



Recommendation 89-1

Peer Review and Sanctions in the Medicare Program

(Adopted June 15, 1989)

As the Administrative Conference noted in Recommendation 86-5,¹ the Medicare program relies heavily on implementation of federal requirements by localized carriers, intermediaries and, increasingly, peer review organizations (PROs).

The PRO system was created in 1982. It is made up of state-wide, physician-controlled organizations under individual contracts with the Department of Health and Human Services (HHS). These contracts are negotiated pursuant to a general contractual "Scope-of-Work" promulgated by HHS every three years. PROs are delegated a number of important responsibilities under the Medicare system. They identify substandard, unnecessary or inappropriate services rendered to Medicare beneficiaries, and oversee education and corrective actions for substandard providers (e.g., hospitals) and medical practitioners. They also recommend to HHS that it sanction providers and practitioners when they find seriously improper practices, deny Medicare payment for inappropriate or unnecessary services, and protect the rights of beneficiaries.

This recommendation follows the suggestion made in Recommendation 86-5 that the PRO program was deserving of further study. It recognizes the evolutionary nature of the PRO's role in Medicare, and the administrative difficulties posed for HHS in overseeing this decentralized program—especially since new legislative directions affecting the program appear regularly, often contained in year-end omnibus budget reconciliation acts. Nevertheless, the Conference urges the Department (and, where necessary, Congress) to make changes designed to improve the accessibility of PRO-related policies, the fairness and firmness of PRO sanctions imposed on providers and practitioners, and the effectiveness of PRO safeguards for beneficiary rights.

In Paragraph A of the Recommendation, the Conference urges several enhancements of HHS' current practices in disseminating, making accessible, and soliciting comments on, PRO program guidelines of general applicability, including the scopes of work, manuals, and the criteria and norms used to evaluate medical care. Paragraph B seeks to promote improvements

¹ ACUS Recommendation 86-5, *Medicare Appeals*, 1 CFR 305.86-5.



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in the PRO's assigned duty of investigating complaints by beneficiaries, and urges Congress to allow PROs to act in response to oral complaints.

Paragraph C recommends invigorating the process of investigating and adjudicating sanctions against health care practitioners and providers charged with violations of their obligations under the Medicare program. The current sanction process begins when a PRO gives formal notice to the practitioner or provider involved that it considers that poor quality care may have been rendered or that other violations have occurred. The PRO is required to have at least one quite formalized meeting with the practitioner or provider to discuss the allegations that the care rendered either "failed in a substantial number of cases substantially to comply" with the statutory obligations to render proper medical care, or "grossly and flagrantly violated such obligations in one or more instances." 42 U.S.C. 1320c-5(b). (In the former type of case, at least two meetings are required.) If, after the meeting, the PRO believes violations have occurred, it recommends to the HHS Office of Inspector General (OIG) that a sanction be imposed, either in the form of an exclusion from participation in the Medicare program for some period of time, or a civil monetary penalty of no more than the amount of the cost of medically improper or unnecessary services. If the OIG agrees that violations have occurred, and in addition finds that the practitioner or provider is unwilling or unable to comply with the obligations to render proper care, the OIG may impose one of these sanctions. If the sanction is exclusion, it becomes effective fifteen days after notice.² The sanction is appealable to an ALJ, then to the Appeals Council; judicial review is subsequently available.

This recommendation seeks to balance the vital interest in protecting the health and safety of program beneficiaries and the need to assure fairness to the accused provider or practitioner whose livelihood is at stake and whose services might be needed. The Conference urges the streamlining of the current PRO sanction process. It also urges permitting all providers and practitioners, not just some to seek a stay of an HHS order to exclude them from the Medicare program, in a proceeding akin to that of a temporary restraining order at the administrative law judge adjudication stage of that process. However, the burden would be on the practitioner or provider to show that no serious risk would be posed to beneficiaries during the pendency of the administrative appeal. The Conference also urges changes that, while maintaining the requirement that the OIG prove that violations have occurred, would eliminate the additional requirement of proving that the practitioner or provider is unwilling or unable to comply with

² Certain practitioners in rural areas are permitted to have the exclusion stayed, pending OIG proof that the practitioner would pose a "serious risk" to program beneficiaries if allowed to remain in the program during the pendency of the administrative appeal.



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the obligations to provide quality care. The offenses or oversights, which have been found both by peers (PROs) and regulators (OIG) to be substantial or gross and flagrant, already serve as indicators of inability or unwillingness to comply. Under the current law, before excluding a provider or practitioner on the basis of these findings, the government must bear an additional evidentiary burden that is inappropriate for this type of proceeding. It must prove what amounts to a speculative negative—that violators would be unwilling or unable to comply with the law in the future. The apparent result of this evidentiary requirement, has been to chill the initiation of exclusion proceedings against providers and practitioners who are providing improper care or otherwise violating the law. Further, the Conference recommends legislative changes to provide for meaningful civil money penalties, as well as for the current sanction of excluding providers and practitioners from the program. It should be noted that the Conference views the changes in the sanction procedure contained in this paragraph as a unified package, one that in its present form balances conflicting interests but that will become unbalanced if any one significant portion were not to be accepted.

Paragraph D urges changes in the PRO statute and regulations to ensure that beneficiaries are better informed of their rights to appeal decisions concerning their lack of coverage or discharge from a hospital or other facility, and that they will not be discharged until such appeals are resolved. Paragraph E covers the PRO's role in denials of payment for care determined to be unnecessary, substandard or rendered in an inappropriate setting. It recommends that HHS implement in final -rules 1985 legislation concerning PRO denials for substandard care.³ It also urges HHS to amend its rules to require that PROs not make any final decisions affecting payment without adequate review by medical practitioners who are qualified in the relevant area. Finally, Paragraph F urges HHS to take steps to permit PROs to share information with provider facilities and state medical boards.

Recommendation

A. Publication and Dissemination of PRO Program Guidelines

1. HHS should enhance its current practice of publishing and disseminating all Peer Review Organization (PRO) program rules having a substantial effect on providers, medical practitioners and beneficiaries by taking the following steps:

³ On January 18, 1989, HHS published a proposed rule covering this subject. 54 FR 1956.



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(a) Notice-and-comment procedures should be used for rulemaking except when the agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.⁴

(b) Proposed PRO "scopes of work" and any generally applicable modifications or interpretations of the responsibilities of PROs during a contract cycle should be published in the Federal Register and disseminated to relevant interest groups. Interested parties should be allowed 30-45 days of commenting, unless explicit Congressional deadlines would be contravened thereby, or unless there is good cause for immediate implementation.

(c) HHS should make PRO contracts, manual instructions, and other guidelines of general applicability regarding the PRO program readily available to the public at convenient locations, including social security offices. HHS should publish an updated list of such materials in the Federal Register at least quarterly.

2. HHS should encourage PROs to use outreach and consensus-building techniques analogous to negotiated rulemaking when they are developing criteria and norms for PRO review of the quality, necessity and appropriateness of medical care.⁵ HHS should further encourage PROs to make these criteria and norms consistent nationwide.

B. PRO Investigations of Beneficiary Complaints

1. Congress and HHS should coordinate the system of PRO review of beneficiary complaints concerning quality of services with other federal and state regulatory schemes. Initially, priority consideration should be given to complaint investigations in the hospital setting, where PROs have the most expertise and where alternative means to investigate complaints are least available.

2. Congress should amend 42 U.S.C. 1320c-3(a)(14) to permit PROs to investigate and otherwise act on oral complaints concerning the quality of services. Until it does so, HHS should require PROs to receive such oral complaints from beneficiaries or witnesses, and reduce them to writing, before acting on them.

3. HHS should require PROs to use investigative techniques that, so far as may be feasible, protect from disclosure the identity of complainants who do not expressly and voluntarily

⁴ See ACUS Recommendation 83-2, *The "Good Cause" Exemption from APA Rulemaking Requirements*, 1 CFR 305.83-2

⁵ See ACUS Recommendations 82-4, 85-5, *Procedures for Negotiating Proposed Regulations*, 1 CFR 305.82-4, 85-5.



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consent to such disclosure. Where the identity of a complainant who desires anonymity cannot be kept confidential, the PRO should give the complainant the option of withdrawing the complaint in lieu of disclosure, although the PRO may at its discretion continue to investigate the underlying problem.

4. HHS should amend the PRO Scope of Work to conform to the 1986 Omnibus Budget Reconciliation Act by requiring PROs to inform beneficiaries fully regarding the final disposition of all complaints, whether involving providers or practitioners. PROs also should be required promptly to inform providers and practitioners of the final disposition of investigations involving them.

5. HHS should establish guidelines and a significantly more expedited schedule than the current several-month process for PROs to complete initial investigations of complaints of potentially life-threatening quality deficiencies. HHS also should establish procedures for receiving and acting on requests for intervention in cases where PROs do not process complaints on a timely basis.

C. Sanctions Against Providers or Practitioners Who Have Provided Improper or Unnecessary Services

Congress should streamline the sanction process by taking the following interrelated steps to promote heightened enforcement, while preserving fairness to the accused provider or practitioner.

1. HHS should seek to ensure greater uniformity among PROs through training and the development of a model sanction referral form. To preserve needed healthcare resources, HHS and the PROs should continue to emphasize education and corrective action rather than sanctions as the primary means of addressing quality problems. HHS should also amend its rules (a) to require that, once a PRO determines that there is a quality problem for which a sanction is the appropriate intervention, it immediately start the sanction process, and (b) to provide that, ordinarily, there will be only one formal meeting between the PRO and the accused provider or practitioner after the sanction proceeding has been initiated.

2. Congress should amend the PRO statute to offer all providers and practitioners (urban and rural), upon their receipt of an HHS notice of exclusion pursuant to 42 U.S.C. 1320c-5(b), the opportunity for a preliminary hearing and decision. Such a proceeding would be conducted by an ALJ on the issue of whether the provider or practitioner would pose a serious risk to patients



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during the pendency of the subsequent ALJ proceeding on the merits of the exclusion. The preliminary hearing would be in the nature of a temporary restraining order proceeding, and would arise and be conducted according to the following procedures:

(a) If, within 10 days of receipt of notice of the exclusion, the provider or practitioner appeals the decision of the HHS Office of Inspector General (OIG) imposing an exclusion, a preliminary hearing on the "serious risk" issue should take place before the exclusion takes effect.

(b) If the provider or practitioner establishes at the preliminary hearing that continued participation in the Medicare program pending the ALJ's decision on the underlying appeal will not pose a serious risk to patients, or that such participation can be restricted to preclude such risk, the HHS exclusion order shall be stayed or modified by the ALJ until the ALJ issues a final decision on the merits of the exclusion.

(c) The ALJ must render the preliminary decision on the "serious risk" issue as quickly as possible but within no more than 30 days after the filing of the appeal, and a final decision on the exclusion within a time period reflecting assignment of the highest priority to the adjudication.

3. Congress should retain the requirement in 42 U.S.C. 1320c-5(b)(1) that sanctions be based on determinations that a practitioner or provider has either (A) "failed in a substantial number of cases substantially to comply" with statutory obligations to render appropriate and quality care, or (B) "grossly and flagrantly violated such obligations in one or more instances." However, Congress should eliminate the separate and additional requirement in 42 U.S.C. 1320c-5(b)(1) that the OIG must determine the provider's or practitioner's "unwillingness or lack of ability substantially to comply" with program obligations before imposing sanctions on the provider or practitioner.

4. Currently the PRO statute [42 U.S.C. 1320c-5(b)(3)] limits monetary penalties to "the actual or estimated cost of * * * medically improper or unnecessary services." In order to provide for a wider range of sanctions, Congress should amend the PRO statute to allow the OIG to assess a substantial civil money penalty for each violation against providers and practitioners who are found to have grossly and flagrantly violated their obligations on one or more occasions, or to have substantially violated such obligations in a substantial number of cases. The OIG should be given the discretion to impose such monetary penalties in addition to an exclusion where appropriate.



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5. HHS should assign PRO sanction cases to ALJs attached to the Departmental Appeals Board (who currently hear other sanction cases in the Department) rather than to Social Security ALJs, as is the current practice.

D. Notice to Beneficiaries of Noncoverage

1. Congress should amend 42 U.S.C. 1320c-3(e)(3) to assure hospitalized beneficiaries that appeal the hospital's notice of noncoverage by noon of the day following receipt of the notice, should not have such coverage discontinued until the PRO rules on their request for review.

2. HHS should amend the PRO regulations to assure that, at the time a hospital informs beneficiaries of its decision to discharge them or of the discontinuance of coverage, they are informed of their discharge appeal rights under the PRO program.

3. The notice of a right to appeal should be on a form drafted by HHS (developed in consultation with beneficiary organizations and other interested parties), and should include a concise and easily understood statement of the basic beneficiary right to a no-liability appeal to the PRO. If the current system of separate appeal tracks (depending on whether the hospital and attending physician concur or not) is retained, separate notices should be given for each track to avoid the confusion caused by a notice that describes multiple procedures.

E. PRO Denials of Payment for Substandard or Unnecessary Care

1. HHS should proceed expeditiously to final rulemaking to implement PRO authority contained in 42 U.S.C. 1320c-3(a)(2), to deny payment to practitioners or providers for care that does not meet professionally recognized standards.

2. HHS should require by regulation that PROs not make final utilization review denials (denials of payment for care that has been determined to be unnecessary or rendered in an inappropriate setting) until a proposed denial and the response to it by the affected provider or practitioner have been reviewed by at least one practitioner qualified by professional training and experience relevant to the matters in controversy. Although HHS should at a minimum apply the same standard to reviews of denials of payment for failure to meet professional standards of care, it may be appropriate in this context to require that the review be performed by a physician practicing in the same care specialty.



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F. PRO Sharing of Information

1. HHS should issue PRO manual instructions and amend the Scope of Work in order to implement the Congressional mandate requiring the sharing of information among the PROs and state medical boards and licensing authorities regarding practitioners and providers who violate quality standards, and should modify its current confidentiality and disclosure regulations to require that a copy of any PRO final sanction recommendation be provided to such bodies. HHS should explore the feasibility of including sanction recommendations in the National Practitioner Data Bank.

2. HHS should amend PRO regulations to require PROs to share with hospitals information about confirmed violations of quality of care standards involving doctors on the staffs of such hospitals, including the contents of corrective action plans.

Citations:

54 FR 28965 (July 10, 1989)

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