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MEMORANDUM IN SUPPORT OF GOVERNMENT'S MOTION FOR SUMMARY JUDGMENT CONCERNING CONSTITUTIONALITY OF PROFESSIONAL STANDARDS REVIEW LEGISLATION

COMMITTEE ON FINANCE

UNITED STATES SENATE

RUSSELL B. LONG, *Chairman*

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, etc., et al.,

Plaintiffs,

v.

CASPAR W. WEINBERGER, Secretary of the United States Department of Health, Education & Welfare, an Agency of the Federal Government,

Defendant.

No. 73 C 1653

MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

CONTENTS

STATEMENT OF FACTS

I.

Background

Until recently in our country's history, the federal government had not acted in any substantial manner as a third-party payer of medical and hospital bills. With the enactment into law of the medicare and medicaid programs, 1/ however, the federal government became the largest health insurer in the United States. 2/

Congress was aware, of course, at the time of the enactment of these social programs that tremendous costs would be incurred; however, recent statements by Congressional committees disclose that the costs actually incurred by medicare and medicaid are far greater than the costs originally anticipated. As the United States Senate Committee on Finance noted:

> According to recent estimates the costs of the medicare hospital insurance program will overrun the estimates made in 1967, by some $240 billion over a 25-year period. The monthly premium costs for part B of medicare -- doctors' bills -- rose from a total of $6 monthly per person on July 1, 1966, to $11.60 per person on July 1, 1972. Medicaid costs are also rising at precipitous rates. 3/

The Senate Committee on Finance felt that the rapidly increasing costs of medicare and medicaid were attributable to two factors: (1) an increase in the unit costs of medical services and (2) an increase in the number of

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1/ Pub. L. 89-97, 79 Stat. 286, July 30, 1965. The medicare program is now set forth in subchapter XVIII to the Social Security Act, 42 U.S.C. §§1395-1395pp; the medicaid program is set forth in subchapter XIX to the Social Security Act, 42 U.S.C. §§1396-1396i.

2/ 118 Cong. Rec. S16111 (daily ed. Sept. 27, 1972) (remarks of Senator Bennett).

3/ Sen. R. No. 92-1230, 92d Cong., 2d Sess. 254 (1972) (hereinafter referred to as "Sen. R. No. 92-1230").

services provided to beneficiaries. With regard to the latter factor, the Committee stated:

> . . . 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. 4/

Since the inception of the medicare and medicaid programs, Congress has grappled with the problem of insuring proper utilization of medical services for beneficiaries. 5/ Because the legislation challenged in the instant suit is Congress' latest attempt to solve this problem, it would

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4/ Sen. R. No. 92-1230 at 254.

5/ In 1965, the Senate Committee on Finance stated with regard to the pending medicare and medicaid legislation:

> The committee is particularly concerned that the utilization and review function is carried out in a manner which protects the patients while at the same time making certain that they remain in the hospital only so long as is necessary, and that every effort be made to move them from the hospital to other facilities which can provide less expensive, but equal, care to meet their current medical needs.

Sen. R. No. 404, 89th Cong., 1st Sess. 47 (1965).

appear helpful to an understanding of the challenged legislation to examine both the methods of utilization review presently in operation and the criticisms of such methods.

II.

Present Utilization Review Methods

Subchapter XVIII of the Social Security Act ["medicare"], 42 U.S.C. §§1395-1395pp, is divided into three parts: Part A, 42 U.S.C. §§1395c-1395i-2, deals with hospital insurance benefits for the aged; Part B, 42 U.S.C. §§1395j-1395w, deals with supplementary medical insurance benefits for the aged; and Part C, 42 U.S.C. §§1395x-1395pp, deals with miscellaneous provisions relative to the entire medicare program. The entire medicaid program is set forth in subchapter XIX of the Social Security Act, 42 U.S.C. §§1396-1396i.

At the present time, the utilization review procedures for benefits provided by Part A of medicare are different from the utilization review procedures for benefits provided by Part B. Similarly, the utilization review procedures for benefits provided by medicaid are different from those used for medicare. For purposes of clarity, therefore, the utilization review procedures for each group of services will be examined separately.

A.

Utilization Review Procedures For Benefits Provided By Part A Of Medicare

Part A of medicare is designed to provide "basic protection against the costs of hospital and related post-hospital services" for eligible individuals aged 65 or older, 42 U.S.C. §1395c. Hospitals and extended care facilities which receive reimbursement for treatment of eligible

individuals under Part A of medicare are required by 42 U.S.C. §§1395x(e)(6) and 1395x(j)(8) to have a utilization review plan which meets the requirements of 42 U.S.C. §1395x(k). Section 1395x(k)(2) provides for a review of hospital services by either (1) "a staff committee of the institution composed of two or more physicians, with or without participation of other professional personnel," or (2) a group outside the institution which is similarly composed and (a) established by a local medical society and some or all of the hospitals and extended care facilities in the locality or (b) established in such other manner as may be approved by the Secretary of Health, Education and Welfare. The review committee must examine on a sample or other basis:

> . . . admissions to the institution, the duration of the stays therein, and the professional services (including drugs and biologicals) furnished (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services . . . . 42 U.S.C. §1395x(k)(1).

Pursuant to 42 U.S.C. §1395hh, the Secretary of Health, Education and Welfare (hereinafter referred to as the "Secretary") has promulgated regulations setting forth the utilization review requirements of Section 1395x(k) in greater detail. One such regulation requires that a hospital's review plan:

> should have as its over-all objective the maintenance of high quality patient care, and an increase in effective utilization of hospital services to be achieved through an educational approach involving study of patterns of care, and the encouragement of appropriate utilization. 20 C.F.R. §405.1035(b)(2).

Other applicable regulations provide, inter alia, that a hospital's utilization review plan be in writing, 20 C.F.R. §405.1035(d); that the review committee be broadly representative of the hospital's medical staff, 20 C.F.R. §405.1035(e)(2)(iii); and that records be kept of the activities of the committee, 20 C.F.R. §405.1035(h).

Regulations also provide for termination of inpatient hospital benefits where a utilization review committee makes a finding that inpatient services are no longer medically necessary, 20 C.F.R. §405.162. A similar provision covers post-hospital care, 20 C.F.R. §405.166. Review is mandatory in "long-stay" (over 20 days) inpatient cases and failure to make such a review requires termination of benefits, 20 C.F.R. §405.163. A similar regulation covers "long-stay" outpatient cases, 20 C.F.R. §405.167. Notice and hearing in case of termination of benefits are also provided for by regulation, 20 C.F.R. §405.617.

If a hospital or extended care facility wishes to be reimbursed through a public agency or private organization for treatment of eligible individuals under Part A of medicare, the Secretary is authorized to enter into an agreement with such agency or organization providing for:

> . . . the determination by such agency or organization . . . of the amount of the payments required pursuant to this part to be made to such providers, and for the making of such payments by such agency or organization to such providers. 42 U.S.C. §1395h(a).

Section 1395h(b) further provides:

> The Secretary shall not enter into an agreement with any agency or organization under this section unless

> . . . he finds . . . (1) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 426 of this title, and the agreement provides for such assistance, and (2) such agency or organization agrees to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section as the Secretary may find necessary in performing his functions under this part.

Regulations issued relative to 42 U.S.C. §1395h provide that the Secretary may enter into an agreement authorized by Section 1395h with an agency or organization if the Secretary finds that:

> Where the proposed agreement is to provide that the nominated agency or organization is to assist providers in the application of safeguards against unnecessary utilization of services under Subpart A of this part, such agency or organization is willing and able to provide such assistance . . . . 20 C.F.R. §405.660(b).[6]

B.

Utilization Review Procedures For Benefits Provided By Part B Of Medicare

Part B of medicare establishes "a voluntary insurance program to provide medical insurance benefits" for eligible individuals aged 65 or

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6/ It has been noted:

> Most non-profit community hospitals as well as some other types of hospitals, (a total of 6876 out of 7906 hospitals) nominated the Blue Cross Association as intermediary through their membership in the American Hospital Association. Additionally somewhat more than half of the extended care facilities also selected Blue Cross as their fiscal intermediary. The balance of the extended care facilities selected various commercial insurance companies as fiscal intermediaries. In addition, certain facilities, primarily government hospitals have elected to deal directly with the Government.

Staff of Senate Comm. on Finance, 91st Cong., 2d Sess., Medicare and Medicaid -- Problems, Issues, and Alternatives 113 (Comm. Print 1970) (Hereinafter referred to as "Staff Report").

older; the program is financed by premium payments from enrollees together with federal funds, 42 U.S.C. §1395j.

Pursuant to 42 U.S.C. §1395u, the Secretary is authorized to contract with carriers 7/ in order to have such carriers disburse the benefits provided by Part B. Section 1395u(a)(2)(B) provides that the carriers operating under such a contract may be authorized by the Secretary to:

> . . . assist providers of services and other persons who furnish services for which payment may be made under this part in the development of procedures relating to utilization practices, make studies of the effectiveness of such procedures and methods for their improvement, assist in the application of safeguards against unnecessary utilization of services furnished by providers of services and other persons to individuals entitled to benefits under this part, and provide procedures for and assist in arranging, where necessary, the establishment of groups outside hospitals (meeting the requirements of section 1395(k)(2) of this title) to make reviews of utilization . . . . 42 U.S.C. §1395u(a)(2)(B). 8/

7/ "Carrier" is defined as:

> . . . a voluntary association, corporation, partnership, or other nongovernmental organization which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee organization. . . . 42 U.S.C. §1395u(f)(1).

8/ The authorization set forth in Section 1395u has been restated by regulation, 20 C.F.R. §405.677(d).

A regulation promulgated in furtherance of the legislative purpose behind 42 U.S.C. §1395u provides:

> A carrier which has entered into a contract with the Secretary shall:
>
> * * *
>
> (c) Institute utilization safeguards which include methods for professionally assuring that payments made under part B title XVIII are for covered services which are medically necessary. If, after appropriate consultation, the carrier concludes that a service or services for which a claim has been made were not medically necessary or that the claim as presented is improper in reflecting the amount and character of services rendered, the carrier is responsible for taking appropriate action with respect to adjustment or rejection of the claim.
>
> (d) Establish methods and procedures for identifying utilization patterns which deviate from medically established norms, and bring such patterns of utilization to the attention of appropriate professional groups.
>
> * * *
>
> (f) Maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under paragraph (c) of this section and otherwise to carry out the purposes of the supplementary medical insurance benefits plan. 20 C.F.R. §405.678.

C.

Utilization Review Procedures For Benefits Provided By Medicaid

Medicaid authorizes a yearly appropriated sum to be made available to states in order to enable the states to furnish medical and rehabilitative

services to families with dependent children and to aged, blind or disabled individuals with insufficient income, 42 U.S.C. §1396. In order to be eligible for medicaid assistance, a state must designate or establish a single state agency to administer the medicaid plan or to supervise the administration of the plan, 42 U.S.C. §1396a(a)(5).

Section 1902(a)(30) of the Social Security Act, 42 U.S.C. §1396a(a)(30), provides that an eligible state plan must:

> . . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy, and quality of care.

The necessary utilization review procedures for state programs receiving medicaid funds are described in 45 C.F.R. §250.20. The regulation provides that the utilization review committee of a hospital established under Part A of medicare may be delegated to act as the review committee for medicaid. If the review is not delegated to this committee, the medical assistance unit of the single state agency must perform and/or monitor utilization reviews. The regulation provides:

> Review of professional services through existing peer review mechanism is encouraged to the fullest extent possible. 45 C.F.R. §250.20(a)(1)(ii).

The regulation further provides that the medical assistance unit of the single state agency is responsible for all utilization review plans and activities under the medicaid program.

III.

Criticism Of Present Utilization Review Procedures

Criticism of the present utilization review procedures varies with the type of procedure concerned; for purposes of clarity, therefore, the criticisms of each review procedure will be discussed separately.

A.

Criticism Of Utilization Review Procedures Under Part A Of Medicare

When the issue of utilization review under Part A of medicare was before the staff of the Senate Committee on Finance in 1970, the staff noted:

> . . . Based on a sample of hospitals taken in the middle of 1968, the Social Security Administration found:
>
> 1. 10 percent of the hospitals not conducting a review of extended stay cases.
>
> 2. 47 percent of hospitals were not reviewing any admissions (a basic statutory requirement).
>
> 3. 42 percent of hospitals did not even maintain an abstract of the medical record or other summary form which could provide a basis for evaluating utilization by diagnosis or other common factor.
>
> In one State, the health agency conducted a detailed program review in November 1968. Their findings were that half of the hospitals and all of the extended care facilities failed to perform any sample reviews of cases which were not in the long-stay category (a statutory requirement).9/

A number of reasons have been proffered for the ineffectiveness of Part A's utilization review procedures. As stated by one Senator:

> Review solely within the hospital is generally inadequate. This sort of review has largely been a failure in the past, as hospital utilization review committees appear reluctant either

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9/ Staff Report at 107.

> to antagonize fellow staff members (who often refer and consult with each other) or to reduce the hospital's bed census. Secondly, institutional utilization review committees are usually too small to make efficient use of computor profiles, and other aids to the review process. Thirdly, and perhaps most important, only one aspect of medical care is reviewed. Hospital utilization review committees, which may meet as infrequently as once a month, do not provide a logical nor comprehensive focus for the continuing review of total patient care -- physicians' office services, skilled nursing home care, drugs, physical therapy, and so forth.[10]

The deficiencies with the present method of institutional utilization review have also been noted by the Senate Finance Committee:

> The detailed information which the committee has collected and developed as well as internal reports of the Social Security Administration indicate clearly that utilization review activities have, generally speaking, been of a token nature and ineffective as a curb to unnecessary use of institutional care and services. Utilization review in medicare can be characterized as more form than substance. The present situation has been aptly described by a State medical society in these words:
>
> > Where hospital beds are in short supply, utilization review is fully effective. Where there is no pressure on the hospital beds, utilization review is less intense and often token.[11]

Review by fiscal intermediaries[12] has also been found to be ineffective. The Senate Finance Committee noted:

> Available data indicate that in many cases intermediaries have not been performing these functions satisfactorily despite the fact that the Secretary may not, under the law, make agreements with an intermediary who is unwilling, or unable, to assist providers of services with utilization review functions.[13]

10/ 116 Cong. Rec. 32845 (1970) (Remarks of Senator Bennett).

11/ Sen. R. No. 92-1230 at 255-56.

12/ See footnote 6, supra, and accompanying text.

13/ Sen. R. No. 92-1230 at 256.

A number of reasons have been suggested for the ineffectiveness of intermediary utilization review:

> For example, one intermediary reported that it was somewhat hesitant to require the hospitals for which it acts as intermediary to do a more effective job of utilization review or to take other steps to control costs, fearing that some of the providers would choose another less critical and more accommodating organization as intermediary. Thus, the intermediary nominating provision, originally intended to furnish assurance to hospitals that they would be dealing with a familiar organization under the new program, may lead to situations which subvert cost control aspects of the program. While there have not been widespread changes in intermediary assignments, the mere threat of change operates in a negative way to dampen positive administration.
>
> Moreover, under this provision it is possible for intermediaries to offer themselves to an institution with the understanding, implicit or explicit, that in return for its nomination the intermediary will give preferential treatment to the institution. We have learned of situations in Florida, Connecticut and in Pennsylvania where the intermediary also began underwriting the casualty and other insurance needs of institutions. Thus, the relationship can be profitable to both the intermediary (despite the fact that it receives no more than costs for its medicare services) and the institution -- to the possible detriment of the program and probably to the beneficiaries as well.[14]

B.

Criticism Of Utilization Review Procedures Under Part B Of Medicare

The basic criticism of utilization review under Part B of medicare arises out of the fact that the responsibility for such review is largely in the hands of non-medical personnel employed by various carriers.[15] The Senate Committee on Finance has stated:

14/ Staff Report at 114.

15/ See footnote 7, supra, and accompanying text.

> Apart from the problems experienced in connection with their determinations of 'reasonable' charges, the performance of the carriers responsible for payment for physicians' services under medicare has also varied widely in terms of evaluating the medical necessity and appropriateness of such services. Moreover, ever since medicare began, physicians have expressed resentment that their medical determinations are challenged by insurance company personnel.16/

During hearings on medicare and medicaid, members of the medical profession indicated displeasure at having non-medical personnel reviewing the medical decisions of doctors. One officer of a medical society stated:

> I think what we are saying is that if there are professionals, both on the private and public level, there would be no problem in the peer review mechanism. The great fear that patients and physicians would have is that there would be any system instituted whereby nonphysician personnel would attempt to evaluate professional activity. Clearly it would not be a very proper situation.
>
> Unfortunately and very regrettably in some sections of the country where there are carriers, insurance carriers, who have not put forth the kind of effort necessary to get effective cooperation from the profession, there are nonprofessionals attempting to evaluate medical problems.17/

Thus, while the criticism of utilization review procedures under Part A of medicare is based largely on the ineffectiveness of institutional review, the criticism of the utilization review procedures under Part B is based largely upon (1) the varying performance records of the different carriers and (2) the fact that non-medical personnel are supervising and often overruling the medical decisions of professional doctors.

16/ Sen. R. No. 92-1230 at 256.

17/ Hearings on Medicare and Medicaid Before a Subcomm. of the Senate Comm. on Finance, 91st Cong., 2d Sess. 651 (1970) (Comment of Dr. Andrew L. Thomas, Secretary, House of Delegates, National Medical Association).

C.

Criticism Of Utilization Review Procedures Under Medicaid

Because the single state agency responsible for monitoring each state's utilization review programs under medicaid is allowed to designate the utilization review committees set up under Part A of medicare as its utilization review mechanism,[18] it necessarily follows that the criticisms of the institutional review procedures of Part A of medicare apply with equal force to institutional review procedures of medicaid.

In addition, there is evidence that state agencies are not well suited to review the medical opinions of doctors. A representative of the New York Department of Health has stated:

> I would say that generally health departments are not particularly enthusiastic about this kind of activity. They have not been trained historically and by activity to be the kind of monitors that are needed.[19]

IV.

The Utilization Review Procedures Established By The Challenged Legislation

Section 249F of Title II of the 1972 amendments to the Social Security Act,[20] codified at 42 U.S.C. §§1320c-1320c-19, added a new Part B to Title XI of the Social Security Act. This new Part, entitled "Professional

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18/ See page 9, supra.

19/ Hearings on Medicare and Medicaid Before a Subcomm. of the Senate Comm. on Finance, 91st Cong., 2d Sess. 520 (1970) (Comment of Dr. Lowell E. Bellin, First Deputy Commissioner, Department of Health, New York, N.Y.).

20/ Act of Oct. 30, 1972, Title II, §249F, 86 Stat. 1429-45.

Standards Review," is the legislation challenged in the instant suit.

The purpose behind the new legislation is to insure 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. §1320c.

The challenged legislation establishes a number of new organizations and creates certain new limitations of liability. For purposes of clarity, therefore, this discussion of the legislation will be broken down into various topics.

A.

Professional Standards Review Organizations

The legislation provides that the Secretary shall, not later than January 1, 1974, establish throughout the United States "appropriate areas" with respect to which "Professional Standards Review Organizations" (hereinafter referred to as "PSRO's") may be designated. At the earliest practicable date after the designation of an appropriate area, the Secretary must enter into an agreement with a "qualified organization" whereby such organization is designated as a PSRO for such area. 42 U.S.C. §1320c-1(a).[21/]

21/ The organization is first conditionally designated the PSRO; if the performance of the organization is satisfactory, the conditional status ceases, 42 U.S.C. §1320c-1(a). The limitations of a conditional status are set forth in 42 U.S.C. §1320c-3. The agreement between the organizatic and the Secretary is for a 12 month period although either party may terminate it earlier under certain prescribed conditions. 42 U.S.C. §1320c-1(d).

A "qualified organization" is defined by the legislation as a nonprofit professional association composed of licensed doctors practicing in the appropriate area, the membership of which includes a substantial proportion of all such doctors in the area.[22] The organization must be organized "in a manner which makes available professional competence to review health care services of the types and kinds with respect to which [PSRO's] have review responsibilities," and have membership voluntary and open to all doctors in the area without requiring membership in or payment of dues to any organized medical society; further, the organization cannot prevent any of its members from serving on or working with a PSRO, 42 U.S.C. §1320c-1(b)(1)(A). In addition, the Secretary must find that the organization is willing and able to perform the functions of a PSRO before it can be designated as such. 42 U.S.C. §1320c-1(b)(2).[23]

22/ Until January 1, 1976, the Secretary must notify the practicing physicians in the area of his intention to enter into an agreement designating an organization as a PSRO. Following such notice, at the request of ten percent or more of the practicing physicians in the area, the Secretary is required to poll the practicing physicians in the area to determine whether or not the organization substantially represents them. If more than 50 percent of the practicing physicians in the area responding to the poll indicate that the organization does not substantially represent them, the organization cannot be designated a PSRO. 42 U.S.C. §1320c-1(f).

23/ There is another legislative definition of "qualified organization":

> [S]uch other public, nonprofit private, or other agency or organization, which the Secretary determines, in accordance with criteria prescribed by him in regulations, to be of professional competence and otherwise suitable . . . . 42 U.S.C. §1320c-1(b)(1)(B).

In regard to this type of organization, the Senate Committee on Finance stated:

> Physician organizations or groupings would be completely free to undertake or to decline

B.

Duties and Responsibilities of PSRO's

Each PSRO is required to assume, at the earliest date practicable:

> . . . 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

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assumption of the responsibilities of organizing a PSRO. If they decline, the Secretary would be empowered to seek alternative applicants from among other medical organizations, State and local health departments, medical schools, and failing all else, carriers and intermediaries or other health insurers. In no case, however, could any organization be designated as a PSRO which did not have professional medical competence. And, in no case could any final adverse determinations by a PSRO with respect to the conduct or provision of care by a physician be made by anyone except another qualified physician.

Sen. R. No. 92-1230 at 259-60. The Secretary cannot enter into an agreement with a section 1320c-1(b)(1)(B) organization until January 1, 1976, nor after such date, unless there is no organization described by section 1320c-1(b)(1)(A) in the appropriate area. 42 U.S.C. §1320c-1(c)(1). If the Secretary has an agreement with a section 1320c-1(b)(1)(B) organization, he cannot renew it if he determines (1) that there is a section 1320c-1(b)(1)(A) organization in the area ready and able to assume the functions of a PSRO and (2) that the selection of the section 1320c-1(b)(1)(A) organization would result in substantial improvement of the PSRO functions in the area. 42 U.S.C. §1320c-1(c)(2).

> (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. §1320c-4(a)(1).[24/]

The challenged legislation places an obligation upon practitioners and providers of health care services to assure that services provided under medicare or medicaid are medically necessary and of professional quality; further, practitioners and providers are obligated to support such assurances with such evidence as may reasonably be required by a PSRO. 42 U.S.C. §1320c-9(a)(1). The legislation also requires practitioners and providers not to take any action which would authorize any individual to be admitted as an inpatient unless inpatient treatment was medically necessary. 42 U.S.C. §1320c-9(a)(2).

If a PSRO, acting pursuant to 42 U.S.C. §1320c-6, reports to the Secretary that a particular practitioner or provider of services has (1) failed, in a substantial number of cases, to comply with any of the above-cited obligations or (2) grossly and flagrantly violated any such obligation in one or more instances and recommends sanctions against such practitioner or provider, and the Secretary agrees with the report and recommendation of the PSRO, practitioner or provider may be excluded from

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24/ Pending the assumption by a PSRO of full review responsibility, the utilization review procedures discussed previously remain in effect. 42 U.S.C. §1320c-2. Once a PSRO begins to assume its review responsibilities, however, the Secretary can waive any or all of the present review procedures. 42 U.S.C. §1320c-1(e).

participation in the medicare and medicaid programs. 42 U.S.C. §1320c-9(b)(1).[25] The legislation provides for notice and hearing of such determinations. 42 U.S.C. §1320c-9(b)(4).

Each PSRO will have the authority to determine, in advance, whether (1) any elective admission to a hospital or other health care facility, or (2) 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. §1320c-4(a)(2). If a PSRO determines that services provided or about to be provided are not medically necessary or could be performed in a more economical manner, no federal funds may be used as payment for such services. 42 U.S.C. §1320c-7. However, a PSRO cannot have any person other than a licensed physician make a final determination as to the professional conduct of any other physician. 42 U.S.C. §1320c-4(c).[26]

Each PSRO is required to determine and publish the types and kinds of cases with respect to which it will exercise the authority conferred upon it under section 1320c-4(a)(2). 42 U.S.C. §1320c-4(a)(3). Also, each PSRO is responsible for maintaining a regular review of profiles of care and services provided to patients, utilizing to the greatest extent

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25/ An alternative sanction is to require the errant practitioner or provider to pay to the United States an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided or (if less) $5,000. 42 U.S.C. §1320c-9(b)(3).

26/ The legislation provides for a hearing and review by the Secretary of all PSRO determinations denying payment for services where the amount in controversy is $100 or more. If the amount in controversy is $1,000 or more, the aggrieved party is entitled to judicial review of an adverse determination by the Secretary. 42 U.S.C. §1320c-8.

possible, "methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part." Profiles are also to be maintained on each health care practitioner and provider of services to determine whether the services ordered or rendered are consistent with the criteria set forth in section 1320c-4(a)(1). 42 U.S.C. §1320c-4(a)(4).[27]

Each PSRO has the power to (1) make arrangements to utilize the services of practitioners or specialists; (2) undertake professional inquiry of services it has a responsibility to review; (3) examine records of any doctor pertinent to the providing of services under medicare or medicaid; and (4) inspect the facilities in which care is rendered or services performed under medicare or medicaid. 42 U.S.C. §1320c-4(b).[28] However, the utilization review of a PSRO is limited to health care services provided by or in institutions, unless the PSRO requests to be charged with the duty and function of reviewing other health care services and the Secretary approves of such request. 42 U.S.C. §1320c-4(g).

The challenged legislation also provides that a PSRO must give notice to any practitioner or provider of any determination (1) denying any request

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27/A PSRO may utilize the services of a hospital or health care facility review committee (see pages 3-5, supra) if the PSRO is satisfied as to the effectiveness of such review committee. 42 U.S.C. §1320c-4(e).

28/Physicians assigned the review of hospital care must have active staff privileges in at least one hospital within the designated area. 42 U.S.C. §1320c-4(a)(5). However, a physician cannot review services provided by an institution in which he has a financial interest. 42 U.S.C. §1320c-4(a)(6).

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. §1320c-10.

C.

Norms Of Health Care Services

Each PSRO is required to apply professionally developed norms of care, diagnosis, and treatment based upon typical practice in its area as principal points of evaluation and review. 42 U.S.C. §1320c-5(a). Such norms are to include (1) the types and extent of health care services considered within the range of appropriate diagnosis and treatment for a particular illness or condition and (2) the most economical type of health care facility considered medically appropriate for a particular illness or condition. 42 U.S.C. §1320c-5(b).

Consistent with the development of norms, each PSRO is required to specify the appropriate time after the admission of a patient for inpatient treatment when the attending physician must certify that further inpatient treatment is necessary. Such certification must be accompanied by information sufficient to enable a reviewing PSRO to evaluate such medical necessity. 42 U.S.C. §1320c-5(d).

D.

Statewide Professional Standards Review Council

The challenged legislation provides that in any State in which there are located three or more PSRO's, the Secretary shall establish a Statewide Professional Standards Review Council (hereinafter referred to

as "Council"). 42 U.S.C. §1320c-11(a). The membership of a Council shall be appointed by the Secretary and shall consist of (1) one representative from each PSRO in the State, (2) four physicians, two of whom may be designated by the State medical society and two of whom may be designated by the State hospital association, and (3) four persons knowledgeable in health care who are selected as representatives of the public in such State (at least two of whom shall be recommended by the Governor of the State). 42 U.S.C. §1320c-11(b).

It is the duty of each Council to (1) coordinate the activities of, and disseminate information among, the PSRO's within the State; (2) assist the Secretary in evaluating the performance of each PSRO; and (3) assist the Secretary in developing and arranging a qualified replacement PSRO if the Secretary deems such replacement necessary. 42 U.S.C. §1320c-11(c).

E.

National Professional Standards Review Council

The challenged legislation establishes a National Professional Standards Review Council (hereinafter referred to as "National Council"). The National Council consists of 11 physicians of recognized standing and distinction, not otherwise employed by the federal government, appointed by the Secretary. 42 U.S.C. §§1320c-12(a) and 1320c-12(b).

The National Council's duties are (1) to advise the Secretary in the administration of the challenged legislation, (2) to provide information and data to PSRO's and Councils which will assist such organizations in the performance of their duties, (3) to review the operations of PSRO's and Councils, and (4) to make or arrange for the making of studies and

investigations with a view to developing and recommending to the Secretary and Congress measures to help accomplish more effectively the purposes of the challenged legislation. 42 U.S.C. §1320c-12(e).

F.

Limitations of Liability

The challenged legislation provides that no person furnishing information to any PSRO shall be criminally or civilly liable by reason of the furnishing of such information unless (1) such information is unrelated to the performance of the duties and functions of such PSRO, or (2) such information is false and the person providing such information knew, or had reason to believe, that such information was false. 42 U.S.C. §1320c-16(a).

The legislation further provides that no person, employed by or serving upon a PSRO, shall be criminally or civilly liable for any act performed by him in the performance of such duties provided he has exercised due care. This limitation does not lie, however, if such act was motivated by malice toward any person affected by such action. 42 U.S.C. §1320c-16(b).

Finally, the legislation establishes the following limitation of liability:

> 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. §1320c-16(c).

V.

The Instant Litigation

On June 26, 1973, the instant lawsuit was filed. Plaintiffs are the Association of American Physicians and Surgeons (hereinafter referred to as "Association"), a not-for-profit corporation whose membership is composed of medical practitioners; and three medical practitioners who are not members of the Association. The defendant is the Secretary of Health, Education and Welfare.

Plaintiffs seek (1) a declaratory judgment that the challenged legislation "is unconstitutional on its face" and (2) a permanent injunction restraining the defendant from implementing or enforcing the legislation.

Plaintiffs have alleged that enforcement of the challenged legislation will violate plaintiffs' constitutional rights in 14 different ways. Stripped of their considerable surplusage, these 14 allegations may fairly be grouped in the following contentions:

> 1. Enforcement of the challenged legislation will deprive plaintiffs of their right to practice their

profession in violation of the fifth amendment to the United States Constitution.[29]

2. Enforcement of the challenged legislation will interfere with the relationship between plaintiffs and their patients in violation of the fifth amendment.[30]

3. Enforcement of the challenged legislation will invade the privacy of plaintiffs and their patients in violation of the first, fourth, fifth and ninth amendments.[31]

4. The challenged legislation is vague and uncertain in violation of the fifth amendment.[32]

5. The challenged legislation imposes limitations of liability which Congress has no power to impose and the imposition of duties upon plaintiffs without valid limitations of liability violates the fifth amendment.[33]

6. The legislation creates presumptions inconsistent with the presumption of competence, good moral character, and regularity of conduct and motive created by plaintiffs' licensure in violation of the fifth amendment.[34]

7. The legislation empowers biased private organizations to exercise quasi-judicial authority over plaintiffs in violation of the fifth amendment.[35]

Each of these contentions will be discussed separately. In addition,

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29/ Complaint, part IV, ¶1

30/ Complaint, part IV, ¶¶2, 3, 5, 7, and 9

31/ Complaint, part IV, ¶¶4 and 10

32/ Complaint, part IV, ¶8

33/ Complaint, part IV, ¶¶12, 13 and 14

34/ Complaint, part IV, ¶6

35/ Complaint, part IV, ¶11

the issues of plaintiffs' standing to maintain the instant suit, this court's jurisdiction over the subject matter, and the reasonableness of the challenged legislation will be discussed.

ARGUMENT

I.

THE CHALLENGED LEGISLATION DOES NOT DEPRIVE PLAINTIFFS OF THEIR RIGHT TO PRACTICE THEIR PROFESSION

Plaintiffs allege:

> A PSRO will have the authority under the law to disapprove payments for services to Plaintiff Physicians, without prior notice or opportunity for hearing. A PSRO will also have the power to recommend the imposition of sanctions against Plaintiffs upon a finding of 'unwillingness or lack of ability substantially to comply' with the law. Upon such a recommendation, the Defendant could, in addition to any other sanction provided by law, temporarily or permanently exclude Plaintiffs from eligibility to provide services on a reimbursable basis under the Social Security Act, or require as a condition of continued eligibility that Plaintiffs pay the actual or estimated cost of the services found to be medically improper or unnecessary, up to the amount of $5,000 . . . .[36]

Although the complaint in the instant case suffers from an acute lack of specificity, it would appear that this allegation is basis for plaintiffs' contention that enforcement of the challenged legislation would interfere with their right to practice their profession in violation of the fifth amendment to the United States Constitution.

The first part of the allegation asserts that PSRO's may disapprove of payments for services "without prior notice or opportunity for hearing." The utter lack of merit of this assertion can be shown by merely reading the legislation. Title 42, United States Code, Section 1320c-10 provides:

36/ Complaint, part III, ¶14.

> Whenever any Professional Standards Review Organization takes any action or makes any determination --
>
> (a) which denies any request, by a health care practitioner or other provider of health care services, for approval of a health care service or item proposed to be ordered or provided by such practitioner or provider; or
>
> (b) that any such practitioner or provider has violated any obligation imposed on such practitioner or provider under section 1320c-9 of this title,
>
> such organization shall, immediately after taking such action or making such determination, give notice to such practitioner or provider of such determination and the basis therefor, and shall provide him with appropriate opportunity for discussion and review of the matter.

Title 42, United States Code, Section 1320c-8 provides that "a provider or practitioner who is dissatisfied with a determination made by a [PSRO]" may demand a hearing before the Secretary if the amount in controversy exceeds $100. If the amount in controversy exceeds $1,000, the practitioner or provider is entitled to judicial review of an adverse decision by the Secretary.

The second part of the allegation asserts that the challenged legislation would interfere with plaintiffs' right to practice their profession; however, the allegation clearly shows that the most severe sanction that could be imposed upon practitioners or providers by a PSRO (with the approval of the Secretary) is disqualification from the medicare and medicaid programs.[37/] Thus, plaintiffs must contend that their right to

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37/ See pages 18 - 19, supra.

receive reimbursement under these social programs is tantamount to their right to practice their profession. Such a contention cannot stand.

Under the challenged legislation, plaintiffs would be able to take any action they wish to take regarding their profession. They may treat any patient they wish to treat; they may use any method of treatment they wish to use. The Senate Committee on Finance has stated:

> PSRO disapproval of the medical necessity for continued hospital care beyond the norm for that diagnosis will not mean that the physician must discharge his patient. The physician's authority to decide the date of discharge as well as whether his patient should be admitted in the first place cannot be and are not taken from him by the PSRO. The review responsibility of the PSRO is to determine whether the care should be paid for by medicare and medicaid. By making this determination in advance, the patient, the institution, and the physician will all be forewarned of the desirability of making alternative plans for providing care or financing the care being contemplated.[38]

Plaintiffs also allege:

> In certain categories of cases, Plaintiff Physicians will be required to obtain approval from a PSRO before they may hospitalize a patient, or enter upon a particular course of treatment, and the PSRO is empowered to deny approval if it deems the hospitalization or treatment medically unnecessary within the meaning of the law, or if it concludes that the particular physician seeking approval would not render services in conformity with the norms of the law. . . .[39]

This allegation simply is not true. The challenged legislation in no way interferes with plaintiffs' right to treat beneficiaries of medicare or medicaid except insofar as reimbursement under these programs is sought. As one Senator noted:

38/ Sen. R. No. 92-1230 at 263-64.

39/ Complaint, part III, ¶10.

> The physician's privilege of admitting patients to a hospital is absolutely not affected by this amendment. His admission privileges will continue to be governed solely by the limitation presently imposed upon him by the organized medical staff of his hospital. The amendment simply provides that a proposed hospital admission, if disapproved by the [PSRO] in advance will not be payable under Medicare or Medicaid. Thus, the doctor can still admit his patient -- but he, the patient and the hospital would have to look beyond Medicaid for payment. This is similar to the present practice of Blue Cross - Blue Shield and private health insurance with one important improvement. Instead of care being provided and then having payment denied, with the Bennett Amendment, everyone will know where they stand in advance rather than after the fact.40/

Plaintiffs are perfectly willing to accept their fees under the medicare and medicaid programs; they are apparently unwilling, however, to accept any regulation over the payment of such fees. In Wickard v. Filburn, 311 U.S. 111, 131 (1942), the Court stated:

> It is hardly lack of due process for the Government to regulate that which it subsidizes.

In the instant case, it is hardly lack of due process for the Government to insure that the sums it pays out under the medicare and medicaid programs are used only for services which are medically necessary and delivered in the most economical manner possible.

II.

THE CHALLENGED LEGISLATION DOES NOT INTERFERE WITH THE RELATIONSHIP BETWEEN PLAINTIFFS AND THEIR PATIENTS IN VIOLATION OF THE FIFTH AMENDMENT

Plaintiffs allege:

> Plaintiffs' ability to render, and their patients' ability to receive health care in accordance with the

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40/ 116 Cong. Rec. 32845 (1970) (Statement of Senator Bennett).

> highest standards of medical practice will be seriously impaired if Plaintiffs are required to conform their medical judgments to a system of pre-set norms of diagnosis, treatment and care. Proper medical practice demands that, in diagnosing and treating a patient, a physician take into consideration a host of often-changing factors that are unique to each patient, and inherently incapable of reduction to 'norms'. Superimposition of a system of norms of diagnosis and treatment upon the judgments of medical practitioners 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.

This allegation appears to be the basis for plaintiffs' assertion that the challenged legislation unconstitutionally interferes with the relationship between plaintiffs and their patients. It is obvious, however, there are at least two things seriously wrong with this allegation.

First of all, the norms which plaintiffs assert will have a "chilling effect" on the doctor-patient relationship have yet to be established. Thus, because it is impossible to determine what effect a particular norm might have prior to its creation, it would appear plaintiffs have not presented the court with an actual case or controversy. As the Court stated in United Public Workers v. Mitchell, 330 U.S. 75, 89-90 (1947):

> The power of courts, and ultimately of this Court, to pass upon the constitutionality of acts of Congress arises only when the interests of litigants require the use of this judicial authority for their protection against actual interference. A hypothetical threat is not enough.

It is clear that the threat posed by the proposed norms will remain hypothetical until such time as the norms are actually established and

enforced.[41/]

Secondly, there is absolutely no authority for plaintiffs' assertion that the relationship between a doctor and his patient is within the definition of "life, liberty, or property" as protected by the Due Process Clause of the fifth amendment. It is already well settled that a beneficiary's right to receive Social Security benefits is not within that definition. Richardson v. Belcher, 404 U.S. 78, 80 (1971). It would appear obvious, therefore, that a relationship created to pass those benefits from the beneficiaries of the Social Security Act to the plaintiffs is not entitled to any greater protection or stature.

III.

THE CHALLENGED LEGISLATION DOES NOT INVADE THE PRIVACY OF PLAINTIFFS AND THEIR PATIENTS IN VIOLATION OF THE FIRST, FOURTH, FIFTH, AND NINTH AMENDMENTS

Plaintiffs allege:

> If Plaintiffs are required to supply information concerning their patients to PSRO's for use in creating physician and patient profiles, and maintain and disclose information necessary to convince a PSRO that they are

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41/ If the norms are established in conformity with Congress' intent, as they must be, it appears that the "chilling effect," which plaintiffs indicate the norms will engender will never occur. The Senate Committee on Finance has noted:

> Neither should the use of norms as check-points, 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.

> complying with the law, Plaintiffs will no longer be able to afford their patients the privacy and confidentiality in their relationship that is necessary to foster the full and candid communication essential to diagnosis and treatment.42/

This allegation is obviously the basis for plaintiffs' assertion that the challenged legislation violates the privacy of plaintiffs and their patients in violation of first, fourth, fifth, and ninth amendments.

In Felber v. Foote, 321 F. Supp. 85 (D. Conn. 1970) (three judge district court), a physician challenged the constitutionality of a Connecticut statute requiring him to report the names of "drug-dependent" patients to the Connecticut State Commissioner of Health. The physician argued that the statute invaded his right of privacy and required him to violate "unspecified professional standards of conduct or ethics."

In finding the statute constitutional, the court stated:

> Plaintiff further makes the unwarranted assumption that the special nature of the doctor-patient relationship affords him a constitutionally protected right to privacy in his conduct of the relationship. There is no 'general constitutional right to privacy.' . . . Id. at 88.

After discussing the cases cited by the physician in support of his argument, the court held:

> In short, the right to privacy asserted by the plaintiff is not supported by the Constitution or any federal law. Id. at 89.

The Connecticut statute provided that the physician's report was inadmissible in criminal prosecutions. The protection awarded the information required by the challenged legislation is much greater.

42/ Complaint, part III, ¶13.

Title 42, United States Code, Section 1320c-15, provides:

> (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 by 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.

It is submitted that the decision in Felber v. Foote, supra, is dispositive of plaintiffs' assertion that the challenged legislation invades their right to privacy.

IV.

THE CHALLENGED LEGISLATION IS NOT VAGUE AND UNCERTAIN IN VIOLATION OF THE FIFTH AMENDMENT

Plaintiffs allege that the duties and obligations imposed upon them by 42 U.S.C. §1320c-9 are stated in such vague and uncertain terms "that Plaintiffs must necessarily guess at their meaning" contrary to the fifth amendment.[43/]

In United States v. Petrillo, 332 U.S. 1, 7-8 (1947), the Court stated:

> . . . 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.

43/ Complaint, part IV, ¶8.

Physician Plaintiffs, all highly qualified members of the medical profession, [44] claim that they must guess at the meaning of the phrases "medically necessary," "quality which meets professionally recognized standards of health care," "professionally recognized health care standards," and so forth.

In determining whether the language of a statute is unconstitutionally vague, the test to be applied is whether men of common intelligence must necessarily guess at its meaning. Hosack v. Smiley, 276 F. Supp. 876, 878 (D. Colo. 1967), aff'd., 390 U.S. 744 (1968). Since the challenged legislation imposes its duties only upon practitioners and providers of service, the test must be rephrased to include only members of the medical profession of common intelligence. Accordingly, in order to hold the challenged legislation unconstitutionally vague, this Court must hold that members of the medical profession of common intelligence must guess at the meaning of the phrases "medically necessary," "professionally recognized health care standards," "proper care" and so forth. Not only would such a holding have a frightening effect on the recipients of medical care, but it also would be totally unjustified by common experience. Congress has done the best it can with the language of the challenged legislation; to require, as plaintiffs seem to argue, that Congress must specify in its legislation when a kidney must be removed or how long a gall bladder case should be hospitalized would be to impose a higher standard of legislative specificity than that demanded by the Constitution.

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[44] Complaint, part II, ¶¶2, 3, and 4.

V.

THE CHALLENGED LEGISLATION DOES NOT VIOLATE THE FIFTH AMENDMENT BY IMPOSING LIMITATIONS OF LIABILITY WHICH CONGRESS HAS NO POWER TO IMPOSE AND IMPOSING DUTIES UPON PLAINTIFFS WITHOUT VALID LIMITATIONS OF LIABILITY

Plaintiffs allege (1) that Congress has no power to grant legal immunity against common law tort liability,[45] and (2) if the immunity provisions of the challenged legislation[46] are enforceable, the challenged legislation imposes duties and obligations on plaintiffs which may unconstitutionally expose them to civil liability.[47]

It is readily apparent that this case is not in a proper posture to adjudicate the constitutionality of the limitations of liability. As plaintiffs impliedly admit, the only persons having the right to challenge the constitutionality of the statutory limitations of liability are the beneficiaries of medicare and medicaid.[48] Accordingly, plaintiffs have

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45/ Complaint, part IV, ¶¶12 and 13.

46/ See pages 23-24, supra. Apparently, plaintiffs are only challenging the limitations of liability set forth in 42 U.S.C. §1320c-16(c).

47/ Complaint, part IV, ¶14.

48/ Plaintiffs allege:

> The legal immunity against common law tort liability granted to medical practitioners, providers and others by Section 1167 of said law [42 U.S.C. §1320c-16] violates rights of federal health care recipients guaranteed by the Fifth and Seventh Amendments to the United States Constitution . . . .

Complaint, part IV, ¶13.

not presented this issue in the form of an actual case or controversy. Golden v. Zwickler, 394 U.S. 103 (1969).[49/]

It is also readily apparent that Congress does have the power to impose such limitations of liability. In Silver v. Silver, 280 U.S. 117, 122 (1929), the Court stated:

> . . . the Constitution does not forbid the creation of new rights, or the abolition of old ones recognized by the common law, to attain a permissible legislative object.

There are numerous cases upholding Congressional limitations of liability. See, e.g., Carr v. United States, 422 F.2d 1007 (4th Cir. 1970) (abolition of common law right of action against fellow employee held constitutional); Stumo v. United Air Lines, 382 F.2d 780 (7th Cir. 1967) (abolition of right to jury trial for wrongful discharge from employment held constitutional).

Despite the fact that the limitations of liability established by the challenged legislation are obviously constitutional, this court is nevertheless requested by the movant to defer a ruling on this issue until an actual case or controversy exists regarding the constitutionality of such limitations.

49/ In Flast v. Cohen, 392 U.S. 83, 99-100 (1968), the Court stated:

> . . . when standing is placed in issue in a case, the question is whether the person whose standing is challenged is a proper party to request an adjudication of a particular issue and not whether the issue itself is justiciable.

VI.

THE CHALLENGED LEGISLATION DOES NOT VIOLATE THE FIFTH AMENDMENT BY CREATING PRESUMPTIONS INCONSISTENT WITH THE PRESUMPTIONS OF COMPETENCE, GOOD MORAL CHARACTER, AND REGULARITY OF CONDUCT AND MOTIVE CREATED BY PLAINTIFFS' LICENSURE

Plaintiffs allege:

> Under Section 1160 of the law [42 U.S.C. §1320c-9], Plaintiffs will have the burden of demonstrating by evidence in such form and fashion and at such times as a PSRO may require that they are complying with the norms of practice and cost control measures established by the law, and that they are assuring, to the extent of their influence and control, compliance with the law by their patients and the institutions in which they practice.50/

This allegation is apparently the basis for plaintiffs' assertion that the challenged legislation violates the fifth amendment by creating presumptions inconsistent with the presumptions of competence, good moral character, and regularity of conduct and motive created by plaintiffs' licensure. This assertion is frivolous.

Stripped of its verbiage, plaintiffs' contention is that the federal government is constitutionally prohibited from requiring evidence of performance of services from those persons to whom the government pays money for such services. As Chief Justice White once noted: "To state the proposition is to refute it."51/

In Perkins v. Lukens Steel Co., 310 U.S. 113, (1940), governmental contractors challenged the enforcement of a federal statute requiring the

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50/ Complaint, part III, ¶12.

51/ The Employers' Liability Cases, 207 U.S. 463, 502 (1908).

contractors to pay wages at least as high as the prevailing minimum wages in the locality. In refusing to enjoin enforcement of the act, the Court stated:

> Like private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases. Acting through its agents as it must of necessity, the Government may for the purpose of keeping its own house in order lay down guide posts by which its agents are to proceed in the procurement of supplies, and which create duties to the Government alone. Id. at 127.

Since it is firmly established that the Government may fix the terms and conditions upon which it may purchase supplies, it necessarily follows that Congress has the power to fix the terms and conditions upon which it may procure the services of professional personnel. Congress has created such terms and conditions in the challenged legislation; they should remain undisturbed by the judiciary.

VII.

THE CHALLENGED LEGISLATION DOES NOT VIOLATE THE FIFTH AMENDMENT BY EMPOWERING QUASI-JUDICIAL AUTHORITY OVER PLAINTIFFS TO BIASED PRIVATE ORGANIZATIONS

Plaintiffs allege:

> Said law, and in particular Section 1152 of said law [42 U.S.C. §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 . . . .[52/]

52/ Complaint, part IV, ¶11.

Plaintiffs apparently are asserting that they are being deprived of "life, liberty, or property" by a partial tribunal in violation of the fifth amendment. This assertion is incorrect for several reasons.

First of all, the PSRO's are incapable of depriving plaintiffs of their "property" as protected by the fifth amendment. As noted previously,[53] the right to receive reimbursement under the medicare and medicaid program is not protected by the fifth amendment.

Secondly, no inference of partiality can be drawn solely from the fact that PSRO's are private organizations. Courts have long recognized that federal agencies can contract with private organizations in order to have such organizations perform governmental functions. See, e.g., State of Texas v. National Bank of Commerce of San Antonio, 290 F.2d 229 (5th Cir.), cert. denied, 368 U.S. 832 (1961). The only issue which may be raised by plaintiffs is whether the administrative scheme allows for a hearing on the private organization's determinations. Coral Gables Convalescent Home, Inc. v. Richardson, 340 F. Supp. 646 (S.D. Fla. 1972). It is obvious the challenged legislation meets the requirements of procedural due process.[54]

Plaintiffs have presented no basis, other than a bald allegation, for their assertion that PSRO's will be biased against them. The assertion is remarkable in that one major factor behind the enactment of the challenged legislation was to eliminate the bias of profit-motivated fiscal

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53/ See pages 28-32, supra.

54/ See pages 27-28, supra.

intermediaries which the non-profit PSRO's are eventually to replace.[55]

VIII.

THIS COURT LACKS JURISDICTION OVER
THE SUBJECT MATTER OF THE INSTANT SUIT

Plaintiffs allege this court has jurisdiction over the subject matter of the instant suit pursuant to 28 U.S.C. §1331. That section provides:

> (a) The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $10,000, exclusive of interests and costs, and arises under the Constitution, laws, or treaties of the United States.

Although plaintiffs have alleged that the matter in controversy exceeds $10,000, exclusive of interest and costs,[56] they have failed to make any factual assertions of financial detriment.

In suits brought for injunctive relief, the amount in controversy is the value of the right to be protected or the extent of the injury to be prevented. Goldsmith v. Sutherland, 426 F.2d 1395, 1398 (4th Cir.), cert. denied, 400 U.S. 960 (1970). Since plaintiffs have failed to show injury to any legally enforceable right, it is urged that the amount in controversy is not in excess of $10,000. Accordingly, this court lacks jurisdiction over the subject matter.

IX.

THE CHALLENGED LEGISLATION IS A VALID
EXERCISE OF CONGRESSIONAL POWER

A rather lengthy statement of facts has been set forth herein in order to show the court the congressional purposes behind the challenged

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55/ See page 12, supra.

56/ Complaint, part I, ¶1.

legislation. A summary of the statement is as follows.

The costs of medicare and medicaid were found by congressional committees to be increasing at a frightening pace. The increase in the costs of these social programs was found to be attributable in a large part to the overutilization of medical services. Prior legislative attempts to prevent overutilization were found by Congress to be ineffective for a number of reasons set forth herein. In the challenged legislation, Congress sought to remedy the defects of the prior systems. Where single institution review committees were found to be ineffective, Congress formed review organizations covering many institutions. Where profit-motivated fiscal intermediaries suffered from a conflict of interest by having utilization review duties placed upon them, Congress formed non-profit review organizations which would suffer no such conflict. Where doctors complained of having their medical decisions reviewed by non-medical personnel, Congress insured that all medical decisions would be reviewed only by professional medical personnel.

The challenged legislation was the product of considerable give and take within Congress' chambers. Many persons and organizations, including the plaintiff organization, 57/ testified or otherwise made their views known to Congress.

Defendant does not at this time urge upon this Court that the challenged legislation is a wise law or an efficient law; the sole issue before this Court is whether the challenged legislation is a valid law. It is respectfully submitted that it is.

57/ Hearings on H.R. 1 Before the Senate Comm. on Finance, 92d Cong., 1st and 2d Sess. 3390-94 (1971-72) (Statement of Dr. Rafael Solari, Vice-Chairman of the California Chapter of the Association of American Physicians and Surgeons).

CONCLUSION

It is respectfully urged that defendant's motion for summary judgment be granted for the reasons stated herein.

Respectfully submitted,

JAMES R. THOMPSON
United States Attorney

CERTIFICATE OF SERVICE

It is hereby certified that service of the Memorandum In Support Of Defendant's Motion For Summary Judgment has been made on opposing counsel by hand delivery on this 11th day of December, 1973, to the following individuals:

R. R. McMahan, Esq.
Harold L. Jacobson, Esq.
Hugh C. Griffin, Esq.
Lord, Bissell and Brook
135 South LaSalle Street
Chicago, Illinois 60603

PAUL F. STACK
Assistant United States Attorney

SUBSCRIBED and SWORN TO
before me this _____ day
of December, 1973.

NOTARY PUBLIC