PSROs AND FEDERAL CIVIL IMMUNITY:  
A BRIEF ANALYSIS

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The 1972 Bennett Amendment1 to the Social Security Act established Professional Standards Review Organizations (PSROs) as a review mechanism to promote both cost- and quality-control in the Medicaid and Medicare programs. The stated goals of this amendment were to insure that Medicaid and Medicare services that were provided and subsequently reimbursed by the federal government were in fact "medically necessary"2 and rendered in conformance with "appropriate professional standards."3 The actual intent of the legislation, the structure of PSROs on the regional, state, and national level, and the procedures for promulgating norms, standards, and criteria for diagnosis and treatment, have been dealt with at length elsewhere;4 this paper will examine some of the legal implications of one specific provision of this important federal program, the so-called "civil immunity clause."5

This clause attempts to confer immunity from civil liability upon any health care provider who acts in compliance with or reliance upon the norms, standards, and criteria developed by a PSRO, as long as such person is in fact functioning in his role as a provider of health services and exercises "due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment"6 (emphasis added). Although to date no cases have been reported in which a defendant provider attempted to rely on this rather broad immunity provision, a good deal of legal discussion and speculation regarding its efficacy has been generated in the five years since enactment. This study will briefly examine some of the more important legal questions raised by the civil immunity clause.

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1. 42 U.S.C. Sec. 1320c to c-19 (Supp. IV, 1974).
5. 42 U.S.C. Sec. 1320c-16 (Supp. IV, 1974).
At the outset one must question whether the federal government can in fact preempt state tort law regarding negligence and medical malpractice. This is apparently the only important issue which has been presented squarely to the judiciary, and the court involved failed to resolve it. In Association of American Physicians and Surgeons v. Weinberger, the plaintiffs challenged the constitutionality of Congress' attempt to legislate immunity from common law tort liability, fearing that the purported immunity provision would be ineffective and that the promulgation of specific norms and standards for diagnosis and treatment would potentially subject them to an increased risk of liability in violation of the Fifth Amendment. Holding that the plaintiff physicians did not face the type of real or immediate threat of injury as would confer the requisite standing to sue, the court stated that Medicaid and Medicare beneficiaries would be the proper parties to bring such an action and thus specifically declined to rule on the constitutionality of the immunity clause. In its motion for summary judgment, the government had alleged, first, that Congress could in fact abolish common law rights or create new rights if it did so in pursuit of a permissible legislative objective; second, it had contended that the PSRO legislation met this test as a permissible attempt to provide for the "general welfare" under Article I, Section 8, of the Constitution, pursuant to both the taxing power and "necessary and proper clause" contained likewise in Article I, Sec. 8. Although technically still an open question since the court did not reach the merits of this point, it appears that the government would be able to defend successfully its usurpation of state common law tort liability.

A separate but related issue is raised by the "due care" proviso cited above, requiring that a provider use due care in all conduct "reasonably related to" reliance upon or compliance with PSRO norms of care. The interpretation given to this somewhat nebulous guideline could well determine the ultimate efficacy of the immunity clause, and there are at least three differing interpretations which might be applied. First, it could be argued by a plaintiff that the language "reasonably related to, and resulting from," etc., would mandate that a provider use due care both in selecting the appropriate PSRO standards of diagnosis and treatment and in actually carrying out the chosen treatment. This all-inclusive view of due care would render the statutory grant of immunity virtually meaningless and thus would not seem to comport with the intent of the legislation. At the other extreme, it might be argued that Congress intended the grant of immunity to supersede any common law notions of due care and that, accordingly, the protection afforded is absolute; that is, it would extend to the decision to follow a given course of treatment (in accord with PSRO norms and standards)

and to the actual treatment rendered. Again, however, this would not seem to reflect true Congressional intent, as it would obviate the inclusion of the due care proviso within the immunity clause and remove virtually all legal recourse for a plaintiff who had, in fact, been the victim of truly negligent treatment.

The third alternative, seemingly better-reasoned and espoused most often by commentators on the issue, is an intermediate position. Under this, the physician would still be charged with due care in the actual treatment given a patient, but would be accorded an irrebuttable presumption of non-negligence in diagnosis and selection of a course of treatment, if applicable PSRO norms and standards were followed. The caveat here is that the norms and standards chosen would in fact have to be applicable to the case in question; the plaintiff still might be able to show either that the initial diagnosis of his condition was entirely wrong, or that his particular case of a given malady was so atypical as to move it outside the range of established PSRO norms and standards. In either case, the protection of the immunity clause would be lost, as it assumes that compliance with accepted PSRO procedures is in fact justified compliance. This would seem to be the preferable view, in that it would provide complete immunity within the narrow sphere of a physician's justifiable choice of and reliance upon appropriate PSRO norms and standards of diagnosis and treatment, and yet would allow a plaintiff recourse for actual negligent treatment through a traditional common law malpractice action.

One commentator has approached the question of properly interpreting the due care proviso on a procedural basis. Like most writers on the subject, he too favors the intermediate alternative outlined above; since the presumption of non-negligence (within the well-defined sphere of PSRO compliance) would operate as a matter of law, he expresses the opinion that it could be brought up by the defendant via a motion for summary judgment. Such a motion would be heard by the judge before a trial on the merits, and to overcome the presumption, the plaintiff would be forced to show either that his particular case was misdiagnosed and did not fall at all within the PSRO standards applied by the defendant or was such an atypical case that it moved outside the ambit of normal treatment prescribed by the PSRO guidelines. This of course implies that the physician would be under an obligation to assess independently the patient's condition rather than merely adhering blindly to the PSRO criteria.

Using this approach, if the only issue before the court were the defendant's diagnosis and subsequent choice of a course of treatment under PSRO norms, and the plaintiff were unable to overcome the presumption of non-negligence...

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14. E.g., Carter, supra note 13, at 627-38.
15. E.g., Carter, supra note 13, at 627-38.
16. E.g., Carter, supra note 13, at 635-36.
17. E.g., Carter, supra note 13, at 635-36.
18. "The issue in a malpractice action brought against a physician who has acquiesced in the norm is not the validity of the norm, but whether a substantial minority of the profession would have independently determined that care in excess of the PSRO norms was not necessary .... If this cannot be established, the physician may not be able to raise successfully the immunity clause defense. On the other hand, when the physician has utilized all the review procedures and his requested treatment is disapproved in accordance with the norms, the effect of the immunity clause is to hold him to no higher standard of care than that established by the norm as applied to the particular case." Note, Professional Standards Review and the Limitation of Health Services: An Interpretation of the Effect of the Statutory Immunity on Medical Malpractice Liability, 54 B.U.L. Rev. 931, 935-36 (1974).
gence by either of the two above methods, the defendant should prevail on the motion for summary judgment. If, on the other hand, the case involved an allegation of lack of due care in performance of the diagnosis or treatment actually undertaken, lack of due care in applying PSRO norms to the plaintiff's own case, or failure to obtain informed consent, it should be allowed to be heard by the jury. The commentator who used this procedural analysis believed that it would be the most feasible means of preserving the primary functions of judge and jury under state law and yet complying with the statutory intent to provide complete immunity under certain circumstances.

A greatly simplified hypothetical example of the above might be seen in the case of a Medicaid or Medicare beneficiary who came to his physician with an earache. Let us assume that the physician diagnosed the condition as a minor ear infection and, pursuant to the applicable PSRO norm or standard, prescribed 500 units of penicillin (or another common antibiotic) daily. Further assuming that the particular drugs prescribed were not contraindicated by anything in the patient's medical history, what would happen if the patient's condition were in fact aggravated by the treatment or grew progressively worse in spite of it?

If the patient chose to sue his physician only on the choice of treatment selected, the physician would be able to interpose his compliance with accepted PSRO norms to succeed on a motion for summary judgment. The patient could possibly avoid such a result if able to show that the physician originally misdiagnosed his condition, such that the course of treatment selected was not at all appropriate, or that his condition was so atypical (e.g., perhaps a very severe, persistent infection) as to move it outside the particular norms relied upon by the physician. To accomplish either of these, the plaintiff would be allowed to introduce expert testimony at the pre-trial summary judgment hearing. If, however, the plaintiff's suit alleged that the medication in question was prescribed in the wrong dosage or perhaps negligently administered to him by the physician, the question of due care would be allowed to go to the jury.

A third potential problem, intimated by the plaintiffs in Weinberger, is the fear by physicians that norms, standards, and criteria promulgated under the PSRO legislation might be used offensively by malpractice plaintiffs. The rationale behind this is that the development of specific standards of care will result in "cookbook medicine," with plaintiffs in malpractice litigation attempting to introduce the relevant standards into evidence to prove the physician's deviation therefrom. This has been referred to as the "mirror image" problem: the

22. There is some question as to whether or not the PSRO procedures, including the civil immunity clause, would apply to the treatment of a non-recipient of federal aid. At least one author has suggested that they would not apply unless and until the treating physician actually sought PSRO approval of his course of treatment (thus establishing due care). Heilbrun, The Professional Standards Review Organization: Its Impact on Medical Litigation, 1975 Utah L. Rev. 433, 442 (1975) [hereinafter cited as Heilbrun]. Another commentator has countered that this attitude would not be in accord with legislative intent and that the protections of the civil immunity clause should apply whenever a physician treats a patient in compliance with PSRO norms and standards, whether or not the patient is in fact a recipient of federal aid. Carter, supra note 13, at 632-33 n.65.
idea that the exact converse of the statute's presumption of non-negligence for compliance with PSRO standards might be thought to apply.

While different authors have approached this problem in a number of ways, all agree that the Congressional intent behind the civil immunity provision, as evidenced by the report of the Senate Finance Committee, did not envision the use of PSRO standards as an offensive legal tactic: "Failure to order or provide care in accordance with the norms employed by the PSRO is not intended to create a legal presumption of liability." Since this comment is neither clear nor binding, a logical question arises: If a defendant physician can rely on his compliance with applicable PSRO norms and standards to receive complete civil immunity within a well-defined sphere of activity, why cannot these very standards be offered into evidence by a plaintiff to show his physician's deviation therefrom? Even if this action by the plaintiff did not raise a presumption of negligence by the defendant, but merely an inference, should not the plaintiff be allowed to take like advantage of the statute, notwithstanding Congress' apparent intent to the contrary?

An answer to these questions might be constructed on the basis of materiality. That is, one could argue that Congress' true intent was to effect physician compliance with the PSRO program by establishing certain ranges of acceptable diagnosis and treatment, within which a physician's activity would be immune from civil liability (noting the limitations on this immunity enumerated above). However, this argument would continue, where a physician's activities do not fall within the range of acceptable PSRO standards, the standards are no longer material to the case. Rather than precluding the plaintiff's recovery, this would simply compel him to offer his own expert testimony as to the prevailing standard of care and proof as to the defendant's failure to meet this standard. In essence, if the defendant were unable to prevail on his motion for summary judgment alleging compliance with PSRO procedures, the case would revert to a traditional common law or statutory negligence action. This interpretation would seem to be in accord with the stated intent of Congress that noncompliance with PSRO standards not raise a presumption of negligence.

A possible analogy to this seemingly one-sided use of PSRO standards might be drawn from the Federal Safety Appliance Acts, included as one of the several bases of liability under the Federal Employers' Liability Act. The Safety Appliance Acts require the use of various safety devices, such as braking systems and automatic couplers, on all railroad vehicles, and liability for violation of provisions of the act is absolute. The plaintiff need only establish a causal relationship between his injury and defective (or missing) safety equipment required by the act; this results in an irrebuttable presumption of lia-
bility on the part of the railroad. The defendant railroad cannot interpose its reasonable care in keeping the required appliances in working order, nor its inspection of them, nor the plaintiff's contributory negligence or assumption of risk. In short, liability is absolute. This, of course, is the converse of the PSRO problem, in that the Safety Appliance Acts preclude the defensive use of the standards set forth in the statute; nevertheless, it indicates the ability of the government to foreclose the "mirror-image" use of standards set to further a permissible government objective, especially when Congress has expressed its intent on the matter.

A closely related question is whether PSRO norms would be admissible at all — by either side — to establish the physician's standard of care. At least one jurisdiction has held that such professionally-promulgated guidelines (even if fairly specific) are not admissible for this purpose. Defenders of the civil immunity clause might argue, however, that their introduction of the PSRO standards was not in fact to establish the relevant standard of care, but that this had already been done by the duly delegated regional PSRO which had promulgated the norms. Rather, they might contend that their use of the standards was merely an attempt to show physician compliance with them, thus to secure the statutory grant of immunity. If the particular court refused to recognize this distinction between the introduction of norms to establish a standard of care and introduction to demonstrate compliance with an administratively predetermined standard, an interesting conflict would result. Again, though, based on the various authorities cited by the government in the Weinberger case, it appears that they would be able to justify the federal preemption of state substantive and procedural law on this issue.

It should also be noted that the PSRO legislation contains a fairly strong confidentiality provision, prohibiting disclosure of information acquired by the PSRO in the performance of its official duties. It thus appears that PSRO deliberations and determinations of medical necessity and adequacy of care would not be admissible in a state civil malpractice trial; whether such information would be subject to judicial subpoena has not been resolved, although it appears that the U.S. Department of Health, Education, and Welfare would strongly oppose the subpoena power.

The legal efficacy of the PSRO civil immunity clause is purely speculative at this time, since most PSROs are still in the implementation stage and no court has had to face the question squarely. At the least, the clause ought to afford immunity within a very narrow, well-defined sphere of professional activity and subject to the constraints discussed above. Its future effectiveness would perhaps be enhanced by a statutory amendment clarifying the intent of Congress with respect to such matters as the due care proviso, the possible offensive use of PSRO standards, and the admissibility of such standards into evidence, by either

39. Supra note 10.
41. Carter, supra note 13, at 634 n. 74.
side, in state court proceedings. A number of relevant provisions undoubtedly will be judicially challenged and interpreted once PSROs are fully implemented and become a viable force in the health care delivery system.

42. While several provisions of H. R. 3 (95th Cong., 1st Sess.), introduced by Rep. Dan Rostenkowski, chairman of the Ways and Means Committee's Health Subcommittee, and by Rep. Paul G. Rogers, chairman of Interstate and Foreign Commerce's Health Subcommittee, seek to amend the PSRO statute, none address themselves to the civil immunity issue. Moreover, there is no comparable movement in the U.S. Senate at this time to amend the PSRO statute at all.