federal register

TUESDAY, JANUARY 25, 1977

PART VI

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

■

PROFESSIONAL STANDARDS REVIEW ORGANIZATION DETERMINATIONS

Interim Hearings and Appeals

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER I—MEDICAL CARE QUALITY AND COST CONTROL

PART 101—PROFESSIONAL STANDARDS REVIEW

Interim Hearings and Appeals of Professional Standard Review Organization Determinations

On February 20, 1976, interim regulations were adopted and published in the FEDERAL REGISTER (41 FR 7878), to provide for hearings and appeals of Professional Standards Review Organizations (PSROs) as required under section 1159(b) of the Social Security Act (42 U.S.C. 1320–8). While the regulations became effective immediately on publication, it was anticipated that appropriate revisions might be suggested by the public and interested persons were invited to submit written comments, suggestions or objections, not later than March 22, 1976, concerning these interim regulations. All comments received with respect to the interim regulations were given consideration.

1. A number of comments objected to the requirement, in § 101.1402(a), that the Statewide Council automatically review every adverse PSRO reconsideration. This comment was adopted and the regulation now requires a dissatisfied party to file a request for Statewide Council Review. It is not reasonable to require the Statewide Council to automatically review cases where no party has expressed an interest in obtaining such review. Moreover, a heavy workload and great expense for the Statewide Council would result from automatic review of every adverse PSRO reconsideration. On the other hand, the burden upon a party of filing a request for a Statewide Council review is minimal. Section 101.1402(a) has been amended accordingly.

2. Comments were received which requested that providers and practitioners be afforded hearings by the Secretary under section 1159(b) of the Social Security Act on adverse PSRO determinations. Section 101.1402(b) makes such hearings available to beneficiaries or recipients only. This language substantially parallels the language in section 1159(b) of the Act. Hence, the statute makes no express provisions for providers and practitioners to obtain Secretarial hearings. At the same time, section 1159(a) expressly affords rights to reconsideration of PSRO determinations to providers and practitioners. The limitation of the rights of such parties to reconsideration under section 1159(a) indicates a deliberate legislative design to omit provider and practitioner appeals under section 1159(b). Finally, under section 1159(c) of the Act, hearings in the PSRO program "shall be in lieu of any review, hearing, or appeal under this Act with respect to the same issue." Therefore, providers and practitioners are entitled neither to hearings under section 1159 of the Social Security Act, nor to hearings "on the same issue" (i.e., medical necessity, quality, and appropriateness of health care) under Title XVIII or XIX of the Act. However, on other issues, such as coverage and reasonable charges, providers and practitioners continue to retain rights to Departmental hearings provided under law. Section 101.1402(b) has not been changed, therefore, to provide appeals to such parties.

3. Comments were received questioning whether there is an appropriate method utilized by the Secretary for selecting impartial medical advisors to the Administrative Law Judges, as required under § 101.1404(b), which assures that the advisors are "impartial." It was suggested that advisors be chosen from a permanent panel created by State and local medical societies and that particular doctors be identified by the societies to be consulted in particular cases. It is not clear how this proposed system would insure impartiality. In contrast, under the regulations adopted, the system to be used is expected to operate to reasonably assure the objective of obtaining impartial advice. Under § 101.1404(b)(3), a professional advisor cannot be consulted if he was directly involved in providing services, he or his family have a financial interest in the institution in which care is provided, he participated in the PSRO or Statewide Council decisions, he has staff privileges at the institution where services are provided, or he is on the governing board of the PSRO or Statewide Council. The enumerated cases were considered to indicate the various factors which would prejudice an advisor to an improper degree. However, in order to insure that other cases of bias may be considered, the regulations have been amended to provide that where a reasonable showing is made to the Administrative Law Judge that an advisor may be biased in a case, the advisor's opinion will not be utilized and the Administrative Law Judge must obtain the advice of another professional advisor. Moreover, the selection process described in Comment 4 assures input from local medical societies and is expected to further insure impartiality.

4. It was suggested that language be added to the regulation to assure that the medical advisor is recognized as a peer of the professional whose services are being reviewed. Since the regulation calls for "*appropriate* professional consultation" (emphasis added), the language is considered sufficient. In fact, the system which is used by the Bureau of Hearings and Appeals to assure the competence and qualifications of advisors will also assure that appropriate peers are utilized to review the work of other physicians. The Bureau has entered into contracts with physicians throughout the country to provide appropriate medical consultation for Administrative Law Judges conducting hearings under various titles of the Social Security Act, including Title XI. These physicians are recommended by medical societies and other physicians. Before the physicians are selected, their background and credentials are closely scrutinized in such publications as the American Medical Association's Directorate of Doctors and in other medical literature relating to specialists prepared by the specialty boards and the American Medical Association. An advisor must be a member, in good standing, of his local medical society. After the physicians credentials are verified, interviews are held with members of the staff at the hospital at which he practices. Most of the advisors are board certified and they represent every medical specialty and geographic locale. The broad expertise and the heterogenous nature of this panel of medical advisors will enable the Administrative Law Judge to obtain a consultant in a hearing involving a PSRO determination who has the appropriate qualifications to be considered a peer of the physician who provided the services in question. At the same time, it is the general practice to utilize an advisor residing and practicing in the same area as the practitioner who rendered the services, assuring that, to that extent, a geographic peer will be consulting in the case. However, since advisors who have precisely the same qualifications as the professional under review, or who reside in the same locality as the professional involved, are not always available to consult, it was not considered appropriate to require specific peer qualifications under the regulations.

5. A suggestion was received that the medical advisors be subject to oral cross examination at the hearings or subjected to questions through a deposition form of proceeding prior to the hearing. Past experience in Title XVIII hearings and the procedures adopted for use in Title XI hearings, indicates that cross examination protections or similar protections, will be provided. In the majority of Title XVIII cases, the medical advisor has, in fact, appeared and testified before the Administrative Law Judge at the hearing. At such time, the advisor may be examined by the claimant and/or his representative (20 CFR 404.939). Where an advisor's opinion is obtained in writing, the claimant will be afforded an opportunity to examine the opinion and rebut it through additional evidence, oral testimony or a written statement (20 CFR 404.927).

6. Comment was received questioning whether PSRO medical necessity decisions must be accepted by a Medicaid State agency. Under sections 1154(b), 1155(a) and 1158 of the Social Security Act, PSROs, whether conditionally or unconditionally designated, will have final authority for purposes of payment under the Act on issues of medical necessity, quality, and appropriateness of health care services. Medicaid State agencies have been notified of this by the Department, and regulations are under development within the Department to implement these provisions. However, even in the absence of regulations, section 1164 of the Act provides that the provisions of Title XI, Part B of the Act shall apply automatically to Medicaid State plans.

7. Comment was received that rules regarding confidentiality of appeals data should be made a specific requirement

of these regulations. Data acquired or generated by a PSRO in the exercise of its functions is currently prohibited from public disclosure by section 1166 of the Act except where disclosure is necessary to carry out the purposes of Title XI or where disclosure is otherwise authorized by regulations. Regulations to further implement this provision relating to confidentiality of PSRO data are currently under development within the Department. However, disclosure of PSRO data and information which is necessary to carry out PSRO reconsiderations and Secretarial hearings is clearly authorized under section 1166(a)(1) of the Act, without the necessity for regulations.

8. Comment was received recommending that simplified administrative procedures should be included in the final regulations. Although the requirements for conduct of the hearing itself are lengthy and specified in some detail, this is in order to ensure that full due process is accorded the appellant. However, the procedures for requesting a hearing are very simple and should pose no burden or obstacle to the claimant.

9. It was proposed that a controversy involving a claim of $100 would more appropriately be handled at the local level rather than by the Statewide PSRO Council, and that the required amount in controversy for Statewide Council review should be $1000. The right of providers, practitioners, and beneficiaries and recipients to a review by a Statewide Council from an adverse PSRO reconsideration, where a Statewide Council exists and the claim is at least $100, is statutorily mandated by section 1159(b) of the Act and may not be waived or modified by regulation.

10. Comments recommended that the interim regulations should have been published as proposed rulemaking allowing prior public comment rather than as final rules effective upon publication. As explained in the preamble to the interim regulations, since conditional PSROs are currently making determinations which are conclusive for purposes of payment under the Social Security Act, and since rights to reconsideration, hearing and appeal under section 1159 are statutorily required, the Department believes that good cause existed in accord with the Administrative Procedure Act (5 U.S.C. 553) to make these interim regulations effective upon publication. However, public comment on the interim regulations was invited and considered and revisions set out in this Notice are the result of such public input. Moreover, regulations in proposed form setting out more detailed procedures for PSRO reconsiderations, hearings and appeals will be published in proposed form in the future, providing additional opportunity for public comment.

11. Comment was received suggesting that the regulations should require the hearing body to conduct and decide the hearing within a specified limited time from the date of the request. Since the time needed to conduct the hearing will vary depending in part upon the type and extent of evidence the claimant wishes to present at the hearing, this would not be an appropriate rule and could be disadvantageous to claimants. Administrative efforts to increase the number of hearing officials and other actions are expected to reduce unnecessary delays in the hearing process. Hence, no change in the regulation has been made.

12. It was proposed that language regarding continuance of the States' authority to conduct hearings on issues of scope of Medicaid benefits and eligibility should be incorporated not only in the Preamble but also in the body of the regulations. The language of § 101.1401 of the regulations, which provides that these regulations are applicable only to hearings provided by the Secretary with regard to determinations made by a PSRO under section 1155(a) of the Act, clearly delineates the PSRO's authority since section 1155(a) relates only to PSRO determinations of medical necessity, quality, and appropriateness of health care services. Hence, such additional language regarding coverage determinations and hearings would be redundant.

13. Comment was received that there should be two levels of appeal from a PSRO adverse initial determination prior to Statewide Council review; i.e., a reconsideration by a hospital delegated review functions under section 1155(e) of the Act, and another reconsideration by the PSRO. Section 1159(a) of the Act clearly provides for only one reconsideration of an adverse claims decision. To require another reconsideration, where the statute already requires numerous levels of review, including Statewide Council review, a hearing by the Department, and judicial review would be administratively burdensome, time-consuming and confusing to beneficiaries and recipients.

Accordingly, 42 CFR Part 101, Subpart N is revised as set forth below.

Effective Date. This regulation shall become effective January 25, 1977.

NOTE.—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: December 15, 1976.

THEODORE COOPER,
Assistant Secretary for Health.

Approved: January 18, 1977.

MARJORIE LYNCH,
Acting Secretary.

Subpart N—Hearings and Appeals of Professional Standards Review Organization Determinations Interim Regulations

Sec.

AUTHORITY: Sec. 1159, Social Security Act; sec. 249F, Pub. L. 92-603; 86 Stat. 1429-1445 (42 U.S.C. 1320c-8); sec. 1102 of Social Security Act, 49 Stat. 647 as amended (42 U.S.C. 1302).

§ 101.1401 Applicability.

The regulations of this subpart are applicable to hearings provided by the Secretary pursuant to section 1159(b) of the Social Security Act (hereinafter "the Act") with regard to determinations under section 1155(a) of the Act by a PSRO, including a conditional PSRO, which has assumed full review responsibility in specified health care institutions.

§ 101.1402 Right to reconsideration, review and hearing.

(a) Any beneficiary or recipient who is entitled to benefits under the Act (other than Title V), or a provider or practitioner who is dissatisfied with a determination, with respect to a claim, made by a Professional Standards Review Organization in carrying out its responsibilities for the review of professional activities in accordance with paragraphs (1) and (2) of section 1155(a) of the Act shall, after being notified of such determination, be entitled to a reconsideration thereof by the Professional Standards Review Organization, and, where the Professional Standards Review Organization reaffirms such determination in a State which has established a Statewide Professional Standards Review Council, and where the matter in controversy is $100 or more, such determination shall, upon the written request of the dissatisfied party, be reviewed by professional members of such Council and, if the Council so determines, revised.

(b) Where the determination of a Statewide Professional Standards Review Council is adverse to the beneficiary or recipient (or where there is no such Council in a State and where the matter in controversy is $100 or more), such beneficiary or recipient shall be entitled to a hearing thereon by the Secretary to the same extent as provided in section 205(b) of the Act.

(c) Any review or appeal provided under this section shall be in lieu of any review, hearing or appeal under the Act with respect to the same issue.

§ 101.1403 Utilization of Title XVIII, Part A, hearing procedures.

The procedures specified in § 405.722 (time and place of filing request for hearing), §§ 405.740 through 405.747 (determining amount in controversy), §§ 404.919 through 404.952 and 404.954 through 404.956 (procedures for conduct of hearings and Appeals Council review); §§ 405.750, 404.958, 404.961 through 404.963, and 404.966 (reopening initial or reconsidered determinations and hearings or Appeals Council decisions); and §§ 404.971 through 404.973 (representation of parties) of Title 20 Code of Federal Regulations, except to the extent inconsistent with specific provisions of this Subpart N, shall govern hearings under section 1159(b) of the Act.

§ 101.1404 Professional consultation.

(a) Any decision made by an Administrative Law Judge with regard to a PSRO determination shall be made only after receiving and considering appropriate professional consultation on the matter.

(b) Professional consultation shall be obtained by the Administrative Law Judge, in the form of either testimony or written opinion, from an impartial medical advisor selected by the Social Security Administration in each matter which he is to decide under section 1159(b). Such consultation shall be part of the record, and shall be considered by the Administrative Law Judge along with other evidence of record in deciding the issues before him.

(1) Each party shall have the right to examine all evidence of record, including that obtained from the medical advisor, and to present rebuttal evidence. Such rebuttal evidence shall be made part of the record for consideration.

(2) Such consultation shall be rendered by a licensed doctor of medicine or osteopathy whenever the health care services or items in question were provided or proposed to be provided by another licensed doctor of medicine or osteopathy.

(3) No professional advisor shall be utilized to provide such consultation if; (i) he was directly or indirectly involved in providing the services which are the subject of the hearing; (ii) he or any member of his family has, directly or indirectly, any financial interest in the institution in which such services were provided or were proposed to be provided; (iii) he participated in the PSRO initial or reconsidered determinations or the Statewide Council determination which is the subject of the hearing; (iv) he has staff privileges in the institution in which such services were provided or proposed to be provided; (v) he is a member of the governing body of the PSRO or a member of the Statewide Council which rendered a determination in the matter; or (vi) a reasonable showing is made to the Administrative Law Judge that an advisor may be biased with regard to the case under review. Where a professional advisor is rejected, the Administrative Law Judge shall obtain appropriate professional consultation from another professional advisor who meets the requirements of this Subpart.

§ 101.1405 Determining amount in controversy in case of proposed services.

Where services or items proposed to be provided have been disapproved by the PSRO, the amount in controversy shall be determined upon the basis of reasonable estimates of the amounts which would be charged the individual if such services or items were provided, and shall be computed in accordance with the priciples set forth in section 405.740 of 20 CFR.

§ 101.1406 Right to judicial review.

To the extent authorized by section 1159(b) of the Act, a party to a decision of the Appeals Council (see section 404.960 of 20 CFR), or the decision of an Administrative Law Judge where the request for review by the Appeals Council was denied, may obtain a court review where the amount in controversy after Appeals Council review is $1,000 or more, by filing a civil action in a district court of the United States in accordance with the provisions of section 205(g) of the Act (see § 422.210 of 20 CFR for filing procedure).

[FR Doc.77-2228 Filed 1-24-77;8:45 am]