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COMMITTEE PRINT

MEMORANDUM OF THE FEDERAL COURT
DECISION CONCERNING CONSTITUTIONALITY
OF PROFESSIONAL STANDARDS
REVIEW LEGISLATION

Printed for the use of the
COMMITTEE ON FINANCE
UNITED STATES SENATE
RUSSELL B. LONG, *Chairman*



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In the United States District Court for the Northern District of
Illinois Eastern Division

No. 73-C-1653

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, A NOT-FOR-
PROFIT CORPORATION FOR AND ON BEHALF OF ITS MEMBERS; AND
ROY R. GRINKER, SR., GEORGE E. SHAMBAUGH, JR., AND EDWARD
A. WOLFERT, PLAINTIFFS

v.

CASPAR W. WEINBERGER, SECRETARY OF THE UNITED STATES DE-
PARTMENT OF HEALTH, EDUCATION, AND WELFARE, AN AGENCY OF
THE FEDERAL GOVERNMENT, DEFENDANT

ORDER

This matter having come before the Court on the Motion of De-
fendant to dismiss, or in the alternative, for Summary Judgment, and
the Court having examined all the briefs and having heard oral argu-
ment in the above captioned cause, it is hereby ordered that this cause
be dismissed for failure to state a claim upon which relief can be
granted.

WILBUR F. PELL,
Circuit Judge, United States Court of Appeals.

THOMAS R. McMILLEN,
Judge, United States District Court.

WILLIAM J. LYNCH,
Judge, United States District Court.

Dated: May 8, 1975.

(1)

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, AN AGENCY
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MEMORANDUM OF DECISION

Plaintiffs bring this action seeking to enjoin the Secretary of Health, Education, and Welfare from implementing the Federal "Professional Standards Review" Law (42 U.S.C. Section 1320c through Section 1320c-19) and to declare said law unconstitutional on its face on the ground that it violates rights guaranteed the plaintiff physicians and their patients by the First, Fourth, Fifth and Ninth Amendments to the United States Constitution. Jurisdiction is invoked pursuant to Section 1331 of Title 28 of the United States Code, and a three-judge court has been convened in accordance with the provisions of 28 U.S.C. Sections 2282 and 2284. This cause now comes before the Court on defendant's motion for summary judgment.

Since there are no factual issues presented to the Court, only issues of law relating to the facial invalidity of the challenged legislation, defendant has framed his motion as one for summary judgment. However, defendant has also indicated, at the hearing on said motion, that his motion could properly be treated as a motion to dismiss the Complaint for failure to state a claim upon which relief can be granted. (Transcript at p. 4).

In order to more fully comprehend the constitutional objections to the challenged legislation it is first necessary to examine the basic statutory framework of the "Professional Standards Review" Law as set out in Section 1320c through 1320c-19 of Title 42 of the United States Code. Following this examination the Court will consider the various constitutional attacks on the legislation.

I

THE NATURE OF THE "PROFESSIONAL STANDARDS REVIEW"
LEGISLATION

With the Federal Government assuming the position as the largest health insurer in the United States through the enactment of the medicare and medicaid programs (42 U.S.C. Sections 1395-1395pp

and 42 U.S.C. Sections 1396-1396i respectively). Congress has become increasingly concerned with the tremendous costs incurred in implementing such programs.

In examining the rising cost of these programs the Senate Committee on Finance noted:

* * * The Committee on Finance has, for several years, focused its attention on methods of assuring proper utilization of these services. That utilization controls are particularly important was extensively revealed in hearings conducted by the subcommittee on medicare and medicaid. Witnesses testified that a significant proportion of the health services provided under medicare and medicaid are probably not medically necessary. In view of the per diem costs of hospital and nursing facility care, and the costs of medical and surgical procedures, the economic impact of this overutilization becomes extremely significant. Aside from the economic impact the committee is most concerned about the effect of overutilization on the health of the aged and the poor. Unnecessary hospitalization and unnecessary surgery are not consistent with proper health care. Sen. R. No. 92-1230, 92d Cong., 2d Sess. 254 (1972).

It was directed at this problem of overutilization that Congress enacted Section 249F of Title II of the 1972 Amendments to the Social Security Act, 42 U.S.C. Sections 1320c-1320c-19, entitled "Professional Standards Review." The Congressional intent behind enactment of this legislation is set forth in Section 1320c of Title 42 of the United States Code which provides that payment for services performed under medicare and medicaid will be made:

(1) Only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

(2) In the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion. 42 U.S.C. Sec. 1320c.

In furtherance of this objective Congress has established, under the Act, a number of new organizations and some new limitations of liability.

Under the challenged legislation the Secretary of Health, Education, and Welfare shall establish throughout the United States "appropriate areas" with respect to which "Professional Standards Review Organizations" (hereinafter referred to as "PSRO's") may be designated. Upon designation of an appropriate area, the Secretary must then enter into an agreement with a "qualified organization" which becomes the PSRO for that area. 42 U.S.C. Section 1320c-1(a).

To be qualified under the Act an organization must be a non-profit professional association composed of licensed doctors practicing in the appropriate area, whose membership includes a substantial proportion of all such doctors in the area. The statute sets forth additional requirements for qualification including a finding by the Secretary of

Health, Education, and Welfare that the organization is one that is willing and able to perform the functions of a PSRO. 42 U.S.C. Section 1320c-1(b)(2).

After designation of a "qualified organization" as a PSRO for an appropriate area, each PSRO must assume—

* * * Responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this chapter for the purpose of determining whether—

(A) Such services and items are or were medically necessary;

(B) The quality of such services meets professionally recognized standards of health care; and

(C) In case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type. 42 U.S.C. Section 1320c-4(a)(1).

In order to assure that services provided under medicare and medicaid are medically necessary and of professional quality, the statute requires practitioners and providers of health care services to furnish such evidence as may reasonably be requested by a PSRO. 42 U.S.C. Section 1320c-9(a)(2).

If the Secretary agrees with the report and recommendation of a PSRO that a particular practitioner or provider of services has either (1) failed, in a substantial number of cases to comply with any of the obligations set forth in the statute or (2) grossly and flagrantly has violated any such obligation in one or more instances and that sanctions are warranted, that practitioner or provider may be excluded from participation in the medicare and medicaid programs. 42 U.S.C. Section 1320c-9(b)(1). The legislation provides for notice and hearing of such determinations. 42 U.S.C. Section 1320c-9(b)(4).

Each PSRO will have the authority to determine whether any elective admission to a hospital or other health care facility, or any other health care service which will consist of extended or costly courses of treatment is medically necessary or could be provided for in a more economical manner. 42 U.S.C. Section 1320c-4(a)(2). If a PSRO determines that such services are not medically necessary or that they could be performed in a more economical manner, no Federal funds may be used as payment for such services. 42 U.S.C. Section 1320c-7. However, the Act provides that only a licensed physician can make a final determination as to the professional conduct of any other physician. 42 U.S.C. Section 1320c-4(c).

The legislation also requires a PSRO to give notice of any determination denying a request for approval of health care service or any determination that a practitioner or provider has violated any obligation imposed by the statute. 42 U.S.C. Section 1320c-10. In determining whether the services rendered are consistent with the criteria set forth in Section 1320c-4(a)(1), PSRO's are required to maintain profiles on each practitioner and provider of health care services. A coding method is employed in order to provide maximum confidentiality and objective evaluation. 42 U.S.C. Section 1320c-4(a)(4).

To aid each PSRO in its evaluation and review process certain professional norms of care, diagnosis and treatment are established which shall include the types and extent of health care services considered within the range of appropriate diagnosis and treatment for a particular illness or condition and the most economical type of health care facility considered medically appropriate. 42 U.S.C. Section 1320c-5 (b). In order to coordinate the activities of various PSRO's and to assist the Secretary in evaluating the performance of each PSRO, a number of statewide Professional Standards Review Councils and a National Professional Standards Review Council are to be established by the Secretary. 42 U.S.C. Section 1320c-11(a) and 42 U.S.C. Section 1320c-12(a).

Finally, the challenged legislation provides certain limitations of liability including a section that provides that:

No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization . . . operating in the area where such doctor of medicine or osteopathy or provider took such action but only if—

(1) He takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

(2) He exercised 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. 42 U.S.C. Section 1329c-16(c).

In summary, the Court notes that the "Professional Standards Review" Law is a massive piece of legislation which represents, for the first time, a nationwide program of medical utilization review.

II

CONSTITUTIONALITY OF THE "PROFESSIONAL STANDARDS REVIEW" LEGISLATION

Given these pertinent statutory sections as background, plaintiffs seek a declaratory judgment that the legislation is unconstitutional on its face and a permanent injunction restraining the defendant from implementing the legislation. Plaintiffs' challenges to the constitutionality of the legislation have their origin in the First, Fourth, Fifth and Ninth Amendments to the United States Constitution. The basic constitutional challenges to the legislation are:

(A) That the legislation unconstitutionally deprives plaintiffs of their right to practice their profession in violation of the Fifth Amendment;

(B) That the legislation unconstitutionally interferes with the physician-patient relationship in violation of the Fifth Amendment;

(C) That the legislation unconstitutionally invades the privacy of the plaintiffs and their patients in violation of the First, Fourth, Fifth, and Ninth Amendments;

(D) That the legislation is unconstitutionally vague and uncertain in violation of the Fifth Amendment;

(E) That Congress unconstitutionally exercised its power in imposing limitations of liability under the legislation in violation of the Fifth Amendment;

(F) That the legislation unconstitutionally creates presumptions inconsistent with plaintiffs' licensure in violation of the Fifth Amendment; and

(G) That the legislation unconstitutionally empowers biased private organizations to exercise quasi-judicial authority over plaintiffs in violation of the Fifth Amendment.

Since the Act has yet to be applied, these constitutional challenges are addressed to the constitutionality of the Act on its face. Due to the full panoply of constitutional rights that is alleged to be infringed by numerous provisions of the "Professional Standards Review" legislation and due to the fact that the instant case represents one of the first constitutional challenges to this new legislation, it becomes necessary for the Court to consider each of these contentions separately and in some detail.

A. PLAINTIFFS' RIGHT TO PRACTICE THEIR PROFESSION

Plaintiffs argue that the challenged legislation violates their constitutional rights as guaranteed by the Fifth Amendment in that it is arbitrary and overbroad and interferes with the plaintiffs' right to practice their profession.

Similar arguments were raised in the case of *Rasulis v. Weinberger*, 502 F. 2d 1006 (7th Cir. 1974). The statutory regulation under attack in *Rasulis* established professional standards which physical therapists must meet in order to qualify for reimbursement under the Medicare Program. 20 C.F.R. Sec. 405.1101(q).

In rejecting plaintiffs' argument that the regulation was arbitrary and violative of the Due Process Clause of the Fifth Amendment, the Court of Appeals noted:

The Due Process Clause prohibits only those classifications within a Federal social welfare program that are patently arbitrary and totally lacking in rational justification. *Fleming v. Nestor*, 363 U.S. 603, 611 (1960). Accord, *Gruenwald v. Gardner*, 390 F. 2d 591, 592 (2nd Cir. 1968), *cert. denied*, 393 U.S. 982 (1968); *Price v. Flemming*, 280 F. 2d 956 (3rd Cir. 1960), *cert. denied*, 365 U.S. 817 (1961). And ". . . regulation which is reasonable in relation to its subject and is adopted in the interests of the community is due process." *West Coast Hotel Co. v. Parrish*, 300 U.S. 379, 391 (1937). See generally *Dandridge v. Williams*, 397 U.S. 471, 485 (1970); *McGowan v. Maryland*, 366 U.S. 420, 425-26 (1961); *Williamson v. Lee Optical of Oklahoma*, 348 U.S. 483, 489 (1955). 502 F. 2d at 1009.

Thus, the Court concluded:

The challenged legislation does not stray outside the boundaries of permissible regulation. It merely provides standards for the dispensation of Federal funds. The economic incentive of participation in the Medicare Program does not constitute coercion or

control. See Cardozo J. for the Court in *Stewart Machine Co. v. Davis*, 301 U.S. 548, 589-90 (1937) 502 F. 2d at 1010.

Although the "Professional Standards Review" legislation represents a more comprehensive regulatory scheme than that encountered in *Rasulis*, the constitutional principles to be applied are the same in each. In order to avoid overutilization of health care services and to achieve more effective control over the costs of those services, Congress has enacted the "Professional Standards Review" legislation. The legislation does set forth certain professional standards which must be met in furtherance of this statutory purpose. The statute, however, does not bar physicians from practicing their profession but only "provides standards for the dispensation of Federal funds." Considering the purpose behind this statutory scheme and the requirements set forth in the statute to achieve this purpose, this Court finds that the challenged legislation is not so "patently arbitrary and totally lacking in rational justification" as to be violative of the Due Process Clause of the Fifth Amendment.

In support of their argument that the challenged legislation is arbitrary in violation of the Fifth Amendment, the defendants have mainly relied on three lines of cases: (1) where the legislation was attacked on the ground that it established an arbitrary or invidious discrimination; (2) where legislation was held to have lacked critical elements of procedural due process; and (3) where certain legislation was found to bear no reasonable relationship to any legitimate governmental end.

Plaintiffs have presented a number of cases involving legislation challenged as establishing arbitrary or invidious discrimination. *Memorial Hospital v. Maricopa County*, 94 S. Ct. 1076 (1974); *United States Department of Agriculture v. Moreno*, 413 U.S. 528 (1973); and *Shapiro v. Thompson*, 394 U.S. 618 (1969). However, the instant complaint lacks any specifications of how the "Professional Standards Review" Law creates any arbitrary or invidious discrimination.

In addition, these cases offered by plaintiffs can easily be distinguished from the case at bar. The case of *Memorial Hospital v. Maricopa County*, *supra*, struck down a one-year State residency requirement for county financed medical care on the ground that it created an invidious distinction between classes of citizens. In *United States Department of Agriculture v. Moreno*, *supra*, the Court struck down a statute limiting eligibility for food stamps to households consisting only of related individuals because such a limitation constituted a classification "wholly without any rational basis." 413 U.S. at 538.

Similarly, in *Shapiro v. Thompson*, *supra*, the Supreme Court invalidated a one-year residency requirement for becoming eligible for Medicare on the ground that this legislative scheme established invidious discrimination. Unlike the statutory schemes invalidated as creating an arbitrary or invidious discrimination in *Maricopa*, *Moreno* and *Shapiro*, the challenged legislation in the instant suit does not establish any arbitrary or invidious discrimination in violation of the Fifth Amendment. Thus, the Court finds that these cases are not supportive of plaintiff's position that the "Professional Standards Review" Law is arbitrary in violation of the Fifth Amendment.

Plaintiffs have further argued that this legislation lacks critical elements of procedural due process. Such an argument is not well-founded. Section 1320c-9(b)(4) of Title 42 of the United States Code

provides that no physician can be barred from participation in the Medicare or Medicaid programs without notice and a hearing. Further, the legislation allows a hearing and review by the Secretary of all PSRO determinations denying payment for services where the amount in controversy is \$100.00 or more; and if that amount is \$1,000.00 or more, the aggrieved party is entitled to judicial review of an adverse determination by the Secretary. 42 U.S.C. Sec. 1320c-8. Finally, the challenged legislation provides that a PSRO must give notice to any practitioner or provider of any determination (1) denying any request for approval of health care service or (2) that such practitioner or provider has violated any obligation imposed upon him by the legislation. 42 U.S.C. Sec. 1320c-10.

These statutory provisions satisfy the demands of procedural due process by apprising the practitioner or provider of any adverse determination and by affording him an opportunity to be heard either by the Secretary or through the avenue of judicial review. Such safeguards are consonant with the concept of procedural due process as embodied in the Fifth Amendment.

Finally, plaintiffs argue that the legislation is arbitrary because it bears no reasonable relationship to any end within the competency of government. As the plaintiffs themselves have noted, "the primary purpose of the Act is to control the rapidly rising costs of governmental health care delivery systems." (Plaintiffs' Memorandum in Opposition at page 23). Such a statutory purpose can hardly be considered to be one outside the competency of the Federal Government, particularly in light of the already extensive Government regulation in the health care field.

Plaintiffs have also attacked the Act on the ground that it is unconstitutionally overbroad citing the case of *City of Carmel-by-the-Sea v. Young*, 2 Cal. 2d, 259, 466 P.2d 225, 85 Cal. Rptr. 1 (1970). In *City of Carmel* a State statute requiring all public officers and candidates to disclose not only their own financial investments but also those of their families was struck down as being overbroad.

However, the United States Supreme Court in *Dandridge v. Williams* 397 U.S. 471 (1970), has indicated that the overbreadth doctrine has little application to social welfare legislation.

For this Court to approve the invalidation of State economic or social regulation as "overreaching" would be far too reminiscent of an era when the Court through the Fourteenth Amendment gave it power to strike down State laws "because they may be unwise, improvident, or out of harmony with a particular school of thought." *Williamson v. Lee Optical Co.*, 348 U.S. 483, 488. That era long ago passed into history, *Ferguson v. Skrupa*, 372 U.S. 726. *Dandridge v. Williams*, 397 U.S. at 484-85.

Accordingly, the Court finds plaintiffs' argument that the instant legislation is unconstitutionally overbroad to be wholly without merit.

Finally, plaintiffs argue that the challenged legislation violates the Fifth Amendment in that it unconstitutionally interferes with their right to practice. In support of this argument plaintiffs place heavy reliance on a series of decisions striking down various criminal abortion statutes. *Doe v. Bolton*, 410 U.S. 179 (1973); *Roe v. Wade*, 410 U.S. 113 (1973); *Poe v. Menghini*, 339 F. Supp. 986 (D. Kan. 1972) (three judge court).

In *Doe v. Bolton*, *supra*, and *Roe v. Wade*, *supra*, the Supreme Court struck down the Georgia and Texas criminal abortion statutes respectively. In *Doe v. Bolton*, *Roe v. Wade* and *Poe v. Menghini*, the challenged statutes provided criminal penalties for performing abortions except under specified circumstances.

The "Professional Standards Review" Law does not prohibit a physician from performing any surgical operations he deems necessary in the exercise of his professional skill and judgment. It merely provides that if a practitioner wishes to be compensated for his services by the Federal Government, he is required to comply with certain guidelines and procedures enumerated in the statute.

These statutory requirements do not act in the same mandatory fashion upon the plaintiffs as did the criminal abortion statutes invalidated in *Doe v. Bolton*, and *Roe v. Wade*. Rather the legislation sets forth certain review procedures to be complied with for any practitioner wishing to participate in the program and to be paid by the Federal Government.

Underlying the constitutionality of the challenged legislation is the basic premise that each individual physician and practitioner has the ability to choose whether or not to participate in the program. It is true that there will exist economic incentive or inducement to participate in the program. However, such inducement is not tantamount to coercion or duress.

In *Steward Machine Co. v. Davis*, 301 U.S. 548 (1937), the constitutionality of a social security tax on employers was attacked on the ground that it constituted coercion on States to enact State welfare programs by allowing a credit against the tax for taxes paid to State welfare plans. In rejecting the contention that the legislation unconstitutionally coerced States into enacting welfare programs, Justice Cardozo, speaking for the Court stated:

But to hold that motive or temptation is equivalent to coercion is to plunge the law in endless difficulties. The outcome of such a doctrine is the acceptance of a philosophical determination by which choice becomes impossible. Till now the law has been guided by a robust commonsense which assumes the freedom of will as a working hypothesis in the solution of its problems. [301 U.S. at 589-90]

In applying the "commonsense" approach of Justice Cardozo to the question of whether the instant legislation is coercive in nature, the Court finds that the statute does not act upon the plaintiffs in such a mandatory fashion as to amount to an unconstitutional interference with plaintiffs' right to practice.

B. INTERFERENCE WITH THE PHYSICIAN-PATIENT RELATIONSHIP

Plaintiffs argue that the challenged legislation unconstitutionally interferes with the doctor-patient relationship. Specifically, plaintiffs allege that the system of norms of care, diagnosis and treatment to be established under the statutory scheme, "will have a chilling effect on the case-by-case practice of medicine and innovative progress in medical practice, to the ultimate detriment of plaintiffs and their patients."

Initially the Court notes that plaintiffs' argument appears premature in that the particular norms under attack have yet to be established. The argument is essentially based on the premise that

such norms of diagnosis, treatment and care are inherently incapable of reduction to specific language. (Plaintiffs' Memorandum in Opposition at page 21).

The Court is cognizant of the difficulties encountered in drafting norms with sufficient specificity to afford meaningful notice to the practitioner and with adequate flexibility to reach a multitude of individual medical cases. However, the task is not an impossible one. Although the challenged legislation establishes, for the first time, a unified national program of medical utilization review, norms have been employed in private medical utilization review programs for a number of years. See *R. B. Schumer, Hospital Utilization Review and Medicare: A Survey* at page 8-9 (Government Printing Office, Washington, D.C. 1973).

The statute specifically provides that the norms must include:

* * * the type and extent of the health care service which, taking into account differing, but acceptable modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care . . . 42 U.S.C. Sec. 1320c-5(b)(1).

Further, the purpose behind the implementation of these norms was clearly set forth in the legislative history of the statute.

Neither should the use of norms as checkpoints nor any other activity of the PSRO be used to stifle innovative medical practice or procedures. The intent is not conformism in medical practice—the objective is reasonableness. Sen. R. No. 92-1230 at 263.

Given the legislative standard of reasonableness and the statutory flexibility to take into account various methods of treatment, the Court finds no merit to plaintiffs' argument that the system of norms to be established under the statutory scheme will unconstitutionally interfere with the physician-patient relationship.

C. THE RIGHT OF PRIVACY OF PLAINTIFFS AND THEIR PATIENTS

Plaintiffs argue that the statutory sections requiring plaintiff to furnish information concerning their patients violate the constitutional right of privacy of plaintiffs and their patients as guaranteed by the First, Fourth, Fifth and Ninth Amendments.

The purpose of the information sought from plaintiffs is to enable the Professional Standards Review Organization to assemble patient profiles upon which they can determine whether the services performed under the Medicare and Medicaid Programs were medically necessary and done in an economical manner. The legislation also provides that reporting procedures should utilize to the greatest extent possible "methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part." 42 U.S.C., Section 1320c-4.

Further, the statute provides in pertinent part that:

(a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to

any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall be regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.

(b) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than \$1,000 and imprisoned for not more than six months, or both, together with the costs of prosecution. 42 U.S.C. Section 1320e-15.

These statutory provisions make it clear that the maximum confidentiality is to be maintained concerning the information furnished by the physicians to the Professional Standards Review Organizations.

In *California Bankers Association v. Shultz*, 416 U.S. 21 (1974), the Supreme Court considered whether various provisions of the Bank Secrecy Act of 1970 and regulations promulgated thereunder amounted to an unconstitutional invasion of privacy. Under the authority of the Act, the Secretary of the Treasury promulgated regulations requiring banks to report domestic currency transactions of \$10,000 or more. In upholding the constitutionality of the regulation, the Court stated:

The regulations do not impose unreasonable reporting requirements on the banks. The regulations require the reporting of information with respect to abnormally large transactions in currency, much of which information the bank as a party to the transaction already possesses or would acquire in its own interest. To the extent that the regulations in connection with such transactions require the bank to obtain information from a customer simply because the Government wants it, the information is sufficiently described and limited in nature, and sufficiently related to a tenable congressional determination as to improper use of transactions of that type in interstate commerce, so as to withstand the Fourth Amendment challenge made by the bank plaintiffs. "(T)he inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant. 'The gist of the protection is in the requirement, expressed in terms, that the disclosure sought shall not be unreasonable.'" *United States v. Morton Salt Co.*, supra, at 652-653; see *Oklahoma Press Publishing Co. v. Walling*, 327 U.S. 186, 208 (1946).

The challenged legislation in the instant suit seeks information for a legitimate governmental purpose. The manner in which the information is gathered and maintained is reasonable in light of the above-quoted statutory provisions that are designed to assure proper confidentiality. The Court finds that these provisions do not infringe on the constitutionally protected right of privacy of plaintiffs.

In support of their argument that the legislation violates their right of privacy, plaintiffs place heavy emphasis on the case of *Roe v. Ingraham*, 480 F.2d 102 (2d Cir. 1973). In *Roe* the Second Circuit Court of Appeals considered the constitutionality of a New York law which required that certain drugs be prescribed only on a State prescription form, two copies of which had to be filed with the State Department of Health. In reversing the District Court's dismissal of the suit, the Court of Appeals significantly noted:

If it were clear that the State had taken or proposed to take effective steps, by regulation or otherwise, to limit access to the patients' names on the prescription forms as rigidly as is consistent with accomplishment of the asserted statutory purpose, the grounds for constitutional attack might disappear, 480 F. 2d at 109.

The case of *Roe v. Ingraham*, *supra*, can be distinguished from this suit. Unlike the statute under constitutional attack there, the "Professional Standards Review" Law does limit access to the information under penalty of criminal sanctions. After reviewing a number of cases dealing with the right of privacy, the Supreme Court in *Roe v. Wade*, *supra*, noted:

Although the results are divided, most of these courts have agreed that the right of privacy, however based, is broad enough to cover the abortion decision; that the right, nonetheless, is not absolute and is subject to some limitations; and that at some point the State interests as to protection of health, medical standards, and prenatal life, become dominant. We agree with this approach. [410 U.S. at 155]

The "Professional Standards Review" legislation contains provisions that properly balance the plaintiffs' right of privacy with the Government's interest in maintaining proper health care in an economical manner.

Finally, in regard to plaintiffs' contentions concerning their right to privacy, the Court notes that plaintiffs have argued that the legislation violates the constitutional right of privacy of their patients. It is not at all clear that plaintiffs have the requisite standing in this case to assert the constitutional rights of their patients.

In *California Bankers Association v. Schultz*, 416 U.S. 21 (1974), the Supreme Court considered whether a private bank had standing to assert the right of their depositors. There the Court noted:

It is true in a limited class of cases this Court has permitted a party who suffered injury as a result of the operation of a law to assert his right even though the sanction of the law was borne by another, *Pierce v. Society of Sisters*, 268 U.S. 510 (1925), and conversely, the Court has allowed a party upon whom the sanction fails to rely on the wrong done to a third party in obtaining relief, *Barrows v. Jackson*, 346 U.S. 249 (1953); *Eisenstadt v. Baird*, 405 U.S. 438 (1972). Whether the bank might in other circumstances rely on an injury to its depositors or whether, instead, this case is governed by the general rule that one has standing only to vindicate his own rights, e.g., *Moose Lodge v. Iris*, 407 U.S. 163, 166 (1972), need not now be decided, since, in any event, the claim is premature. 416 U.S. at 51.

Under the circumstances of this case, the claim of the plaintiffs on behalf of their patients is similarly premature. This suit attacks the constitutionality of the legislation on its face, and thus far there is no showing that a real and immediate injury or threat of injury exists to particular patients of these plaintiffs.

As the Supreme Court stated in *California Bankers Association v. Schultz*, *supra*:

Plaintiffs in the Federal courts "must allege some threatened or actual injury resulting from the putatively illegal action before a Federal court may assume jurisdiction." *Linda R. S. v. Richard D.*,

410 U.S. 614, 617 (1973). There must be a "personal stake in the outcome" such as to "assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination of difficult constitutional questions." *Baker v. Carr*, 369 U.S. 180, 204 (1962) . . . Abstract injury is not enough. It must be alleged that the plaintiff "has sustained or is immediately in danger of sustaining" some direct injury as a result of the challenged statute or official conduct. *Massachusetts v. Mellon*, 262 U.S. 447, 488 (1923). The injury or threat of injury must be both "real and immediate," not "conjectural" or "hypothetical." *Golden v. Zwickler*, 394 U.S. 103, 109-110 (1969); *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *United Public Workers v. Mitchell*, 330 U.S. 75, 89-91 (1947); *O'Shea v. Littleton*, 414 U.S. 488, 493-494 (1974). 416 U.S. 21, 68-69.

In summary, the Court finds that the reporting procedures in the challenged legislation do not unconstitutionally interfere with plaintiffs' right to privacy. These procedures are reasonable in scope in that they contain provisions designed to assure confidentiality. Like the reporting procedure upheld in *California Bankers*, through these provisions "Congress is simply imposing a condition on the spending of public funds." 416 U.S. at 50.

D. VAGUENESS

Plaintiffs have argued that numerous works and phrases contained in this lengthy statute are so vague and uncertain "that plaintiffs must necessarily guess at their meaning" and that this lack of specificity is contrary to the requirements of the Fifth Amendment. In support of this position plaintiffs have cited numerous decisions involving criminal statutes invalidated under the vagueness doctrine.

Initially, the Court notes that much of plaintiffs' argument appears premature because of the absence of any application of these provisions. Nevertheless, the Court will consider plaintiffs' constitutional objections as they relate to the vagueness and uncertainty of the legislation on its face.

The test in determining whether or not a statute is unconstitutionally vague is whether men of common intelligence must necessarily guess at its meaning. Due to the particular application of this statute to physicians and other practitioners, the Court must also consider whether members of the medical profession must necessarily guess at the meaning of phrases set forth in the statute, such as "medically necessary," "professionally recognized health care standards," and "proper care."

Although the Court recognizes that these phrases are not highly specific, the Court believes that the language of the challenged legislation is not impermissibly vague or uncertain. As the Supreme Court stated in *United States v. Petrillo*, 326 U.S. 1, 7-8 (1947):

* * * The Constitution does not require impossible standards.

The language here challenged conveys sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices. The Constitution requires no more. Plaintiffs' reliance on numerous decisions invalidating various crim-

inal statutes on the grounds of vagueness is misplaced. The present statutory scheme does not impose criminal sanctions. Nor does it provide for severance from the medical profession for non-compliance. See e.g., *Hewitt v. Board of Medical Examiners*, 148 Cal. 590, 84 P. 39 (1906). Rather the instant legislation only sets forth conditions for being compensated by Federal funds under the Medicare and Medicaid Programs. As was stated earlier, Congress faced a difficult task in drafting this statute with sufficient specificity to give the physicians, practitioners and providers of health care service adequate notice of the new requirements of the law and at the same time to maintain enough flexibility to cover a variety of medical cases. In accomplishing this task Congress did not stray beyond the permissible boundaries of the Constitution.

E. CONSTITUTIONALITY OF THE LIMITATIONS OF LIABILITY

The challenged legislation establishes certain limitations as provided, *supra*, in Section 1320c-16(c) of Title 42 of the United States Code. Plaintiffs contend that Congress lacks authority to grant legal immunity against common law tort liability; and if the immunity provisions of the challenged legislation are enforceable, the legislation imposes duties and obligations on plaintiffs which may unconstitutionally expose them to civil liability.

The Court does not now reach the merits of these claims because the plaintiffs lack the requisite standing to challenge the constitutionality of these limitations of liability. The proper party to raise such objections would be the beneficiaries or recipients under the Medicare and Medicaid Programs.

Further, plaintiffs' allegation that they "will be exposed to a serious risk of civil liability as a result of complying with the law" does not amount to a real and immediate threat of injury which would confer standing on these plaintiffs at this time.

The norms which are to be established and which the plaintiffs must comply with are, by definition, typical medical practices within the region where the physician practices. If a physician does not follow such typical procedures, he might be held liable for malpractice under State common law. The risk of civil liability arises from common law standards of negligence, not from the statute.

Thus, the possibility of exposure to civil liability sometime *in futuro* as a result of complying with these statutory norms does not amount to that type of real and immediate threat of injury which is necessary to sharpen the issues and place them in proper posture for adjudication. See *Baker v. Carr*, 369 U.S. 186, 204 (1962). There being no actual case or controversy at this time, the Court does not now reach the issue of the constitutionality of the limitations of liability established by the "Professional Standards Review" Law.

F. PRESUMPTIONS INCONSISTENT WITH PLAINTIFFS' LICENSURE

Plaintiffs contend that the medical license carries certain presumptions of competence, good moral character, and regularity of motive and conduct, and that inconsistent presumptions are created by the statutory requirement that plaintiffs must provide evidence

of their performance of services. In support of this position plaintiffs rely on language in the decision of *Doe v. Bolton*, *supra*, which struck down the two doctor concurrence requirement in the Georgia criminal abortion statute because such a requirement had "no rational connection with a patient's needs and unduly infringes on the physician's right to practice." 410 U.S. at 199.

The case of *Doe v. Bolton* is inapposite, however. It involved a criminal abortion statute which barred performance of a surgical operation. The section challenged by plaintiffs here merely provides that practitioners must furnish evidence of their services in order to be compensated.

To read *Doe v. Bolton* as holding invalid any regulation of physicians other than by licensure is unfounded as noted by the Second Circuit Court of Appeals in *Roe v. Ingraham*, *supra*:

Also, we do not read the portion of *Doe v. Bolton*, *supra*, 410 U.S. at 198, 93 S. Ct. 739, striking down Georgia's "two doctor concurrence" requirement as meaning that a State is wholly without power to regulate the practice of medicine or the activities of physicians except by professional censure, deprivation of licenses, or enforcement of the criminal law. 480 F. 2d at 108.

Accordingly, plaintiffs' contention that the statute creates presumptions inconsistent with plaintiffs' licensure in violation of the Fifth Amendment is without merit.

G. DELEGATION OF AUTHORITY TO PRIVATE ORGANIZATIONS

Plaintiffs contend:

Said law, and in particular Section 1152 of said law (42 U.S.C. Section 1320c-1), empowers private organizations that are inherently biased against plaintiffs by their contractual relationship with defendant and their economic self-interest, to exercise quasi-judicial authority over plaintiffs. . . . [Complaint, Part IV, Paragraph 11.]

In support of this argument plaintiffs rely on the case of *Tumey v. Ohio*, 273 U.S. 510 (1927), where the Supreme Court struck down a State statute which provided that certain crimes be tried before the Mayor of a town who received remuneration only if the defendant was found guilty. Plaintiffs argue that like the Mayor in *Tumey*, the PSRO's in the instant case will have a financial interest in retaining their contract. This argument is ill-founded for several reasons.

First, by statute, PSRO's must be non-profit organizations, 42 U.S.C., Section 1320c-1(c)(1). Second, these PSRO's will be reimbursed by the Secretary for their expenses, including the salaries of personnel performing review functions. 42 U.S.C. Section 1320c-4(f)(2). Accordingly, the amount of salary is not related to performance as was the case in *Tumey v. Ohio*, *supra*. Membership in a PSRO is open to every physician in the PSRO's area, 42 U.S.C. Section 1320c-1(b)(1)(A); and all review of medical decisions must be made by physicians, 42 U.S.C. Section 1320c-4(e). Thus, plaintiff's allegation that these private organizations will be biased is totally without merit.

Finally, it has been held permissible for agencies of the Federal Government to contract with private organizations in order to have

such organizations perform governmental functions as long as the particular administrative scheme provides for a hearing on the determinations made by those private organizations. See *State of Texas v. National Bank of Commerce of San Antonio*, 290 F. 2d 229 (5th Cir.) *Cert. denied*, 368 U.S. 832 (1961), and *Coral Gables Conalescent Home, Inc. v. Richardson*, 340 F. Supp. 646 (S.D. Fla. 1972).

III

VALID EXERCISE OF CONGRESSIONAL POWER

Plaintiffs' final argument, buttressed by a lengthy amicus curiae brief filed by the Association of Councils of Medical Staffs of Private Hospitals, Inc., is a broad attack upon the legislation as an inefficient and unnecessary interference with their right to practice medicine. This Court has already held, *supra*, that the "Professional Standards Review" legislation does not unconstitutionally interfere with plaintiffs' right to practice their profession in violation of the Fifth Amendment.

Congress has enacted this legislation as a vehicle to better control expenditures of the Federal Government in connection with the Medicare and Medicaid Programs. In view of the already extensive presence of the Federal Government in the health care sphere, it can hardly be said that a statutory scheme designed to achieve better cost control in the field of health care is outside the competency of the Federal Government.

The means that Congress has chosen to attain these economic goals are not arbitrary and totally lacking in rationality. Underlying the constitutionality of the legislation is the fact that the program is a voluntary one in which a physician may freely choose whether or not to participate. However, should a physician choose to participate, he must then comply with these new requirements in order to be compensated for his services.

This legislation represents the first medical utilization review program that is national in scope. In attempting to avoid overutilization and to achieve better cost control in the health care field, the "Professional Standards Review" Law comes in close proximity to the rights of those physicians and other providers of health care services in the Medicare and Medicaid Programs. Yet there must be a balancing between those interests and the Government interest in providing and maintaining medical care to those most in need of it.

The "Professional Standards Review" legislation properly preserves that balancing of interests. In upholding the constitutionality of the legislation on its face, this Court does not reach the validity of the statute as it will be applied. Nor does this Court pass upon the wisdom of this particular piece of legislation. Whether the implementation and application of this statute may result in an unwieldy bureaucracy of monstrous proportions is a policy question for the consideration of the legislative rather than the judicial branch of the Government.

As the United States Supreme Court noted in upholding the constitutionality of a provision of the Social Security Act in *Richardson v. Belcher*, 404 U.S. 78 (1971):

We have no occasion, within our limited function under the Constitution, to consider whether the legitimate purposes of Congress might have been better served . . . or to judge for ourselves whether the apprehensions of Congress were justified by the facts. If the goals sought are legitimate, and the classification adopted is rationally related to the achievement of those goals, then the action of Congress is not so arbitrary as to violate the Due Process Clause of the Fifth Amendment. *Id.* at 84.

IV

CONCLUSION

For the foregoing reasons, defendant's motion to dismiss for failure to state a claim upon which relief can be granted, or, in the alternative, for summary judgment, is hereby granted.

The Cause is dismissed.

WILBUR F. PELL, *Circuit Judge,*
United States Court of Appeals.
 THOMAS R. McMILLEN,
Judge, United States District Court.
 WILLIAM J. LYNCH,
Judge, United States District Court.

Dated: May 8, 1975.

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