, the Secretary has reason to believe that the conditional PSRO is not performing in a satisfactory manner the duties and functions which it was found capable of performing, then the Secretary shall notify the conditional PSRO of the grounds for such belief and of the action which the Secretary proposes to take regarding the conditional PSRO. Such action may include:

(1) Placing restrictions upon the exercise of review responsibility or the performance of certain duties and functions by the conditional PSRO, including revision of the conditional PSRO's phase-in timetable;

(2) Requiring the conditional PSRO to take corrective action, including the acceptance of technical assistance to improve its performance;

(3) Suspending the authority of the PSRO to make conclusive determinations pursuant to Subpart E of this part for a period of time. During such period of suspension, the PSRO shall continue its review activities, the PSRO's determinations shall not be conclusive for purposes of payment under the Act but shall be only advisory to Medicaid State agencies and Medicare fiscal agents, and the provisions of Titles XVIII and XIX of the Act, relating to utilization review and control, physician certifications and State agency surveys and certifications, shall be deemed to be satisfied.

(4) Terminating the agreement with the conditional PSRO upon 90 days notice to the PSRO, pursuant to section 1154(c) of the Act;

(5) Such other action as the Secretary may deem appropriate.

(c) *Notice to fiscal agencies.* The Secretary will, as soon as practicable, notify the appropriate Medicaid and Title V State agencies and Medicare fiscal agents, and affected health care institutions, of his belief under paragraph (b) of this section and any action he intends to take pursuant thereto, and solicit

their comments on the action he proposes to take.

(d) *Informal meeting and decision.* The notice to the conditional PSRO under paragraph (b) of this section shall offer the conditional PSRO an opportunity to submit written material and to meet informally with an official designated by the Secretary to show cause why the action proposed by the Secretary should not be taken. If the conditional PSRO does not submit written material or request an informal meeting within 14 days after receipt of the Secretary's notice, the Secretary's tentative decision shall become final and he will so notify the PSRO, Medicaid and Title V agencies, and Medicare fiscal agent(s), and state the basis for his decision. If the conditional PSRO submits written material within 14 days, the Secretary will consider this material prior to making a final decision. If the conditional PSRO requests an informal meeting within 14 days after receipt of the Secretary's notice, such a meeting will be scheduled as soon as practicable. After such meeting, the official designated by the Secretary will render promptly a recommended decision to the Secretary. The Secretary will adopt, revise or set aside the recommended decision and will notify the PSRO, appropriate Medicaid and Title V agencies and Medicare fiscal agent(s) of such decision and the basis for such decision.

[FR Doc.77-1948 Filed 1-21-77;8:45 am]

[ 42 CFR Part 101 ]

**PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS**

**Conclusive Effect of Determinations on Claims Payment**

Notice is hereby given that the Assistant Secretary for Health of the Department of Health, Education, and Welfare, with the approval of the Secretary of Health, Education, and Welfare, proposes to add a new Subpart E to Part 101 of Title 42, Code of Federal Regulations.

The proposed Subpart E would require Medicare fiscal agents and State Medicaid agencies, within their respective areas of responsibility, to accept as conclusive in institutions in which the PSRO has assumed review responsibility, disapprovals by a PSRO of health services as being medically unnecessary, of inadequate quality or provided at an inappropriate level of care. Those PSRO determinations, in accordance with sections 1155 and 1158 of the Social Security Act (42 U.S.C. 1320c-4 and 7) will, except as provided in section 1159 (42 U.S.C. 1320c-8), constitute the conclusive determination on those medical issues in connection with items or services for which payment of Federal funds may be made under the Act.

As a corollary, the claims for payment must be accompanied or supported by evidence of PSRO review and approval, routine certification, or other appropriate actions by the PSRO indicating that the services have not been disap-

proved and the payment agencies will accept the PSRO determinations on those medical issues. However, PSROs will not review services where the Secretary has made a determination under section 1862(d) of the Act to exclude services rendered by a provider or health care practitioner from coverage under Title XVIII of the Act or to terminate a provider's agreement.

The State Medicaid agencies are also bound by PSRO decisions under section 1164 of the Act, which makes the provisions of Title XI, Part B, directly applicable to the State Medicaid plans.

Subpart E thus represents a change in the general status of utilization review decisions under the Social Security Act, since unlike the findings of utilization review committees under both the present utilization review regulations of Titles XVIII and XIX (20 CFR 405.1035; 45 CFR 250.20) and the proposed utilization review regulations (41 FR 13452, 13457, March 30, 1976), the findings of the PSROs will always be conclusive upon Medicare fiscal agents and Medicaid State agencies.

Separate regulations implementing the provisions of section 1158(a) of the Act, which authorizes payment of Federal funds for services which have been disapproved by a PSRO when the Secretary has determined that the claimant is without fault, are under development and will be published for public comment in the FEDERAL REGISTER.

Interested persons are invited to submit written comments, suggestions or objections concerning Subpart E to the Director, Bureau of Quality Assurance, Health Services Administration, Room 16-A-55, 5600 Fishers Lane, Rockville, Maryland 20852, on or before March 25, 1977. All comments received in timely response to this Notice will be considered and will be available for public inspection in the above-named office during regular business hours.

It is proposed to make Subpart E effective upon republication in the FEDERAL REGISTER.

The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: November 18, 1976.

THEODORE COOPER,  
Assistant Secretary for Health.

Approved: January 11, 1977.

MARJORIE LYNCH,  
Acting Secretary.

**Subpart E—Conclusive Effect of PSRO Determinations on Claims Payment**

Sec.	
101.501	Definitions.
101.502	PSRO action as condition of payment of claims.
101.503	Effect of PSRO disapproval of services.
101.504	Effect of affirmative PSRO determinations.
101.505	Coverage determinations.

AUTHORITY: Sec. 1164(b), 1155(a)(1), 1158, 1164, Social Security Act, 86 Stat. 1432, 1433, 1437, 1442; (42 U.S.C. 1320c 3(b), 4, 7, 13);

sec. 1102, Social Security Act, 49 Stat. 647, as amended (42 U.S.C. 1302)

**Subpart E—Conclusive Effect of PSRO Determinations on Claims Payment**

**§ 101.501 Definitions.**

As used in this subpart:

(a) "Act" means the Social Security Act, as amended (42 U.S.C. Chapter 7).

(b) "Review responsibility" means (1) the responsibility of a PSRO to perform duties and functions prescribed under Title XI, Part B of the Act and the regulations of this part in accord with the phase-in timetable approved by the Secretary; and (2) the authority of a PSRO to make determinations in specified health care institutions under sections 1155(a)(1) and (2) of the Act which, with respect to issues arising under sections 1155(a)(1) and (2) of the Act, are conclusive under the Act, pursuant to section 1158 of the Act and this subpart.

(c) "Medicare fiscal agents" means intermediaries which are parties to agreements entered into by the Secretary pursuant to section 1816 of the Act and carriers which are parties to contracts entered into by the Secretary pursuant to section 1842 of the Act.

(d) "Medicaid State Agency" means an agency which is established or designated under section 1902(a)(5) of the Act to administer a State plan to provide medical assistance under Title XIX of the Act.

(e) "PSRO" means a Professional Standards Review Organization which is conditionally or unconditionally designated.

(f) "Title V State agency" means an agency which is established or designated pursuant to section 505(a)(2) of the Act to administer the State plan under Title V of the Act.

**§ 101.502 PSRO action as condition of payment.**

No Federal funds appropriated under Title XVIII or XIX of the Act shall be used (directly or indirectly) for the payment of any claim for services or items provided in a health care institution where a PSRO is exercising review responsibility for such institution unless (a) the claim for payment is accompanied or supported by evidence of PSRO review and approval, routine certification, or other appropriate action indicating that the services or items have not been disapproved; or (b) such services or items have been approved pursuant to section 1159 and the applicable regulations of this part.

**§ 101.503 Effect of PSRO disapproval of services.**

(a) Except as provided in section 1159 of the Act and the applicable regulations of this part, no Federal funds appropriated under Title XVIII or XIX of the Act for the provision of health care services or items shall be used (directly or indirectly) for the payment, under such titles or any program established pursuant thereto, of any claim for the provision of health care services or items (unless the Secretary, pursuant to applicable regulations of this part, determines that the claimant is without fault), if:

(1) The provision of such services or items is subject to review by a PSRO under Title XI, Part B of the Act;

(2) The PSRO has disapproved of the services or items giving rise to such claim; and

(3) The PSRO has notified the practitioner or provider who provided, or proposed to provide, such services or items, and the individual who received, or was proposed to receive, such services or items, of its disapproval of the provision of such services or items.

(b) Wherever any PSRO disapproves of any health care services or items, the PSRO shall, after giving the notifications required under paragraph (a) of this section, promptly notify the Medicaid or Title V State agency or Medicare fiscal agent having responsibility for acting upon claims for payment for or on account of such services or items in accordance with the regulations of this Part.

**§ 101.504 Effect of affirmative PSRO determinations.**

Where a PSRO is exercising review responsibility, no Medicare fiscal agent or Medicaid State agency shall deny the payment of Federal funds for a claim for the provision of health care services or items under Title XVIII or XIX of the Act which are subject to such review, on the grounds that such services were not medically necessary, or were not of a quality which meets professionally recognized standards of health care, or were provided inappropriately on an inpatient basis, or could have been provided more economically in an inpatient health care facility of a different type, unless such services or items have been disapproved by the PSRO or disapproved under section 1159 of the Act.

**§ 101.505 Coverage determinations.**

Nothing in this subpart shall be construed as precluding the Secretary, a Medicare fiscal agent, or a Medicaid State agency, in the proper exercise of its duties and functions, from reviewing claims for benefits under Titles XVIII and XIX of the Act, or from determining whether they meet the coverage requirements of such Titles XVIII and XIX, in accordance with the implementing regulations of Titles XVIII and XIX and the applicable regulations of this Part providing for the correlation of these functions with those functions of the PSRO under Title XI, Part B of the Act.

[FR Doc. 77-1949 Filed 1-21-77; 8:45 am]

**[ 42 CFR Part 101 ]**

**PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS**

**Correlation of Functions Under Title XI, Part B of the Social Security Act With Other Provisions of the Act**

Notice is given that the Assistant Secretary for Health of the Department of Health, Education, and Welfare, with the approval of the Secretary of Health, Education, and Welfare, proposes to add a new Subpart F, entitled "Correlation of Functions Under Title XI, Part B of the Social Security Act with Other Provisions of the Act."

The purpose of the present proposal is to correlate, under section 1165 of the Social Security Act (the Act), the various activities of professional Standards Review Organizations (PSROs) with those of the Medicare, Medicaid and Title V agencies and other organizations having review-related functions. In some cases this correlation will require that the PSRO's activities replace those of other agencies. For example, since section 1155(a)(1) of the Act provides that each PSRO will assume exclusive "responsibility" in its area for the review of the medical necessity, quality and appropriate level of care of health services and items which may be paid for under the Act "notwithstanding any other provisions of law," the PSRO's review activities will replace the present utilization review activities of Title XVIII and XIX agencies in those institutions for which a PSRO has assumed responsibility.

On the other hand, in accord with section 1158 of the Act, PSRO activities will replace the present claims payment functions of Medicare and Medicaid agencies only insofar as a PSRO's determinations of medical necessity, quality and level of care will be conclusive with regard to these issues. Pertinent coverage regulations and guidelines, such as relate to the number of hospital days covered or the reasonableness of charges, will continue to apply to payment determinations, and claims payment agencies will not be precluded from rendering coverage and reimbursement determinations with regard to issues which are not the subject of the PSRO determinations.

Similarly, physician certifications required under Title XI will be performed in lieu of similar requirements under Titles XVIII and XIX of the Act, but pertinent coverage regulations and guidelines authorized under those provisions of the Act will continue to apply to payment determinations.

Regulations are under development regarding the relationship of PSRO review and physician certifications to physician certifications made pursuant to section 1814(h) of the Act (relating to "presumed coverage" of a Medicare beneficiary in a skilled nursing facility). In the interim, Subpart F clarifies that, as is the case with an adverse finding by a skilled nursing facility's utilization review committee when the care is not subject to PSRO review, the beneficiary is not eligible for a period of "presumed coverage" in a skilled nursing facility when a PSRO determines that the skilled nursing care to which the physician certifies is not medically necessary.

Survey and monitoring responsibilities of State survey agencies and claims payment agencies, to assure that utilization review functions are being conducted in health care institutions in accordance with section 1861(k) of the Act will no longer be applicable under the law where PSROs are exercising review responsibilities in such institutions.

Finally, since section 1159(c) of the Act provides for an exclusive hearing procedure on PSRO issues, other hearing procedures provided under the Act on the issues of medical necessity, quality and appropriate level of care will be superseded by the procedures of section 1159 of the Act.

It should be noted that, since section 1158 of the Act makes clear that PSRO determinations are to be advisory for purposes of services provided under Title V of the Act, none of the provisions of Title V will be superseded in health care institutions where PSROs perform review and both the PSRO and Title V review systems may operate simultaneously.

It should also be noted that the correlation of PSRO activities with activities of other agencies with respect to particular institutions will only take place at the time PSROs assume review responsibility with regard to those institutions. With respect to institutions where PSROs have not yet begun to function, the Medicare and Medicaid claims payment agencies will continue to exercise all those functions required of them under the Act.

Interested persons are invited to submit written comments, suggestions or objections concerning Subpart F to the Director, Bureau of Quality Assurance, Health Services Administration, Room 16A55, 5600 Fishers Lane, Rockville, Maryland 20852, on or before March 25, 1977. All comments received in timely response will be considered and will be available for public inspection in the above-named office during regular business hours.

It is proposed to make Subpart F effective upon republication in the FEDERAL REGISTER.

The Department of Health, Education, and Welfare has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: November 18, 1976.

THEODORE COOPER,  
Assistant Secretary for Health.

Approved: January 11, 1977.

MARJORIE LYNCH,  
Acting Secretary.

Subpart F—Correlation of Functions Under Title XI, Part B of the Social Security Act With Other Provisions of the Act

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AUTHORITY: Sections 1154(b), 1155(a)(1), 1158, 1164 and 1165 of the Social Security Act, 86 Stat. 1432, 1433, 1437, 1442, and 1443, (42 U.S.C. 1320c-3(b), 4, 7, 13, 14); Section

1102 of the Social Security Act, 49 Stat. 647, as amended (42 U.S.C. 1302).

Subpart F—Correlation of Functions Under Title XI, Part B of the Social Security Act With Other Provisions of the Act

§ 101.601 Definitions.

As used in this subpart:

(a) "Act" means the Social Security Act, as amended (42 U.S.C. Chapter 7).

(b) "PSRO" means a Professional Standards Review Organization which is conditionally or unconditionally designated.

(c) "Review responsibility" means (1) the responsibility of a PSRO to perform duties and functions prescribed under Title XI, Part B of the Act and the regulations of this Part in accord with the phase-in timetable approved by the Secretary and (2) the authority of a PSRO to make determinations in specified health care institutions under sections 1155(a)(1) and (2) of the Act which, with respect to issues arising under sections 1155(a)(1) and (2) of the Act, are conclusive under the Act, pursuant to section 1158 of the Act and Subpart E of this Part.

(d) "Health care institution" 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 the Act.

§ 101.602 Applicability.

The provisions of this Subpart shall be applicable only to health care services and items provided by or in those health care institutions in which a PSRO has assumed review responsibility in accordance with the applicable provisions of this Part.

§ 101.603 Correlation of Title XI functions with Title XVIII functions.

(a) *Utilization review activities.* The review activities of PSROs under section 1155(a) of the Act shall be in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), 1861(j)(8), 1861(j)(12), 1861(k) and 1865 of the Act.

(b) *Certifications.* (1) The certifications made by attending physicians under section 1156(d) of the Act with regard to the issue of medical necessity of health care services, shall be in lieu of the physician certifications required under sections 1814(a)(2)(A), (B), (C), and (E), 1814(a)(3), and 1835(a)(2)(B) of the Act. However, pertinent coverage regulations and guidelines authorized and established pursuant to the provisions of title XVIII of the Act cited above shall continue to apply to payment determinations.

(2) A Medicare beneficiary is not eligible for a period of presumed coverage under section 1814(h) of the Act when a PSRO determines that the care specified in section 1814(a)(2)(C) of the Act is not medically necessary or appropriate.

(c) *Payment determinations by Medicare intermediaries and carriers.* Determinations of PSROs under section 1155 (a) of the Act with regard to the medical necessity, quality and appropriate level of care of health care services, shall be conclusive with regard to these issues on decisions of Medicare intermediaries and carriers under sections 1814(a)(4), 1814(a)(5), 1814(a)(6), 1862(a)(1) and 1862(a)(9) of the Act. However, pertinent coverage regulations and guidelines authorized and established pursuant to the provisions of title XVIII of the Act cited above shall continue to apply to payment determinations, and claims payment agencies shall not be precluded from rendering coverage and reimbursement determinations with regard to issues which are not the subject of such PSRO determinations.

(d) *Survey, compliance and assistance activities.* The activities of PSROs in performing review directly in health care institutions under section 1155(a) of the Act and the monitoring activities of PSROs in assuring compliance with requirements of Title XI, Part B of the Act in health care institutions which are delegated review responsibilities under section 1155(e)(1) of the Act shall be in lieu of the survey, compliance and assistance activities required of State survey agencies under section 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and intermediaries and carriers under sections 1816(b)(1)(B), and 1842(a)(2)(A) and (B) of the Act. The Secretary will notify appropriate State survey

agencies, intermediaries, and carriers of all health care institutions for which a PSRO has assumed review responsibility.

(e) *Review and appeals activities.* Pursuant to section 1159(c) of the Act, any reviews or appeals of PSRO determinations provided under section 1159 (a) and (b) of the Act shall be in lieu of appeals provided under sections 1842 (b)(3)(C) and 1869(b) of the Act with respect to the issues of medical necessity, quality and level of care of health care services as determined by such PSRO.

**§ 101.604 Correlation of Title XI functions with Title XIX functions.**

(a) *Review activities.* The review activities of PSROs under section 1155(a) of the Act shall be in lieu of the medical, utilization and independent professional review activities required under sections 1902(a)(26), 1902(a)(30), 1902(a)(31), 1903(g)(1) and 1903(i)(4) of the Act.

(b) *Certifications.* Certifications made by attending physicians under section 1156(d) of the Act shall be in lieu of physician certifications required under section 1903(g)(1)(A) of the Act.

(c) *Payment determinations.* Determinations of PSROs under section 1155 (a) of the Act, with regard to the medical necessity, quality and appropriate level of care of health care services, shall be conclusive with regard to these issues on decisions of State Medicaid agencies under section 1903(g) and 1903(i)(4) of the Act. However, such PSRO determinations shall not preclude appropriate coverage determinations under the provi-

sions of Title XIX of the Act with regard to issues which are not the subject of such PSRO determinations.

(d) *Survey and compliance activities.* The activities of PSROs in performing review directly in health care institutions under section 1155(a) of the Act, and the monitoring activities of PSROs in assuring compliance with the requirements of Title XI, Part B of the Act in health care institutions which are delegated review responsibilities under section 1155(e)(1) of the Act, shall be in lieu of the validation procedures performed by the Secretary under section 1903(g)(2) of the Act and the survey procedures required of State survey agencies under section 1902(a)(33) of the Act.

(e) *Review and appeals activities.* Pursuant to section 1159(c) of the Act, any reviews or appeals of PSRO determinations provided under sections 1159 (a) and (b) of the Act shall be in lieu of fair hearings before State agencies provided under section 1902(a)(3) of the Act with respect to the issues of medical necessity, quality and level of care of health care services as determined by such PSRO.

**§ 101.605 Continuation of functions not assumed by PSROs.**

Any of the duties and functions of a PSRO under Title XI, Part B of the Act for which responsibility has not been assumed by a PSRO shall be performed in the manner and to the extent otherwise provided for under the law.

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