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P/S/R/O Update

From Boston University Medical Center

Foundations Submit Four Planning, Two Conditional PSRO Proposals

The five Foundations for Medical Care in Massachusetts have submitted their proposals for formation of Professional Standards Review Organizations in the state to the Department of Health, Education, and Welfare's Office of Professional Standards Review.

Applications for conditional status were completed by the Bay State Foundation for Medical Care and the Charles River Health Care Foundation. Conditional contracts require an organization to implement a system for reviewing the quality, necessity and appropriateness of medical care provided Medicare, Medicaid and Maternal and Child Health program beneficiaries. Among other requirements, conditionally-designated organizations must demonstrate a membership comprised of at least 25 per cent of the physicans in the PSRO area.

Four foundations submitted applications for planning status — the Health Care Foundation of Western Massachusetts, Central Massachusetts Health Care Foundation, Pilgrim Foundation for Medical Care and Charles River Health Care Foundation. Planning contracts require a group to design a formal plan for assuming the duties and functions of a PSRO. Applicants must demonstrate the capability of obtaining membership by at least 25 per cent of the physicians in their areas prior to conditional designation.

The Charles River Foundation thus submitted proposals for both conditional and planning designation. It clearly prefers conditional status, but completed a planning proposal in the event that rejected conditional proposals would not automatically be considered in the planning category. The other conditional applicant, Bay State Foundation, appeared willing to gamble that a fallback proposal would not be necessary.

Initial decisions on acceptability of PSRO proposals were slated for about May 20, with financial negotiations between the federal government and the PSROs immediately thereafter.

Commonwealth Institute Proposes Support-Center Designation

The Federal Office of Professional Standards Review is currently weighing a proposal from the Commonwealth Institute of Medicine under which CIM would establish a PSRO Support Center for Massachusetts.

In an interesting regional approach to the PSRO program, the proposed PSROs of Vermont and Rhode Island have formally requested CIM to serve as their Support Center as well. Development of a similar relationship with the PSROs of New Hampshire and Maine are also under discussion. CIM is believed to be the only proposed Support Center that would offer its expertise to out-of-state PSROs on such a basis.

The CIM Support Center role has been foreshadowed by the organization's year-old Commonwealth Hospital Admissions Monitoring Program, better known as CHAMP. In anticipation of the passage of the PSRO statute, CIM had developed this program of monitoring utilization of acute inpatient care, and CHAMP was implemented by contract between CIM and the Commonwealth of Massachusetts last July.

CIM, formally organized by the Council of the Massachusetts Medical Society in 1972 to continue studies launched by MMS in 1969, has been concerned with the development of workable programs for the evaluation of cost-effectiveness and the quality of medical care systems. In line with this interest, CIM has aimed to implement such programs in concert with other organizations by developing guidelines for evaluation of medical care and acting, where appropriate, as a nonpartisan liaison among the medical community, insurers and the government. CHAMP has formalized this expressed goal of CIM, and is presently

(Please turn to pg. 4)

PSRO Update is published by Boston University Medical Center to update Massachusetts physicians on the development of Professional Standards Review Organizations (PSROs) and related trends in the practice of modern medicine. Publication is supported by a grant from the Tri-State Regional Medical Program for technical assistance and continuing education in the planning and development of PSROs

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Samuel Stewart, M.D., president
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PSRO Manual Defines 'Concurrent Admission Certification'

Section 705.13 of the ***PSRO Manual*** contains the following information about concurrent review of hospital admissions:

Admission certification will be performed during the initial portion of the hospital stay (concurrent admission certification). At the option of the PSRO, admission certification for elective admissions can be performed prior to admission. . . . When performing concurrent certification for elective and emergency admissions, the initial screening review will occur within the first working day following admission. For elective surgery, certification should be confirmed before surgery is performed. If the admission is certified as medically necessary, an initial length of stay will be assigned. Medicare and Medicaid payment terminates at the end of this period unless recertification takes place. . . . If, however, review indicates that admission is not medically necessary, the attending physician will be notified within two working days of admission in order to afford him an opportunity to present his view prior to the point when a final determination is made. If the final determination is that the medical necessity for the admission has not been shown, the review committee shall verbally notify the hospital, the patient, the attending physician, and, in the case of a Medicaid patient, the State agency, within two working days following admission. Written confirmation of the committee's decision must be sent to the patient, the attending physician, the institution, and in the case of a Medicaid patient, to the Medicaid State agency or its designee, or, in the case of Medicare, the Medicare intermediary, as soon as possible thereafter.

New and Quotable

some things being said about PSRO

"Except for a few MD administrators who participate in foundation and institute activity and account for 10% of those invited to join, the physicians of Massachusetts have concluded that PSRO is a bad law and is unworkable. . . . Although ***Massachusetts Physician*** believes that PSRO is a poorly framed law unacceptable to both physicians and their patients and is an embarrassment to its sponsor, we will offer possible amendments designed to remove a few of the most objectionable features. . . . We commend [eight suggested amendments] to our readers and suggest that all physicians work with vigor and dedication for repeal if the law is not appropriately amended."

Editorial, *Massachusetts Physician,* March, 1974

"I don't think repeal is the issue. The issue is what is the system of quality review that this country is going to have; not whether there is going to be one. If we repeal PSRO and then sit down and ask what kind of system we are going to set up that would be responsible to the public, the profession would design a system like PSRO. . . . It gives the professional the responsibility, it gives him the resources to do the job, and it eliminates nonprofessionals from medical judgments. I don't know what else the profession could ask for, frankly. If you don't agree you need a system, then, of course, you have a very basic problem. I think most of the profession is years past that."

Henry E. Simmons, M.D.
Director
Office of Professional Standards Review
in *American Medical News,* April 1, 1974

"Peering dimly into the future. . . .we can discern what sort of peers will do the peer review. We predict that they will constitute a new nobility (authority without peer), peering into the public records of patients written by physicians whom they no longer regard as their peers. An essentially malignant process, this cancer will be lethal and PSRO will die because the wrong definition of the key noun came to prevail."

Francis D. Moore, M.D.
in "Peer Review and All That,"
an editorial in *Archives of Surgery,* April, 1974

Focus: On Dealing with Federal Agencies

by Jean Rabinow, J.D.

(The author is a research associate in health-services research, Boston University Medical Center, and a member of the technical-assistance component of BUMC's grant from the Tri-State Regional Medical Program for PSRO development. The following is offered as an introduction to some of the issues involved in implementation of the PSRO law and does not constitute legal advice. — Editors)

You may not be able to fight city hall, but you can certainly give any government bureaucracy a run for its money. The trick is in knowing how. The following is a simplified guideline for dealing with the executive agencies of the United States.

Unlike legislation, which is drafted more or less openly and is subject to open vote, regulations are usually drafted by one or two civil servants, passed through the bureaucratic chain of command, and put into nearly-final form before they are made available for public inspection and comment. In the federal bureaucracy, this procedure — drafting, then comment, then promulgation — is regulated by law, and the only time the law encourages the participation of those affected is during the comment period, which normally must be 30 days but which can be — and on occasion is — extended. The comment begins when the government agency (e.g., HEW) publishes a notice of Proposed Rulemaking in the ***Federal Register,*** and ends on the date given in that notice.

To avoid charges of bribery and undue influence, federal bureaucrats are not supposed to ever give consideration to oral communications other than those made at an agency hearing. Once the comment period has started, therefore, any objections you may have should be reduced to writing and sent to the agency involved; mailing addresses will be included in the original notice in the ***Federal Register.***

If you do not communicate your objections to the agency in the proper manner at the proper time, it becomes much harder to win a lawsuit against that agency if the agency goes ahead with whatever regulation you find objectionable and you stay angry enough to sue.

More immune. The agency, it should be noted, is under no obligation to agree with your point of view even if you state it properly. In theory, agencies should be less amenable to public pressure than are legislatures, because legislators have to win elections and civil servants don't. In fact, however, bureaucrats are as likely as legislators (if not more likely) to be persuaded by rational arguments, especially when the argument can be backed up with hard data. Comment periods should be regarded as a time for constructive criticism and used to the fullest possible extent.

Comment periods also provide you with an opportunity to write to your senators and representative, if you feel that that would be productive. The legislators can do nothing directly, but they can and do make their concerns known to agency staffs, who may or may not be receptive. Alternatively, you may be able to take your story to area newspapers. Comments in medical journals, while they help keep your peers informed, will not be as likely to have any effect on the bureaucracy. The more publicity you can generate during the comment period, the more likely you are to have some effect on the regulations' final form.

Once a regulation is published in final form, it has the force of law unless a court finds it invalid, the agency changes its mind, or Congress changes the law under which it was first authorized. If you still disagree with a regulation after it has been published in the Rules and Regulations section of the ***Federal Register***, your only option is to try to influence one of those three processes — either by filing suit, petitioning the agency, or lobbying in Congress, all of which are expensive and time-consuming activities.

In short, it pays to watch the ***Federal Register*** or subscribe to a service that will watch it for you, evaluate proposed regulations as they apear, and comment quickly and vigorously on those with which you disagree. If you or your organization does this, the regulations themselves are less likely to come as an unpleasant surprise.

At the moment, the technical-assistance group at Boston University Medical Center is acting as ***Register***-watcher for developing PSROs in Massachusetts. Through ***PSRO Update*** and other means, the group is attempting to provide "non-legalese" translations of regulations and proposed regulations. For further information on this activity, please contact the PSRO technical-assistance group at (617) 262-4200, extension 5527.

CIM as Support Center . . .

(continued from pg. 1)

in effect for all Title XIX beneficiaries in Massachusetts. It is seen in many quarters as "a preview of PSRO" in which local review and autonomy have been emphasized, with CIM providing the technical and administrative assistance to local organizations functioning in the place of PSROs.

At present, 65 CHAMP Utilization Review Coordinators, employees of CIM, conduct daily concurrent-review studies in 126 acute-care hospitals in Massachusetts. By June, it is anticipated, the program will be implemented in every such institution in the Commonwealth.

Stimulate and Support.

In its Support Center proposal, CIM notes that it will continue to stimulate and support the development of the PSRO program and local PSROs in line with the intent of Congress and policies of the Secretary of Health, Education, and Welfare, since it has already been geared up for the same objectives in an intensive fashion under the CHAMP program.

In carrying out its programs of education for physicians, hospitals and public agencies in the areas of peer review, quality of care, utilization review and data problems, CIM has employed speeches, symposia, correspondence and meetings, large and small, between CIM resource persons and senior staff of PSRO-involved groups around the state.

Building on the core support activities it already has in operation, CIM proposes to formalize and fully staff these activities and expand them in the following ways:

- **Physician Workshops.** The single most important element in the methodology of the Support Center would be a series of local workshops, supplementing those which have already been conducted, aimed at informing individual physicians about the nature of the PSRO program, its objectives and rationale. The stress on this educational mode lies in its face-to-face setting, which will give ample opportunity for question and answers.
- **Leadership seminars.** Such seminars, to be held in centrally-located areas, would deal with major policy and technical issues confronting PSRO board members, executive staff, committee chairmen and members and would employ as resource persons experts in organizational planning, development and recruiting.
- **Monthly newsletter.** The CIM proposal notes that it is essential in the early days of PSROs that timely information be made available to physicians about the changes taking place nationally and locally with regard to PSROs. To this end, ***PSRO Update***, now published monthly by Boston University Medical Center with funding from the Tri-State Regional Medical Program, would be funded by the Support Center. In addition, the Support Center will provide special informational mailings to accompany the newsletter, directed specifically to the physician members of the individual PSROs.
- **Educational materials.** Another component of the Support Center's educational program would be the development and distribution of educational materials for individual physicians. Such materials would include summaries of HEW guidelines, monographs on special subjects, programmed self-instruction texts and audiovisual tapes and films. Some of these materials (for instance, the programmed texts) would be distributed to all physicians in the region, while others (audiovisual materials) would be placed in locations where physicians have enforced "leisure" time, such as surgical dressing lounges and delivery area lounges, as well as hospital libraries and local medical-society and PSRO offices.
- **Information "Hotline."** Anticipating that physicians will still have many questions, despite the educational materials, workshops and the newsletter, the CIM Support Center would provide a toll-free "hotline" to give quick and concise information about PSRO affairs. CIM notes that such a service is particularly essential during the initial six months of PSRO organization. The information line would be staffed approximately six hours per day by information specialists at the Support Center headquarters.

CIM envisions three principal areas in which the Support Center would expect to provide assistance to prospective PSROs: (1) specific technical and developmental assistance to the individual PSROs; (2) general support in statewide and regional policy-making and research; (3) technical aid to the statewide PSRO Council.

To provide assistance to the individual PSROs, the Support Center has set itself five basic tasks: establishment of formal regulations between the PSROs and their area hospitals; development of a formal review plan; development and adoption of norms, criteria and standards; development of plans for data collection; and supplemental activities, such as the training of nonprofessional review assistants and continuing education for physicians.

Flexibility and humanity.

In the area of general support on a statewide and

regional basis, the Support Center would act to abate the "real-world" practical difficulties that the peer-review process is likely to generate. A major concern cited by CIM is the desire to preserve flexibility and humanity in the delivery of government-financed medical services, while introducing a new degree of fiscal and medical rigor, all of which would result in a cost-effective and beneficial medical-care system.

The Support Center, in line with these goals, would serve as a fiscal-medical interface, monitoring various means of peer review and offering comparative studies to document the differential effects after set periods of time.

Also important to the statewide and regional PSRO picture, CIM feels, is the emphasis on medical education/review mechanisms; integration of data among the various PSROs; expansion and further development of review activities for long-term care facilities and mental institutions, as well as ambulatory care; evaluation and special studies; and the development of relationships with other health-related state and federal agencies.

The importance of the State PSR Council is underlined by the CIM's belief that at least three conditionally-designated PSROs will be in operation in Massachusetts within a year. The Support Center would coordinate and integrate its efforts with those of the State Council to bolster the Council's major role of aiding these groups while simultaneously helping the remaining planning PSROs to achieve conditional status.

Egdahl Suggests Working Relationship Between Commonwealth Institute and BUMC

In a letter to Dr. H. Thomas Ballatine Jr., president of the Commonwealth Institute of Medicine, Inc., the director of Boston University Medical Center has endorsed CIM's efforts to establish a statewide Professional Standards Review Organization Support Center. Dr. Richard H. Egdahl also suggested potential areas in which the Medical Center might appropriately undertake activities on behalf of CIM.

BUMC is one of the few academic health centers in the nation providing active technical and educational assistance in the planning and development of PSROs.

Egdahl's letter follows:

Dear Dr. Ballantine,

On behalf of the Boston University Medical Center, I would like to offer our support and endorsement to the Commonwealth Institute of Medicine in its efforts to establish a statewide Professional Standards Review Organization Support Center. We believe that this effort by the Commonwealth Institute of Medicine will be a valuable contribution towards improving medical care in the state.

Further, I would like to indicate the willingness and availability of the staff of the Boston University Medical Center to undertake through appropriate administrative arrangements any or all of the following activities for the Commonwealth Institute of Medicine:

- PSRO education programs for physicians, including speeches, workshops, development of educational materials, etc;
- assistance in the development of contract and grant applications related to PSRO activities;
- assistance in developing PSRO managerial and fiscal structures.
- legal assistance related to corporate structures, voting procedures, bylaws, and confidentiality procedures;
- assistance in the methodological development, testing and evaluation of medical care criteria and standards for short-stay and long-term-care hospitals, reliability and validity of review procedures and in-house review evaluation mechanisms.

These are the areas we believe we are capable of being helpful with in your potential plans for operation of a statewide Support Center.

If there is any further way that we can be of assistance to you, please do not hesitate to contact me. Our best wishes and support in your efforts to undertake this important Support Center program.

Very sincerely yours,

Richard H. Egdahl, M.D.
Director
Boston University Medical Center

Pennsylvania Group Garners Milestone PSRO Contract

The Pennsylvania Medical Care Foundation has received the first contract awarded by the federal Office of Professional Standards Review.

The Pennsylvania group was awarded $243,000 to become the PSRO Support Center for the Quaker state. The board of the foundation consists of 13 medical-society representatives, as well as representatives of the Pennsylvania Osteopathic Medical Association, the Pennsylvania Hospital Association, Blue Cross, Blue Shield; in addition, four individuals were appointed by the state government.

The initial application period for PSRO planning, conditional and Support Center contracts ended April 30. As this issue went to press, it appeared that about 100 planning, 20 conditional and 15 Support Center applications had been elicited.

National Health Insurance: Kennedy Retreats, Joins with Mills

Passage of a national health-insurance program may be closer as the result of a new bill introduced by two major Congressional leaders, Sen. Edward M. Kennedy (Dem. - Mass.) and Rep. Wilbur D. Mills (Dem. - Ark.)

Introduction of the Kennedy-Mills package ("Comprehensive National Health Insurance Act") enhances passage of some form of national health insurance, since many elements of the political spectrum seem to be moving toward a centrist kind of legislation. In many ways, the Kennedy-Mills bill closely resembles a proposal ("Comprehensive Health Insurance Program") submitted a few months ago by the Administration. (See ***PSRO Update No. 2.)***

The Nixon bill calls for compulsory employer participation, while individuals would take part voluntarily. It also includes federal assistance for high medical-risk families with incomes under $7,600, and Medicare for those over 65. Estimated "new" cost to the federal government for the Nixon approach is $6 billion.

The Kennedy-Mills bill is more sweeping, although not nearly as broad as the Health Security Act formerly sponsored by Kennedy and Rep. Martha W. Griffiths (Dem. - Mich.) and backed by many elements of organized labor.

Kennedy-Mills mandates compulsory participation by all individuals, except those covered by Medicare, under a program that establishes broad benefits and would be paid for through payroll taxes and general revenue. Its initial cost is estimated at $6.1 billion.

The compromise bill would mandate a plan to be administered through a new, independent Social Security agency. While premiums would be paid through taxes, private insurers would act as financial intermediaries, as they now do for Medicare. **A role for the private insurers is a major area of compromise for Sen. Kennedy.** The Health Security Act provided for total operation by the federal government.

For all services, except preventative care, families would be responsible for the first $300 of medical bills annually, and 25 per cent of the remainder — up to a family limit of $1,000. **Inclusion of a copayment feature in Kennedy-Mills represents another major retreat for Kennedy.** The Health Security bill and the Massachusetts senator's own previous public statements adamantly called for an insurance program that would provide comprehensive health services from cradle to grave — without copayments.

The cost-sharing feature would be linked to income in care of the poor. Supporters of the Health Security bill criticize the means test that would be required to designate those individuals and families who would have reduced copayments under the Kennedy-Mills bill.

National Health Insurance: Implications for PSRO

As the Congressional debate over national health insurance begins its Springtime perking, it appears that three proposals occupy legislative center-stage — those submitted by the Nixon Administration and by Kennedy and Mills (see above), and a third, submitted last Fall by Sens. Russell B. Long (Dem. - La.) and Abraham A. Ribicoff (Dem. - Conn.) The latter features a benefits package designed to protect against expenses involved in catastrophic illness.

The three major proposals differ in their approaches to benefits, payments and copayments, roles of intermediaries, cost-sharing, administration and the like. But they share remarkably their approach to the issue of quality control: **Any proposal for national health insurance likely to reach a Congressional vote will undoubtedly incorporate the PSRO concept and provisions of existing PSRO law to provide for peer review of at least all inpatient hospital services.**

Two Academic Centers Join To Support Training Proposal

Transcontinental cooperation is the password as the American Association of Foundations for Medical Care Institute for Professional Standards enters its bid to become the national training site for key PSRO personnel. Boston University Medical Center, in conjunction with the Commonwealth Institute of Medicine and the Harvard School of Public Health, has joined with the University of the Pacific to support the AAFMC in its proposal to the Office of Professional Standards Review.

If the Institute for Professional Standards proposal is funded, Boston University and the University of the Pacific would become curriculum-development centers for the project, and any of the five PSROs in Massachusetts might become a field-training site for future groups of PSRO directors who participate in the program.

Focus: Quality Assessment and PSROs

by Daniel S. Bernstein, M.D.

(The author is Boston University Medical Center's program director for postgraduate medical education and Boston University School of Medicine's associate dean for hospital affiliations. He is also project director of the educational component of the Medical Center's grant from Tri-State Regional Medical Program for PSRO development in Massachusetts — Editors)

With the initiation of PSROs, an unusual opportunity has been presented to physicians to begin to measure the quality of medical care on a broad basis. While the PSRO law does not mandate quality-assurance programs directly, it is reasonable to expect that the data that will be collected concerning hospital and physician care will provide a fertile field for study.

The basic principles of a quality-assessment system should include:

- The collection of uniform, reliable statistical data that measure the performance of the hospital and physician as well as the results experienced by the patient;
- Careful study and interpretation of these data against pre-established criteria and standards of care;
- Eventually, return of the results to the physician and hospital;
- Institution by the PSRO "Committee on Medical Education" as well as the hospital utilization-review committee of appropriate methods to produce desired changes.

These tasks will not be easy to perform, but they are not overly complicated either. The federal government has published a guide to the establishment of a uniform hospital-discharge abstract for hospitalized patients.* The suggested abstract details such data as age, sex, race, place of residence; diagnoses; procedures; length of stay; condition of the patient at the time of discharge; and physician or physicians responsible for care of the patient. Analysis of these types of data would begin to provide information concerning utilization rates, length of stay, and case-fatality rates. Installation of this type of system can be easily coupled with a series of routinely performed studies of selected conditions where both the process as well as the outcome of care can be derived. Such studies have already been initiated by many hospital utilization-review committees in Massachusetts.

With the establishment of quality assessment studies in individual hospitals coordinated by the PSRO medical audit committee, physicians will begin to resolve some of the most basic questions regarding their care of patients. These studies will provide for an analysis locally, regionally and across the country of our present system for medical treatment. As well, quality assessment will provide for the development of acceptable criteria and standards of care by physicians. And, most important, it will provide an assessment of programs designed to improve the performance of physicians and hospitals and thus ensure the provision of high-quality health care.

*Uniform Hospital Discharge Abstract. Minimum Basic Data Set. Department of Health, Education, and Welfare Pub. No. HSM 73-1451. Rockville, Md.: National Center for Health Statistics, 1972.

Membership in PSRO Necessary for Hospital-Based MDs?

Although membership in a PSRO is voluntary for the individual physician, a section of the ***PSRO Manual*** issued by the federal Office of Professional Standards Review would stimulate membership by hospital-based MDs.

Section 520.04 (c) (2) states: "An institution is eligible for PSRO delegation of review functions **only if a majority of physicians with active staff privileges are members of the PSRO** and are willing to participate in the PSRO's performance of its contractural responsibilities." (Emphasis added.)

Thus, if a hospital desires to have its utilization-review committee designated by the local PSRO as responsible for monitoring in that hospital, over 50 per cent of the "Active" staff physicians must be members of the local PRSO. Several questions remain:

- "Active" staff is nowhere defined in the ***Manual***.
- The ***Manual*** itself does not have the force of regulations, still to be released.
- Finally, this section implies that physicians can join more than one PSRO if their office and hospital practices are centered in different PSRO areas. This point requires further clarification.

Questions and Answers About PSROs and Foundations

In response to several requests, the following questions and answers about Professional Standards Review Organizations are being reprinted from ***PSRO Update No. 2:***

Q: Does the PSRO law mandate that physicians join a PSRO?

A: Public Law 92-603 states that PSROs must be nonprofit corporations, with membership open to any physician or osteopath in the geographically designated area. There are no associated dues or fees. To be designated as a "planning" PSRO, an organization must show evidence of the potential to represent at least 25 per cent of the physicians and osteopaths in the area. For designation as a "conditional" PSRO, an organization must actually represent at least 25 per cent of the physicians and osteopaths in its area.

The law also makes clear that, whether or not a physician or osteopath is a "member" of a PSRO, the PSRO will nevertheless monitor his care of Medicare, Medicaid and Maternal and Child Health patients.

Q: What advantages are there to joining a PSRO voluntarily?

A: Although no physician or osteopath must join a PSRO, it would be to his advantage to do so. The advantages include (1) involvement in committees that will establish standards of practice, criteria and retrospective audit; (2) involvement in appeals and policy decisions; and (3) involvement in contractural arrangements with the Department of Health, Education, and Welfare and other state and federal agencies.

Q: In Massachusetts, it appears that Foundations for Medical Care are actively engaged in forming the state's five PSROs. Must physicians join a foundation? If membership is voluntary, what advantages exist?

A: No physician must join a foundation, although, again, membership is clearly to his advantage, especially if the foundation in his area enters into contractural arrangements to monitor medical care with, in addition to the federal government, other third-party payers, such as Blue Shield/Blue Cross. (It should be noted that PSROs may also enter into such arrangements.) In addition, foundations may initiate HMOs and other group-practice approaches.

Q: Assuming that a physician's office and hospital practices overlap designated PSRO areas, to which PSRO(s) does the physician relate?

A: At the time of writing, no clear answer is available. Federal regulation eventually will provide the answer.

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