HEALTH LAW
Newsletter

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A Message from the Section Chair

Welcome to the Health Law Section! It is hard to believe, but in less than a year we have grown from a mere proposal listed on the agenda of the House of Delegates to a vibrant Section composed of approximately 500 members. We have a strong and diverse committee structure, the advice of which has been actively sought by both the Legislature and the Governor's office. Our programs, "Managed Care: The New York Perspective" and "A Primer on Health Law" have provided timely and thorough continuing legal education (and 743 pages of materials) to hundreds of attorneys at numerous sites throughout the state. Speakers at these events included leaders in Health Law from both government and the private bar.

This is just the beginning. You are all aware of the 1996 Health Law Section Retreat, the first opportunity for all of us to get together as a group. The Committees will also make presentations. We have also planned an active program for the NYSBA Annual Meeting to be held in January. At that time, we will present "An Insider's View of the Health Care Revolution in New York State." In addition, your section, in cooperation with the Elder Law Section, will address the controversial issue of Physician-Assisted Suicide.

The Committees

I would like to reinforce the fact that the committee structure is the place within which most of the work of the Section takes place. Committees get together more frequently than the Section, meeting either personally or by telephone. They are also able to address specific issues that may be of interest to you. I therefore encourage those of you have not yet joined a committee to do so. There is no cost involved. Please feel free to fill out the Committee Assignment Request Form on page 47.

Professional Discipline

Your Executive Committee has recently voted to create a Committee on Professional Discipline. The purpose of this group will be to examine the disciplinary process as it applies to health care professionals. If you handle cases before the Office of Professional Medical Conduct, Office of Professional Discipline, the Office of Alcoholism & Substance Abuse Services, work for those entities or are interested in the field of professional discipline, please join. This will be an exciting and lively committee. Again, feel free to use the form on page 47 to request membership.

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Committee Chairs Needed

The newly created Committee on Professional Discipline and the Consumer/Patient Rights Committee each need Chairs. If you have experience in either of these areas and are interested, please write to me at Thuillez, Ford, Gold & Conolly, LLP, 90 State Street-Suite 1500, Albany, New York 12207, or send e-mail to healthlaw@juno.com.

In Conclusion

I can think of no area of practice that is more exciting than Health Law. It deals with significant issues of importance to us all as attorneys and, more importantly, as the recipients of health care. Your Section hopes to serve its members by providing a forum for timely discussion, education, legislative input, legal writing, scholarly thought and just plain fun in our chosen field. Please become an active part of this process.

Barry A. Gold
Chair

From the Editor

The first issue of our newsletter is devoted to managed care, which was also the topic of our Section's first CLE program. Claudia Torrey's article, which opens the discussion, reviews several of the unresolved issues that managed care presents. The second article, by David Henry Sculnick, deals with a specific issue: the liability of HMOs for malpractice in light of potential ERISA preemption. Geraldine Reilly's article, which follows, explores the use of managed care for treating work-related injuries covered by workers' compensation. Next are reprinted portions of a monograph that, although it is titled "Medicare & Managed Care," addresses concerns relevant to all managed care settings. Of the topic to which the final article is devoted, two commentators have said: "Physician-assisted suicide may be a lethal weapon in the managed care revolution." (*See* M. Cathleen Kaveny & John P. Langan, "The Doctor's Call," New York *Times*, July 15, 1996, at A13 col. 2.) Although physician-assisted suicide may never really come to achieve that dubious status, it is a subject worth considering as part of a complete discussion of managed-care issues.

Future issues of this newsletter will feature substantive articles as well as updates about important cases and legislative developments. The members of the Publications Committee would welcome your submission of timely articles on topics of interest to Health Law Section members. Please submit your articles in double-spaced, one-sided hard copy (and on disk if at all possible!) to:

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Albany Law School
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Thank you, and I hope you enjoy this issue of the newsletter.

Dale L. Moore
Editor

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Managed Care: What Price Quality?*

by Claudia O. Torrey, Esq.**

Change has come to health care, and more change will inevitably follow. Perhaps no greater change has been, or will be, but in the way physicians practice their profession. Soaring medical costs have propelled the concepts of managed competition and managed care to new heights. Health Maintenance Organizations (hereinafter "HMOs"), and an alphabet soup of other organized health care entities abound (for example: PHOs, PPOs, IPAs and SHMOs, also known as Physician-Hospital Organizations, Preferred Provider Organizations, Independent Practice Associations and Social HMOs, respectively).

The concept of managed care, of course, springs forth from the concept of managed competition. Briefly, managed competition demands that vertically integrated, competing (primarily regional), capitated plans vie for patients on the basis of costs, quality of care and quality of service(s). Thus, managed care seeks to control health care costs by "regulating" the utilization of health care. Keep in mind that the main driving force behind managed care is to decrease the cost of health care. We can only hope that quality does not suffer.

The typical managed care patient does not usually submit a claim for services rendered, as with traditional fee-for-service medicine. Managed care is often influenced by the financial structure of the plan and practice guidelines (sometimes called parameters or protocols). A preauthorization request may or may not apply to a limited number of services, and it is quite possible that a reduction or termination of a course of treatment could occur, without the patient's prior knowledge, based upon financial consideration and/or management oriented practice guidelines.

Most HMOs, as well as the managed care arrangements being developed between health care providers and others, contract to provide certain services for a set prepaid fee. This fee is known as a capitation fee. The physicians are paid a fixed dollar amount, for each member assigned to them, instead of being paid a fee for the services used by the patients.[1]

For the most part, little is known about how managed care will affect such things as the continuity of care, the quality of care and the fiscal stability of health care entities. Only time will tell whether or not perceived quality and/or patient satisfaction varies greatly between not-for-profit managed care plans and for-profit managed care plans; whether or not the quality of care a patient receives under a managed care plan will vary significantly in response to the way a physician is paid; whether or not quality will vary with regard to the amount of risk a group of physicians assumes; whether or not managed care will weaken such traditional health care providers as specialty hospitals and teaching hospitals; whether or not managed care compromises a physician's autonomy; and, whether or not managed care will truly be the solution state governments are looking for with regard to their uninsured and low income populations. Answers to these types of key questions can come from collecting thorough, cogent outcomes data. Such data would yield, over time, the real value of managed care to patients, to providers and to politicians.

In August 1995, due to the proliferation of managed care entities, the National Association of Insurance Commissioners (hereinafter "NAIC") sent out a draft bulletin to all state insurance commissioners, directors, etc., regarding health care entities that primarily operate on a capitated basis.[2] The NAIC draft bulletin states that if a health care provider enters into an arrangement with an individual, employer or other group that results in the provider assuming all or part of the risk for health care expenses or service delivery, the provider is engaged in the business of insurance. Such a provider should obtain the appropriate license in order to be in compliance with state insurance laws.

According to the NAIC draft bulletin, the only arrangement wherein a provider *does not* need to obtain an insurance license occurs when the provider agrees to assume all or part of the risk for health care expenses or service delivery under a contract with a duly licensed health insurer for that insurer's enrollees. An example of such is an arrangement between a group of physicians or a hospital with an HMO to provide health care services to the HMO's enrollees in exchange for a fixed prepayment. Thus, the survival of some managed care models in a capitated marketplace seems questionable.

Recent inquiries to the NAIC by this author have revealed that the NAIC will continue to work on the "business of insurance" issue, with the goal of developing a permanent ruling in December, 1996.

The long-term success of managed care as the majority health care system in the United States is yet to be seen. The collection of outcomes data could be greatly enhanced by uniform practice guidelines for all managed care entities concerning the different medical practice areas.

Regardless of what may happen at the federal level concerning national health care reform, many changes are occurring in our health care system under the rubric of managed care. Quality of care and perceived quality of care should be our most important priority.

Endnotes

1. Gayle L. Holland, *Health Maintenance Organizations: Member Physicians Assuming the Risk of Loss Under State and Federal Bankruptcy Laws*, 15 J. OF LEG. MED. 445, 447 n. 19 (1994).
2. *NAIC Cautions That Health Care Entities Accepting Capitation May Be in Business of Insurance, Violating State Laws*, CAPITATION CONTRACTS: A GUIDE TO NEGOTIATING SUCCESSFUL AGREEMENTS, September 1995, at 1, 2.

** This article is updated from an article by the author in NASHVILLE MEDICAL NEWS, November 1995, and is reprinted with permission of NASHVILLE MEDICAL NEWS with the author's thanks.*

**** Claudia O. Torrey is an attorney and an economist. She currently (1994-1996) serves as the American Bar Association/Young Lawyers Division Liaison to the Forum Committee on Health of the American Bar Association. She previously served in the New York State Senate as an Assistant Counsel, covering several legislative committees including Aging, Child Care and Health. Ms. Torrey can be reached at Post Office Box 150234, Nashville, Tennessee 37215.**

HMO Liability and ERISA Preemption for Medical Malpractice*

by David Henry Sculnick**

We have been living with medical cost containment systems of one form or another for many decades. The escalating cost of medical services has had such a substantial impact on our economy and on the cost of doing business, however, that it has become increasingly essential to devise new systems intended to make medical care available and affordable. In this article, we will examine how various courts have addressed an ancillary, yet ever-present issue in health care delivery, the medical malpractice claim.

This article will explore the impact of ERISA on medical negligence claims against HMOs, and it will focus on the circumstances where those claims have been allowed to proceed, and what, if anything, the medical practitioner-defendant can do to share liability with those entities. A sufficient body of decisional law now exists from which we can fairly conclude that a plaintiff's claim for medial negligence against an HMO for inadequate care, as distinguished from a claim against the physician or hospital, can be pursued and is not preempted by ERISA. The nature of the claim that can be asserted against the HMO is not unlimited in scope; and to survive, such claims have generally rested on a theory of vicarious liability for the acts of the health care deliverer. HMOs can and must expect to face inclusion in medical malpractice litigation as their involvement and control of service delivery systems increases, especially where catastrophic injuries compel the plaintiff to seek multiple, deeper pockets, at least in those jurisdictions which have not imposed statutory ceilings on non-economic loss.

There is a very definite split of judicial authority on the question of whether or not ERISA preempts tort actions against health maintenance organizations seeking to hold them vicariously liable for medical malpractice. Those jurisdictions which reject preemption[1] generally hold that litigation which attacks the quality of the care rendered does not involve an attack upon the nature or administration of the benefit plan itself, and is therefore permissible. Those jurisdictions which oppose this view, and which interpret preemption broadly,[2] see malpractice claims as merely a variant attack on the nature and mechanism of the employee benefit plan itself, which is precisely what they maintain ERISA was intended to control and curtail.

I. The Statute Involved

The Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1144(a) states in pertinent part as follows: "Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title." While all courts which have addressed the issue start at the same point, the opposing groups diverge quickly in their assessments. All agree that "ERISA is a comprehensive statute designed to promote the interests of employees and their beneficiaries by regulating the creation and administration of employee benefit plans."[3] Those courts which uphold preemption do so in the belief that Congress [only] intended and drafted the preemption clause to be applied in "broad terms."[4] Those courts which have declined to find such claims preempted cite the notion that the Supreme Court "has determined that Congress intended the complete-preemption doctrine to apply to state law causes of action which fit within the scope of ERISA's civil-enforcement provisions."[5]

Even in those cases where the tort action has been allowed, the courts have made it clear that an ERISA preemption still exists and that there is a clear class of claim which falls squarely within the preempted and prohibited category. As we will discuss, it is this prohibited category of claims which may yet have the most substantial impact on physician efforts to spread the risk of claim exposure. Claims will be permitted only so long as they do not seek to recover plan benefits due under the terms of the plan, or to enforce rights under the terms of the plan, or seek to clarify the right to future benefits due under the terms of the plan.[6]

II. Malpractice

A. Vicarious Liability

Vicarious liability, or ostensible agency, were the earliest theories by which the plaintiff sought to impose responsibility on the HMO for professional negligence committed by a physician. In jurisdictions where ostensible or apparent agency is permitted under state law, district courts have utilized that theory as a barrier against preemption.[7]

In applying vicarious liability, courts have usually examined the nature and structure of the relationship between the HMO and the physician delivering the service. No court appears to have had any difficulty imposing liability based upon *respondeat superior* in delivery systems like Kaiser's where the health care provider is actually employed by the larger organization. Where the HMO raises the independent contractor status of the physician as a basis for avoiding vicarious liability, courts will then examine the nature of the relationship and the degree of control exercised. If the HMO merely "approves" the physician in much the same way that a hospital would grant admitting privileges, or simply requires that the recipient select the physician from the list of doctors under contract to the HMO, that has generally not been a sufficient predicate to impose vicarious liability.[8] Several courts have turned to Restatement (2d) of Agency, § 267, comment (a) for

support in establishing vicarious liability: "[T]he rule normally applies where the plaintiff has submitted himself to the care or protection of an apparent servant in response to an invitation from the defendant to enter into such relations with such servant."[9]

Early cases either ignored ERISA altogether or developed a set of criteria upon which to predicate vicarious or agency liability. Those decisions were generally reached at the pleading stage where, in response to motions for summary judgment, the court ruled that the allegations were sufficient to create a question of fact.

One of the first, and most frequently cited decisions is the case of *Boyd v. Albert Einstein Medical Center*.[10] The case involved an IPA model HMO and ERISA preemption was not raised as an issue. On appeal from a grant of summary judgment the court reversed, finding a material question of fact existed "as to whether the participating physicians were the ostensible agents" of the HMO. In examining the contract relationship between the HMO and physicians, the court found it persuasive that the HMO operated on a direct service rather than indemnity basis and that the participant paid his fees to the HMO, and not to the physician of choice. In addition to providing a list of physicians from which the participant was to select his primary physician, the court noted that the HMO had undertaken a fairly extensive pre-screening process of physicians before they were approved, that the physicians were required to comply with a list of regulations established by the HMO, and that the practitioners were governed by a capitation system which created "a pooled risk-sharing fund as a reserve against specialty referral costs and hospital stays."[11] There were two factors found relevant, and which reappear as themes in subsequent cases. First, whether the patient looked to the "institution" or the individual physician for care and second, whether the HMO "holds out" the physician as its employee. In addressing the second factor, the court concluded that "because appellant's decedent was required to follow the mandates of the HMO and did not directly seek the attention of the specialist, there is an inference that appellant looked to the institution for care and not solely to the physicians; conversely, that appellant's decedent submitted himself to the care of the participating physicians in response to an invitation from HMO."[12]

Shortly after *Boyd* was decided, a Pennsylvania federal court was presented with a situation in which the HMO brought suit to enjoin a then pending state court malpractice action on the dual grounds that the suit was at best premature because the claimant had failed to exhaust the internal grievance procedures established by the HMO, or, in the alternative, because the state court action was preempted by ERISA.[13] The District Court concluded that ERISA's purposes were "not advanced by preemption of state common law claims which are not premised on violation of duties imposed by ERISA." The preliminary injunction was denied because ERISA had no requirement that a participant first exhaust plan remedies before bringing suit, and because, in any event, the tort action did not arise under ERISA to begin with.[14]

What then are the theories under which HMOs can be held liable for medical malpractice, and do any of them provide a basis for the cross claim which a physician or hospital might assert? In *Raglin v. HMO Illinois, Inc.*, 595 N.E.2d 153 (Ill. App. 1992), an Illinois state court identified three theories upon which to predicate HMO liability in a case not involving ERISA preemption issues. Those theories were: (1) vicarious liability on the basis of *respondeat superior* or ostensible agency; (2) corporate negligence based upon negligent selection and negligent control of the physician; and (3) corporate negligence based upon the corporation's independent acts of negligence. The example offered for this third theory was negligence in the management of utilization control systems. The example given by the court does not appear correct, however, because utilization review systems fall into the class of claims which invariably have been denied because of ERISA preemption.

Courts that have enforced preemption interpret the statute broadly, ruling that any type of malpractice claim against the HMO necessarily "relates to the plan" document and generally "asserts [that] the services provided did not measure up the benefit plan's promised quality."[15] That has not been the view of those courts which have declined to preempt state law malpractice claims. "That a state law may increase the costs of operating a benefit plan does not result in preemption or such plans would enjoy 'a charmed existence that never was contemplated by Congress.' "[16]

In *Dukes v. U.S. Healthcare, Inc.*,[17] the Third Circuit reversed two separate District Court cases which had declined to permit damage claims against HMOs. The facts in both cases are fairly typical of the situations which are likely to be encountered in this litigation, and which periodically make their way to the city section of most metropolitan newspapers.

Mr. Dukes was a member of an HMO through an employer-sponsored health care program. He underwent surgery on his ears and was given a prescription by his physician to have blood tests. The hospital refused to do the tests for reasons which are unknown. A few days later he went to a second physician who also ordered a blood test which was performed. His condition continued to deteriorate and he died a short time later. His blood sugar level at the time of death was extremely high. In the second case, Mrs. Visconti developed preeclampsia during pregnancy and delivered a stillborn child. They sued the obstetrician and the HMO. Both the Dukes and the Viscontis alleged that the HMO should be liable under ostensible agency theories for the negligence of the various doctors, and was subject to direct negligence liability for its selection and oversight of the medical personnel who actually rendered care.

In remanding to the state court, the Third Circuit rejected U.S. Healthcare's arguments that the medical care received was itself a plan benefit. The significant distinction as far as the court was concerned involved the fact that the plaintiffs did not claim "that the plans erroneously withheld benefits due" but instead attacked the quality of the benefit actually

received.[18] The court noted that the HMO played two different roles, a utilization review role and "arrang[ing] for the actual medical treatment for plan participants."[19]

The dispute between these competing schools of thought turns, in major part, on their view of whether or not the claim "relates to" the employee benefit plan. "We are confident," wrote the Third Circuit in *Dukes*, "that a claim about the quality of a benefit received is not a claim under § 502(a)(1)(B) to 'recover benefits due . . . under the terms of [the] plan.'"[20] As one District Court saw it, "plaintiffs are not asserting any claims *under* ERISA, nor are plaintiffs using state laws to obtain insurance benefits. [The malpractice claim against the HMO was] based not on the insurance plan between HMO and plaintiff . . . but on the principles of professional malpractice and the contractual relationships between the defendant HMO and the doctors who treated" the patient.[21]

III. Preempted Claims

The Tenth Circuit has identified four categories of laws which "relate to" an employee benefit plan and which are, therefore, prohibited: (1) laws which regulate the type of benefits or terms of the plan; (2) laws which create reporting, disclosure, funding or vesting requirements; (3) laws which provide rules for the calculation of the amount of benefits to be paid under the plan; and (4) laws and common-law rules which provide remedies for misconduct growing out of the administration of the plan itself.[22]

The structure and relationship between physician and HMO has and will continue to be a likely subject for the press to scrutinize. Tabloid news pieces about premature hospital discharge, failure to refer to appropriate specialists, and declined benefits provide good ratings and sell copy. There are stories about administrative snafus, delayed or denied approval for continued hospitalization, specialized testing or expensive treatment. Physicians will frequently find themselves in the middle of the battlefield, sometimes as partisan, and as often as a noncombatant trying desperately to remain neutral.

IV. Sharing Liability

The physician or hospital named in a malpractice suit will face significant limitations on the theories for contribution which they can successfully assert against an HMO. If the physician's ability to render care has been compromised because of the Plan's internal procedures, approval systems, restrictions, or cost containment methods, those factors will not form a predicate for a cross-claim or an apportionment of liability. Those are precisely the kinds of claims which all courts have ruled are preempted by ERISA.

The first and most important way for physicians to properly protect themselves, however, will require that they become "parliamentary pirates." They will need to be fully familiar with and prepared to follow all of the HMO's internal procedures for requesting, appealing and if necessary contesting payment or approval procedures which have the potential to impact negatively on their patients. Administrative defenses that may be available to the HMO will generally not be available to the physicians, and may actually work against them. Quite apart from the fact that ERISA preemption will undoubtedly be applied to prevent the physician from asserting utilization or capitation defenses against the HMO, courts are unlikely to feel particularly unsympathetic to physician wailings about the red tape they must wade through in order to properly treat their patients. The observations of one California court are instructive on this point.

> [T]he physician who complies without protest with the limitations imposed by a third-party payor, when his medical judgment dictates otherwise, cannot avoid his ultimate responsibility for his patient's care. He cannot point to the health care payor as the liability scapegoat when the consequences of his own determinative medical decisions go sour.[23]

Efforts to hold the HMO liable for negligence in the administration of the plan itself, for example, in negligently evaluating the patient's condition or requiring transfer from one facility to another, is a preempted claim.[24] Claims against the HMO which assert that the physician was restricted for economic reasons from referring the patient to a specialist or from using expensive testing modalities, or failing to provide promised benefits are also preempted claims and will not form the basis for an apportionment of liability between physician and HMO.[25] If the plaintiff's direct claim and/or the physician's cross-claim against the HMO is predicated on "decisions [the HMO] might have made while acting in [its] utilization-review role," preemption will most probably apply.[26]

But, even some of the courts which have adhered to the strict interpretation of ERISA preemption applicability have voiced reservations with the effect that preemption could have on the plan beneficiary. In *Corcoran v. United Healthcare, Inc.*,[27] the court expressed some serious concerns with the consequences of ERISA preemption of state law malpractice actions. Although the court found that those claims, in any guise, were preempted, the Fifth Circuit recognized that "a system of prospective decision making [precertification of treatment] influences the beneficiary's choice of treatment options to a far greater degree than does the theoretical risk of disallowance of a claim facing a beneficiary in a retrospective system."[28] Their decision, however, left the plaintiff with "a gap" in remedies which the court found "troubling for several reasons." To begin with, "it eliminates an important check on the thousands of medical decisions routinely made in the burgeoning utilization review system."[29] The net effect could be less oversight of substandard medical decision making. Secondly, the court recognized what it characterized as "tension between the interest of the beneficiary in obtaining quality medical care and the interest of the plan in preserving the pool of funds available to compensate all beneficiaries."[30] The

court felt that if there was a way to compensate beneficiaries for the consequences of significant errors, that might benefit all concerned.

The last factor noted by the court was a recognition that "cost containment features such as the one at issue in this case did not exist when Congress passed ERISA. . . . Fundamental changes such as the widespread institution of utilization review would seem to warrant a reevaluation of ERISA so that it can continue to serve its noble purposes of safeguarding the interests of employees."[31]

So, while the Fifth Circuit concluded that it had no choice but to enforce Congress's intent to preempt state laws in this field in the broadest manner possible, it recognized the possible risks and injustices which necessarily might flow from such an interpretation. The court invited Congress to reconsider, or at least reexamine, the metamorphosis that has taken place in the health care delivery system in the two decades since ERISA was enacted. Similar disquiet can be seen in a decision from the Eighth Circuit.

While also taking a strict constructionist point of view on ERISA preemption, the court in *Kuhl v. Lincoln National Health Plan*[32] was presented with a situation where the decedent underwent extensive tests and was found to be in need of immediate cardiac bypass surgery. The plan specialist concluded that the hospitals in decedent's area did not have the equipment necessary to do the surgery and referred the patient to St. Louis. The surgery was scheduled but, about two weeks before it was to take place, the plan refused to precertify payment because the anticipated hospital was outside of the plan service area. Although the plan finally agreed to authorize the procedure, about two weeks after the surgery was to have been performed, by that time the cardiac surgical team was booked and had no operative openings for at least six weeks. The patient's condition deteriorated in that interval of time and he was no longer a candidate for a bypass. While waiting for a heart donor organ to become available, the patient died.

Although the court concluded that preemption applied because the decision not to precertify the payment related directly to the administration of benefits, the court went on to state that its decision did "not imply that how the surgery was canceled would be immaterial in every case. In a different case, the cancellation of a beneficiary's surgery by an ERISA benefits provider may lay the basis for non-preempted state law claims."[33] In recounting allegations which the plaintiffs had not made, the court left the distinct impression that were it to be presented with a fact pattern where such allegations did appear, the result might be different. The court obviously found it significant in this instance that the plaintiffs had failed to allege any difference between canceling surgery and denying precertification, or that the patient would have had surgery even if the plan had refused to pay for it, or that the patient was in some fashion "thwarted in his efforts to arrange other financing for the surgery" once the plan refused to pay for it.

V. Conclusion

Whether or not a common law malpractice claim can be pursued against an HMO will depend in large part on the jurisdiction where the claim arises, at least until Congress or the Supreme Court clarifies or resolves the question. The factors which govern a plaintiff-beneficiary's right to bring such a claim will have equal bearing on the physician's effort to seek apportionment of liability with the co-defendant HMO. In either instance, the claim against the HMO will have to avoid targeting the ERISA plan itself. "As long as a state law does not affect the structure, the administration, or the type of benefits provided by an ERISA plan, the mere fact that the [law] has some economic impact on the plan does not require that the [law] be invalidated. . . . Ultimately, if there is no effect on the relations among the principal ERISA entities — the employer, the plan, the plan fiduciaries, and the beneficiaries — there is no preemption."[34]

It may be that the physician can pursue a cross claim if he can establish that the HMO employed health professionals of its own who made independent assessments as to the actual need for a proposed treatment or testing. The more involved the "review" process, the greater the possibility that a court can be convinced that these were not administrative, but medical decisions which had an adverse impact on patient health outcome. It is unlikely that early cases will be successful, since a body of case law assessment will have to evolve in order to provide an educational predicate from which the judiciary can more fully appreciate the impact and interaction between HMO, physician, and patient. Physicians seeking to pursue these claims may face economic difficulties or contractual turbulence in their ongoing relationships with the HMOs with which they participate. As HMO style health care becomes more and more pervasive, physicians and ultimately the courts may have to become more sensitive to, and understanding of, the economic realities of practicing medicine, i.e., without sufficient HMO affiliation, physician practices will shrink significantly.

In certain cases the physician may seek to predicate his or her defense on the bureaucracy or incompetence of the HMO utilization process without ever asserting a claim against the HMO itself. In those jurisdictions where the HMO is protected from a common law malpractice action, situations may arise where part of the physician's defense might reasonably include demonstrating that a delay in diagnosis or treatment was not the result of his or her negligence, but rather the HMO's incompetent or tight-fisted administration of benefit certification. Developing that type of defense, where the HMO is not a party, may prove costly and taxing, but, nevertheless necessary.

It is clear that ERISA has not created as absolute a bulwark against common law liability as HMOs would like. The defense of physicians in malpractice actions in which benefit plan administrative procedures are intimately intertwined in

health care delivery will require aggressive defense counsel with a working appreciation of ERISA and HMO structure. And similarly, the representation of an HMO defendant in a malpractice action will require counsel who have experience in and an understanding of medical malpractice litigation, rather than administrative law alone.

Endnotes

1. Cases declining to grant preemption: *Pacificare of Oklahoma v. Burrage*, 59 F.3d 151 (10th Cir. 1995); *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350 (3d Cir. 1995); *Lupo v. Human Affairs Int'l Inc.*, 28 F.3d 269 (2d Cir. 1994); *Paterno v. Albeurne*, 855 F. Supp. 1263 (S.D. Fla. 1994); *Dermas v. Av-Med Inc.*, 865 F. Supp. 816 (S.D. Fla. 1994); *Burke v. Smith-Kline Bio-Science Labs*, 858 F. Supp. 1181 (M.D. Fla. 1994); *Haas v. Group Health Plan Inc.*, 875 F. Supp. 544 (S.D. Ill. 1994); *Smith v. HMO Great Lakes*, 852 F. Supp. 669 (M.D. Ill. 1994); *Jackson v. Roseman*, 878 F. Supp. 820 (D. Md. 1995); *Kearney v. U.S. Healthcare, Inc.*, 859 F. Supp. 182 (E.D. Pa. 1994); *Elsesser v. Hosp. of Phil. College of Osteopathic Med.*, 802 F. Supp. 1286 (E.D. Pa. 1992); *Independence HMO, Inc. v. Smith*, 733 F. Supp. 983 (E.D. Pa. 1990).
2. Cases supporting preemption: *Corcoran v. United Healthcare, Inc.*, 965 F.2d 1321 (5th Cir.), *cert. denied*, 506 U.S. 1033, 113 S. Ct. 812, 121 L. Ed. 2d 684 (1992); *Kuhl v. Lincoln Nat'l Health Plan*, 999 F.2d 292 (8th Cir. 1993); *Reilly v. Blue Cross/Blue Shield United of Wis.*, 846 F.2d 416 (7th Cir.), *cert. denied*, 488 U.S. 856, 109 S. Ct. 145, 102 L. Ed. 2d 112 (1988); *Settles v. Golden Rule Ins. Co.*, 927 F.2d 505 (10th Cir. 1991); *Altieri v. Cigna Dental Health, Inc.*, 753 F. Supp. 61 (D.Conn. 1990); *Rice v. Panchal*, 875 F. Supp. 471 (N.D. Ill. 1994); *Pomeroy v. John's Hopkins Med. Serv., Inc.*, 868 F. Supp. 110 (D. Md. 1994); *Kraft v. Northbrook Life Ins. Co.*, 813 F. Supp. 464 (S.D. Miss. 1993); *Ricci v. Gooberman*, 840 F. Supp. 316 (D.N.J. 1993); *Nealy v. U.S. Healthcare HMO*, 844 F. Supp. 966 (S.D.N.Y. 1994).
3. *Pilot Life Ins. Co. v. Dedeaux*, 41 U.S. 41, 44, 107 S. Ct. 1549, 1551, 95 L. Ed. 2d 39 (1987).
4. *Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 137, 111 S. Ct. 478, 481, 112 L. Ed. 2d 474 (1990).
5. *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d at 352, 354, citing *Metropolitan Life Ins. Co. v. Taylor*, 41 U.S. 58, 66, 107 S. Ct. 1542, 1547-48, 95 L. Ed. 2d 55 (1987).
6. *Dukes*, 57 F.3d at 351-52.
7. *Dukes*, *supra*; *Kearney*, *supra*. For cases which have applied ostensible agency theories without directly addressing ERISA issues, see generally *Schleier v. Kaiser Foundation Health Plan*, 876 F.2d 174 (D.C. Cir. 1989); *Boyd v. Albert Einstein Med. Ctr.*, 547 A.2d 1229 (Pa. Super. 1988); *Sloane v. Met. Health Council*, 516 N.E.2d 1104 (Ind. 1987); *Smith v. St. Francis Hosp.*, 676 P.2d 279 (Okla. App. 1983); *Sonnichsen v. Streeter*, 239 A.2d 63 (Conn. Cir. 1967).
8. *Kearney*, 859 F. Supp. at 188.
9. *Boyd*, 547 A.2d at 1234.
10. 547 A.2d 1229.
11. 547 A.2d at 1234.
12. 547 A.2d at 1235.
13. *Independence HMO, Inc. v. Smith*, *supra*.
14. 733 F. Supp. at 988.
15. *Pomeroy*, 868 F. Supp. at 113-114.
16. *Kearney*, 859 F. Supp. at 186, citing *United Wire v. Morristown Mem. Hosp.*, 995 F.2d 1179, 1194 (3d Cir. 1993).
17. *Dukes v. U.S. Healthcare, Inc.*, 57 F.3d 350.
18. *Dukes*, 57 F.3d at 356.
19. *Dukes*, 57 F.3d at 361.
20. *Dukes*, 57 F.3d at 357.
21. *Smith*, 852 F. Supp. at 671-72 (emphasis added).
22. *Pacificare*, 59 F.3d at 153 citing *Nat'l Elev. Indus., Inc. v. Calhoun*, 957 F.2d 1555, 1558-59 (10th Cir.), *cert. denied*, 506 U.S. 953, 113 S. Ct. 406, 121 L. Ed. 2d 331 (1992).
23. *Wickline v. State*, 183 Cal. App. 3d 1064, 228 Cal. Rptr. 661, 671 (Cal. App. 2d Dist. 1986).
24. *Dearmas*, 865 F. Supp. at 818.
25. *Kearney*, 859 F. Supp. at 186.
26. *Corcoran*, *supra*. See *Dukes*, 57 F.3d at 361.
27. 965 F.2d 1321.
28. *Id.* at 1332.
29. *Id.* at 1338.
30. *Id.* at 1338.
31. *Id.* at 1338.
32. 999 F.2d 298.
33. *Id.* at 303.
34. *Airparts Co. v. Custom Benefit Servs. of Austin, Inc.*, 28 F.3d 1062, 1065 (10th Cir. 1994); *Pacificare of Oklahoma, Inc.*, 59 F.3d at 154.

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The Use of Managed Care in the Workers' Compensation Law*

by Geraldine A. Reilly, Esq.**

The compulsory use of health related Managed Care Organizations ("MCOs") has been posited as the solution to rising medical costs in an increasing variety of contexts. Managed care has been implemented for state Medicaid clients, a great number of employee group plans, and as a result of recent legislation has become available for the first time to certain New York employers for the treatment of Workers' Compensation covered injuries and occupational disease.

In an unusual mid-winter session of the joint houses of the New York State Legislature (December of 1993), legislation intended to reform certain portions of the Workers' Compensation law of our state was decisively passed.[1] The Workers' Compensation Managed Care bill represents a carefully crafted, balanced omnibus approach to reform. It contains segments which create the Offices of Advocate for Small Business and Advocate for Injured Workers. It provides for a less cumbersome and more expeditious administrative resolution for certain Workers' Compensation cases; it establishes an inter-agency Task Force on Workplace Safety, and imposes additional penalties for Workers' Compensation fraud. But the cornerstone of the legislation is its landmark component extending a mandatory Managed Care program to certain employers participating in a Pilot Program.[2]

This Pilot Program was created in response to concern about rising premium rates, since Workers' Compensation premiums are the sole responsibility of the employer, and may not be assumed, even voluntarily, by the employee.[3] The Pilot Program contains a structure allowing a limited percentage of employers to utilize required Managed Care Organizations for the treatment of employee workplace injury or occupational disease.[4] The term "Managed Care Organization" is not specifically defined in the legislation, but it is defined in regulations as an organization that "provides or arranges for comprehensive and coordinated medical services for workers' compensation claimants employed by participating employers."[5] The legislation does detail the services which the Managed Care Organization must provide.

It is estimated that Workers' Compensation treatment costs rose tenfold to $28.39 billion in 1993, at a rate nearly twice the rate of general medical inflation.[6] With the enactment of this legislation, signed by the executive as Chapter 729 of the Laws of 1993,[7] New York joined the growing number of states seeking to contain premium costs paid by employers[8] without compromising the care received by injured workers. But the New York legislation differs from that instituted by certain other states, and those differences evidence a commitment to worker safety and protection long championed by progressive forces within the state.[9] An enduring reflection of that commitment is embodied in the statute's creation of a Standing Labor Management Committee to advise the Chair of the Board on the administration of the Pilot Program, and to be an active participant in the selection of employers and Managed Care Organizations.

The introduction of a compulsory Managed Care component into the New York Workers' Compensation system is particularly significant since the right to the benefits of Workers' Compensation springs from a state constitutional amendment, which authorized the legislature to enact such workplace protective laws.[10] In addition, the New York Workers' Compensation law acknowledges an entrenched mistrust of the "company" doctor's role in determining the extent of injury by providing that any interference with an employee's choice of treating physician would be a misdemeanor.[11] For these reasons the use of a Managed Care medical source in which an employee's care by a particular doctor is compulsory, subject only to a limited "opt-out period," rightfully generated well-founded concern. In response, the Bill acknowledges that the limitation on choice is a significant restriction. The Bill's legislative intent reiterates that, "the use of managed care must be carefully studied before it is made a permanent part of the Workers' Compensation system."[12]

Labor-Management Cooperation

At the heart of the New York Pilot Program is a Standing Labor Management Committee, consisting of the chair of the Workers' Compensation Board, and six voting members.[13] These six members represent private sector organized labor, public sector organized labor, private sector employees, the business community, small business employers and New York State public employers. All voting members are appointed by the Governor at the recommendation of organizations such as the AFL-CIO, the Business Council of New York State and the National Federation of Independent Business;[14] they serve at the Governor's pleasure and receive no compensation for their service except for expenses.[15]

The Labor Management Committee serves the crucial role of reviewing rules and regulations necessary for implementing the Pilot Program, to ensure that the intent of the statute is fairly effectuated.[16] The Committee has a voice in the selection of employers chosen to participate in the Pilot Program,[17] although the statute dictates a list of employers to represent different categories of employers from across the state.[18]

Given the strong role organized labor plays in protecting the rights of workers, the statute also includes an affirmation of the employer's duty to collectively bargain the introduction of the Pilot Program in a unionized workplace, and precludes

any implementation without the agreement of the certified collective bargaining agent for the affected employees.[19]

A comprehensive report of the Managed Care Pilot Program by the New York State School of Industrial and Labor Relations at Cornell University is to be submitted by June 1, 1997.[20] The study will examine a number of factors including whether or not the legislative intent was accomplished, comparison of other states' programs, effectiveness of the opt-out provisions and whether any competitive advantage inures to the employers participating.

Participation in the Pilot Program is limited in its first year to employers representing fifteen percent of the state labor force, to increase to twenty-four percent after the second year of the Pilot Program's existence.[21] This strict imitation is intended to allow a judicious examination of the program and its results before expansion of the concept could be contemplated.

The statute defines what types of employers are eligible to qualify for inclusion in the Pilot Program and it is clear that the legislature aspired to include a wide range of employers in the experience. Eligible employers include those who have negotiated with their unions for participation, employers in a Safety Group as defined by the State Insurance Fund, multi-employer associations of fifty or fewer employees; the self-insured employer as well as "any employer or employer group which does not qualify in any of the above categories."[22] The statute also directs that the selection of employers should reflect the diverse geographic regions of the state, no doubt intending that both upstate and New York City metropolitan area entities are represented in the fifteen percent of those certified.[23]

The law specifies that every employer application to participate in the Managed Care Pilot Program be accompanied by a detailed program summary which fully describes its anticipated methods and procedures, and names two or more certified Managed Care Organizations in the pertinent geographic region which employees would be expected to utilize for the treatment for workplace injuries or occupational disease.[24] Thus employees, who previously had virtually an entire universe of physicians from which to select for treatment are now narrowly limited to the two employer-sanctioned MCOs. The new statute does sanction an employer owned medical bureau as a Managed Care Organization, as in the case of hospitals seeking to be the medical provider for their own employees, but this medical bureau would only qualify as a third option, and only after disclosure to employees.[25] Furthermore, there is a prohibition against insurance companies which provide Workers' Compensation coverage to an employer from having a financial interest in the Managed Care Organization.[26] This prohibition reflects the potential conflict of interest which exists when the financial interest of the employer or insurance company might in some way influence a decision regarding treatment, return to work, or categorization of extent of injury for compensation purposes.

Managed Care Organizations will be certified for inclusion in the Managed Care Pilot Program by the Commissioner of Health based on a range of criteria including the quality of and convenient manner of treatment; a sufficient number of, but not less than two specialists within, the service area; appropriate financial incentives which do not compromise service; proper reporting; and peer review.[27]

The legislation also contains an "opt out" provision, which is an option for employees to seek alternative care if after fourteen days of treatment by the employer-sanctioned Managed Care Organization they are dissatisfied with the treatment.[28] In any case, an injured employee maintains the right to seek treatment through the New York State Occupational Heath Clinic Network at the time of initial referral.[29] Lastly, in a creative attempt to hasten dispute resolution, the statute provides an opportunity for a second medical opinion which, if rendered by a member of a special panel created by the board, would be binding on both the employer and employee.[30]

Conclusion

The Managed Care Pilot program will be closely monitored as it begins to function. As of this writing the first employers and Managed Care Organizations have been certified and a host of others should be shortly. Improvements in the program, such as expanding the duration of the Pilot Program and increasing the percentage of the workforce participating, are subjects which will no doubt confront the legislature in the near future.

Endnotes

1. Act of Dec. 27, 1993, ch. 729, 1993 N.Y. Laws 1805.
2. *Id.*
3. N.Y. Work. Comp. Law § 31, § 32 (McKinney 1994).
4. Act, *supra* note 1 (codified as N.Y. Work. Comp. Law § 126 (McKinney 1994).
5. N.Y. Comp. Codes R. & Regs. art. 4, § 730.1 (1994).
6. Freudenheim, *supra* note 5, at 1.
7. Act of Dec. 27, 1993, ch. 729, 1993 N.Y. Laws 1805.
8. *See* Pennsylvania 77 P.S. § 531 (1993); Arkansas Ark.Stat. Ann. § 11-9-508 (1993); Nebraska R.R.S. Neb. § 48-120, 48-120.02 (1993).
9. Although the bill is consciously crafted to protect worker rights, it was offered by the governor as an employer oriented initiative. *See* Memoranda approving L. 1993, c. 729: "To the large employers, small businesses and employees around the State who told us that they are being crushed by the costs of doing business, we say: We heard you." McKinney's Session laws, 1993 p. 2924-25, v. 2.
10. N.Y.S. Const. art. I, § 18. The article also limited the law with regard to protecting employees injured "solely" from their own intoxication or their willful intention to bring about the injury or death of themselves or another. *Id.*
11. N.Y. Work. Comp. Law § 13-a(6) (McKinney 1994). The limitation was found to be a constitutional exercise of police power in *Hogan v. Lawlor & Cavanaugh Co.*, 286 App. Div. 600, 146 N.Y.S.2d 119, 1955.
12. N.Y. Work. Comp. Law § 126 (McKinney 1994).
13. N.Y. Work. Comp. Law § 126-2 (McKinney 1994).
14. N.Y. Work. Comp. Law § 126-2(a) (McKinney 1994).
15. *Id.*

16. N.Y. Work. Comp. Law § 126-2(b) (McKinney 1994).
17. *Id.*
18. N.Y. Work. Comp. Law § 126-2(c) (McKinney 1994). The list includes multi-employer associations of fifty employees or fewer, self insured employers, employers in a State Insurance Fund Safety Group and others. *Id.*
19. *Id.* at 18.
20. *Id.* at 2(b).
21. *Id.* The statue further provides that the labor management committee may recommend subsequent reduction to 15% depending upon the results of the Cornell study. *Id.*
22. *Id.* at 2.(c)(vi).
23. *Id.*
24. *Id.* at 3.
25. *Id.*
26. *Id.*
27. *Id.* at 5.
28. *Id.* at 12.
29. *Id.* at 12.
30. *Id.* at 11.

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Medicare and Managed Care

Edited excerpts from a forthcoming monograph to be published by the Government Law Center of Albany Law School and reprinted with the permission of the Government Law Center. The conference on which the monograph is based was held in November 1995.*

Contents

Keynote Address: **Jeffrey Kang, M.D.**
Senior Medical Advisor to
Bruce C. Vladeck, Ph.D.,
Administrator,
Health Care Financing Administration

**** From a pure policy perspective, it is my and the Office of Managed Care's belief that managed care can save the Medicare system, and I underscore "can." The potential benefits of managed care for reorganizing the health care system in a cost-effective way, that maximizes patient clinical outcomes, is limitless. We are all aware of the perverse incentives and administrative and regulatory barriers in Medicare's fee-for-service system. By placing capitated dollars in the hands of the health care delivery system, all these barriers are removed. For example, in the fee-for-service system, we have an artificial barrier that says that you need a three-day hospitalization in order to get skilled nursing facility care. In a managed care system, many managed care Medicare providers are realizing that it is an artificial barrier that does not need to be there, so they have actually waived that three-day rule. This is just one simple example of how managed care can better rationalize how we deliver health care.

However, with the potential upside of managed care, there is also a larger downside, and that is a potential for abuse and delivering insufficient care for the purposes of maximizing profit. . . . For these reasons, HFCA [the Health Care Financing Administration] is aggressively pursuing performance and outcomes measures as a way of holding plans accountable for the delivery of health care. Unfortunately, the science of these outcomes measures is in its nascency. ****

It turns out that the private purchasers with 60 to 70 percent of their employees in managed care have exactly the same concerns as we do in the public sector. We are giving the capitated dollars to these managed care programs. How do we hold them accountable? How do we make sure that the value we're receiving for our health care dollar is excellent? It's odd when I reflect back that this notion of the public sector sharing its experiences and common goals with the private sector is a simple one, and one wonders why HFCA did not do this earlier. ****

[HCFA also] has been working on a consumer information strategy to empower beneficiaries to use their purchasing power and market forces to hold plans accountable. It is very important to remember that the Medicare market, as distinguished from the commercial . . . markets, is an individual market. That means Medicare beneficiaries decide to enroll in managed care on an individual basis, while in . . . the commercial market, that decision is made as groups. In Medicare, individuals decide whether they want to stay in fee-for-service or enroll in managed care. In addition, there currently is no lock in. They actually have the ability to enroll and disenroll on a thirty-day basis. These two elements, an individual market and this ability to enroll and disenroll, from our experience, have been the single most important element for holding the managed care industry accountable for the care it delivers. In addition, I would be remiss if I did not mention that the Office of Managed Care looks at disenrollment rates for managed care as one of the early signs that we have a problem with the plan, and I do want to begin to work with many of the advocacy groups to actually look at whether we can publish the disenrollment rates at large. In the long run, such information to beneficiaries along with the information on access, cost and clinical outcomes, I believe, will empower consumers to basically vote with their feet and hold the managed care industry accountable. ****

[Dr. Kang next addressed issues raised by the federal legislation under consideration in the fall of 1995.]

There is a fundamental paradigm shift that the public does not really understand. Over the last thirty years, Medicare has been a "defined benefit" program. In other words, we have said, look, this is the benefit that we think the elderly population is entitled to. HFCA will then pay for that set of benefits. Under that scenario it turns out that we have been experiencing a ten to eleven percent growth in order to pay for those defined benefits. The Congressional proposals really seek to change this program to a "defined contribution" program. This is accomplished through various caps, statutory limits in growth rates both on the fee-for-service side and the managed care side. The net effect of capitation at the individual level when summed up in the aggregate is just a global budget for Medicare. This ultimately translates in my mind as a clinician to rationing, because you have made the decision that these are the only dollars we are going to spend. . . . [M]y biggest concern here is that this paradigm shift is occurring without public recognition or public discourse. This is a fundamental change that we need to be discussing out in the open. . . . I think that the most ethical thing . . . is to begin with a commit-

ment to a defined benefit package, and then use the market forces and competing managed care plans to deliver that package at the cheapest possible price. Unfortunately, as you all may recall, that's actually what was proposed in the President's plan a year ago under the rubric of managed competition. The notion was, let's guarantee a defined benefit then let's use competition to get the prices as cheap as possible, and I'm sure you all know what happened with that effort. . . .

I need to talk about provider service networks or provider service organizations (IDSs or PHOs, the acronyms are endless). In essence these are provider networks that will get together and contract directly with HFCA on a capitated basis. The concept here is to eliminate the middle man, the managed care insurer, and let HFCA contract directly. The capitation issues are still the same, and these would essentially be managed care entities. **** There are two guiding principles to think about with provider service networks. The first is that the standards must be tough enough to prevent failure of provider service networks. If we in fact allow provider service networks to participate, and they go bankrupt or belly up and leave a lot of beneficiaries without care this would further serve to discredit and destroy the Medicare program. The second principle is that the standards we do come up with have to be the same for the HMO industry and provider service networks. This is to make sure the playing field is level and that the competitive forces can work. Let me identify a few key issues. . . .

Financial solvency. It has been our office's experience . . . from the late seventies and early eighties that roughly two dozen plans went belly up and left beneficiaries wanting for care. When you look closely at that experience, practically all of those plans were provider-dominated plans. . . . [T]hey didn't have the experience to manage risk, nor did they have adequate capitalization to do the start up costs of a managed care plan. In addition, there are tremendous acquisition costs and marketing costs associated with managed care plans. Finally, there are cyclical adverse outcomes and sometimes you end up with a sicker population and you need to be able to weather those times. On the other hand, insurance-dominated plans, back in the eighties, had adequate capital to operate and to weather those tough times. The insurance-dominated plans that did close closed for business reasons, and they usually ended up with a merger or acquisition and there was an orderly transition of beneficiaries to an alternative plan or alternative program. ****

Second, **insolvency protection.** HFCA does have standards for insolvency protection. This is on the outside chance that despite all of our financial solvency standards a plan still has a problem and goes belly up. We have two traditional insolvency protections. The first is reinsurance, and the second is "hold harmless." Now there is considerable concern that the reinsurance market against failure is not going to be willing to reinsure provider service networks because they're such new entities. In the hold harmless agreements, if a plan goes belly up, the providers are agreeing to continue the care into the last month that they were paid for and to not ask the beneficiaries to pay for it out of their own pocket. The difficulty with provider service networks, if they go belly up, is there is no one to hold harmless. So we have serious insolvency protection problems, and we may end up having to ask provider service networks to hold certain restricted cash aside for insolvency protection.

The third big issue on provider service networks is state licensure. As some of you may know, provider service networks are currently exempted from state licensure. This represents a big problem for states and states' rights, but I also think that there is a level playing field problem. Currently HMOs are licensed by the states. There is nothing to prevent the HMOs from reorganizing as a provider service network and then coming in and applying to HFCA as a provider service network. So realistically everyone could end up outside of state control. **** Thank you very much. Let me stop there and answer a few questions. ****

Questions:

1. The question asks whether managed care entities are all for-profit organizations or not-for-profit organizations. It's split. It depends upon the market, some are for-profit, some are not-for-profit. Quite frankly, I think that the for-profits can work just as well if not better, as long as we hold them accountable and that's the key. So the profit or not-for-profit issue is really holding them accountable, not-for-profit systems can work just as badly for a variety of reasons. . . . I think the majority of provider services networks will be conceived as not-for-profits but there will be for-profits, and I think the issue still is holding them accountable to the clinical outcomes that they deliver. . . . [A]s a geriatrician, I think the most important outcome for the geriatric population is functional status. Let's forget for a minute about whether or not the EKG was done right or whether there was a hemoglobin ordered or whatever, the bottom line is whether the beneficiary can go to the store and live independently. . . . The most critical outcomes measure for the Medicare population is functional status. ****

2. The question involves Medicare beneficiaries' desire for freedom of choice. . . . The problem is that managed care plans will have a restricted panel of doctors. Given that, how do you get people enrolled in managed care? This is really more of a market issue. If you look at mature markets, like in California, it turns out that a good 80 to 90 percent of the doctors participate in one plan or another so that eventually, if you get all the doctors in plans, there will come a point where if you like doctor X, you just have to figure out what plan he is in and go with that plan. ****

3. What is [my] view on medical savings accounts? Basically, medical savings accounts . . . are a "cost-er." What happens is the healthy Medicare beneficiary enrolls in Medicare savings accounts and takes the dollars out of the system, leaving the unhealthy in Medicare and leaving less money in the whole program. The notion of insurance is that the healthy people are subsidizing the people who have the misfortune of being unhealthy. Medical savings accounts take those healthy people out. ****

4. Can [I tell] what the incentives will be in managed care programs for taking care of the sickest, most functionally disabled, community-based individuals? Right now there are no formal provisions other than just the integrity of providers, and I think there are a few unscrupulous providers and plans that are dis-enrolling the sickest and the disabled. For the most part my experience has been that the industry is trying to make honest efforts to care for this population. We do pay. The AAPCC [adjusted average per capita cost] methodology does pay more for the oldest, the institutionalized people on Medicaid. . . . Eventually the industry has to come to grips with taking care of this population also. [T]here are two forces here, one is the reality and the second is the professional integrity of the physician, plans, etc. There are no formal enforcement mechanisms, and I am a little concerned that if we go that route and add more regulations, that you will end up with perverse unintended consequences the other way that create more barriers for disabled beneficiaries. ****

5. The question involves the perverse incentives or the downside of managed care, which is under-utilization. The doctors have incentives not to provide the care and not to refer the patient to a specialist, etc. There is no question about it. There is a great upside here but there is just as great a downside. That's what I mean by we need to hold the plans accountable, we need to make sure that the care they deliver and the outcomes are of good quality. In a certain sense, it's not whether the visit or referral was made or not, it's what is the patient's ultimate outcome. I use the example of functional status. Are they doing well? That's what really matters in the long run. I think that you raise a very important question and HFCA needs to get better and smarter about this. Private purchasers have the same problems with their own commercial population. How do they know what kind of care they are getting for the dollars they are paying? So there is a very strong interest amongst private and public purchasers to accelerate the science of outcomes measures to make sure that we're getting good value for what we're paying for.

6. The question was: what is being done about the wide variation in how HFCA pays for plans? What the questioner was referring to is that in some markets we actually pay $300 per month per beneficiary and in another market we may pay $550 or $600 per beneficiary per month, and that's in the same county. That is a huge variation, and there are . . . proposals on to how to squeeze that down. Basically you would stratify counties into high, average, and low. The high people would be tied to a rate of growth of maybe 2 percent, the middle grows at a rate of maybe 6 percent and the low grows at a rate of 7 or 8 percent or something like that. The arguments will be in the details of the formula but that's the general strategy. Again, I would emphasize, though, this does change the notion of the Medicare program from a defined benefit to a defined contribution. ****

7. The question, if I can summarize, involves the use of essentially ancillary or physician extenders as a solution for the primary care shortage. **** I am a supporter of nurse practitioners, physicians' assistants and just the general concept of multi-disciplinary teams for the care of our elderly. I think though that there are fee-for-service barriers to this. . . . [M]anaged care is heavily moving towards mid-level practitioners and nurse practitioners, especially in primary care shortage areas. . . . This in a sense is the upside of managed care. If you look at a lot of managed care units they are using nurse practitioners much more extensively than are being used in the fee-for-service side. Thank you very much.

I. Can Managed Care Save Medicare?

Moderator: Professor David A. Pratt
Albany Law School

Government Perspective: **Asst. Comptroller General Janet L. Shikles**
Division of Health, Education and Human Services
U.S. General Accounting Office, Washington, DC

**** On the program, I'm listed as giving the government perspective; Dr. Kang gave the executive branch's — HCFA's — perspective. I will be giving the perspective from the legislative branch. The GAO is unique in that we are an independent agency working in a very political environment, so my staff and I work for both Republican and Democratic Senators and Representatives. We are heavily involved in doing all kinds of studies for them and technical analyses. **** Both Democrats and Republicans recognize that major change is needed in the Medicare program. While other parts of the health care sector saw a slowing of spending increases, Medicare was, and still is, growing at about 10 percent a year despite some real success stories in slowing spending growth on the hospital side. The estimates are that the program is still growing at about 10 percent a year, and, by the year 2002, Medicare is projected to cost $345 billion, absent any legislative changes. The Republicans have proposed to reduce Medicare's spending by about $270 billion over the next 7 years, which would bring the spending rate to about 7 percent. Many argue that such a reduction is too great. What I think is discouraging to all of us though is that even if spending is reduced this much, we are still not home free because in about 15 years the Medicare program is going to need a major overhaul again. This is because many of the baby boomers will turn 50 this year, and in 15 years they will all turn 65 and become eligible for Medicare. So the current strategy, as overwhelming as it seems to all of us, of trying to reduce the spending rate from 10 percent to some lower rate of spending will not begin to deal with the huge number of baby boomers who will start becoming eligible for Medicare. At that point Medicare will require other changes. **** All members believe Medicare needs a major restructuring; it is 30 years old and has not seen many changes. Those of us working for the Congress have recommended many things, and . . . a report by GAO outlines some of these recommendations. . . .[1] ****

What are the issues? It is interesting that five or ten years ago many of us would not have expected managed care to have the potential that it seems to have today or that it would have been able to produce some of the changes we have seen. What we do not know, however, is how managed care will do in the future as it takes on new populations that it traditionally has not been serving, the aged and disabled, and whether some of the slower rates of growth that we have seen in overall health care spending will continue to be sustained. **** We just finished an investigation of Tennessee. Its experience of quickly enrolling hundreds of thousands of Medicaid recipients in managed care plans has been daunting. A year after enrolling in Tennessee's managed care plan, people still didn't know who their doctor was. The sheer number of potential Medicare enrollees will be a challenge for HCFA to handle. ****

We'll be working with the Congress on the issue of potential adverse selection. I think that the medical savings accounts, as you have heard, pose the risk of attracting the healthier, richer beneficiaries, while individuals with health problems are more likely to stay in fee-for-service plans. Because most of the reductions in Medicare spending are likely to come out of fee-for-service, we wonder, will there be enough money in fee for service to pay providers so they will continue to provide care? We have also done a lot of work on how to pay HMOs fairly. . . . The way you deal with risks and adverse selection is that you make sure that your payments to managed care plans are fair so that they are not financially penalized if they serve a disproportionately sick population.

Finally, there is some concern about whether we can sustain the budget caps that are included in some of the legislative proposals. None of us knows what we really should be spending nationally on health care. The Congress is proposing in some of the bills to set a cap in the Medicare program. We think many of the savings in managed care have been achieved through what can be described as "low-hanging fruit." This would include discounting in urban markets, which have a surplus of physicians and hospitals. What happens when you do not have that surplus in the future and providers are less willing to accept discounts? Another concern is how will we pay for new technology? I think these are issues that will have to be watched. **** At the same time I think it's important for all of you to be very vigilant and to let your members hear from you. They are very interested in your views. Thank you.

Managed Care Organization Perspective: **Kathryn Allen, President**
New York State HMO
Conference and Council

**** To start, I want to . . . review some statistics. We have 37 million Medicare recipients right now, and the federal government spent $162 billion on those recipients in 1994. As was just mentioned we know that those costs are projected to increase by 10 percent if the program remains unreformed, and that very quickly projects out to the Medicare fund becoming bankrupt by the year 2002 or 2006, depending on whether you use pessimistic or optimistic assumptions. And there are 76 million baby boomers coming right up that will exacerbate current fiscal crises that we are now facing.

Also understood and known by us in the health care industry, but less understood by consumers is the "why" behind this fiscal crisis. We all know that the program is having its thirtieth birthday, and in a way that is part of the problem. For 30 years this program has remained frozen in time. Medicare provides a very good look at what the health care delivery system and insurance industry looked like in 1965. There were, and are, a lot of incentives for overutilization; there was, and continues to be, a virtual lack of accountability for quality or cost. Over time the program has developed into having a lot of well-documented fraud and abuse. If any of you have assisted an elderly parent or elderly grandparent through some very intense interactions with the health care system as I have over the last two years, I know that you are probably also appalled at the inefficiency of the system.

Over this last 30 years, particularly over the last 15 years, other purchasers have figured out that health care business as usual would put *them* out of business. They figured out that something had to change. For most of those payers what changed was a real drive to organize the health care delivery system and hold it accountable for both cost and quality. And what is the result? Today we have 50 million people in HMOs and tens of millions more in other types of managed care for a total of more than 60 percent of Americans in some type of managed care. This includes 35 percent of federal employees and millions of Medicaid recipients. But, in Medicare, we have only 1 out of 10 people in managed care, nationally. . . . We have only two hundred thousand Medicare beneficiaries enrolled in Medicare HMOs in New York compared to millions of people with HMO coverage who are covered through their employers. . . . HMOs in New York enroll through virtually every payer source that there is, and we even have seven hundred thousand Medicaid enrollees enrolled in New York. So we can see that nationally, and particularly in New York, Medicare enrollment has lagged behind. In fact, only 10 HMOs in New York have significant Medicare enrollment, and much of the current enrollment is very recent. HFCA has made contracting a difficult process and, as has already mentioned this morning, there are many flaws in the reimbursement methodology which have made HMOs nervous about investing capital in this market.

So while all this organizing and holding HMOs accountable for cost and quality has been going on, Medicare's costs have been rising at two times the rate of the private health care market. What distinguishes the private health care market from the Medicare market is that people under 65 have lots of choices between indemnity plans and HMOs and other forms of managed care. The successes that HMOs and other managed care providers have brought to other group purchasers, which include savings, accountability, quality, customer satisfaction, are documented by research studies. . . . Given all these docu-

mented successes, we find no reason that believe that HMOs cannot contribute significantly to the Medicare crisis.

I want to cite a particular study that I think indicates that greater HMO enrollment may also drive savings on the fee-for-service Medicare side. Dr. Lawrence Baker of Stanford University did a study for the National Institute for Health Care Management. It found that HMO efficiencies "spill over" into fee-for-service Medicare savings. . . . Using data from over 3,000 counties, the study analyzed HMO market share and Medicare spending between 1986 and 1990. They looked at both fee-for-service only costs and aggregate spending including HMO costs. The findings revealed that increases in HMO market share are associated with reductions in overall Medicare spending levels. They projected those savings would be total billions. Now why? The report doesn't speculate why; it just reports the findings, but I would speculate based on my dozen years in the industry. When HMOs [encourage] doctors to improve care and provide efficiencies for their HMO patients, the effects of those changes, that re-thinking, spill over into fee-for-service patients. I want to give you an example. An HMO in Minneapolis launched a very aggressive initiative to provide flu shots to its over-65 members. They theorized that if they could increase the number of flu shots, they could decrease their hospitalizations. In fact, that's what they found. In one year they figured they saved 5 million dollars in averted hospitalizations because this very aggressive campaign, which was directed both at their members and at their physicians, increased flu shots rates significantly. They calculated this in a very controlled way, comparing costs of groups that were not part of the campaign. I do not think those doctors, once they were in the mind set of giving flu shots to their HMO members, turned off that thinking the minute somebody from traditional Medicare walked in the door. It seems logical to assume those fee-for-service Medicare members ended up getting flu shots at higher rates as well, and therefore, Medicare achieved those savings.

So returning to our original question — can managed care save Medicare? *Save* is a very strong word but I would go so far as to say that a well-designed managed care approach is probably Medicare's best shot. And, it is hard to find fault with the concept of offering Medicare beneficiaries the same range of choices available to under-65 Americans, particularly choices that will allow them to have fewer out-of-pocket costs and better benefits. If you do a side-by-side comparison between what Medicare covers under its traditional coverage and what many HMOs offer in their benefit package, sometimes without any premiums at all, you see that HMOs offer, for example, outpatient care for a small copayment rather than 20 percent of the fees for outpatient care. There is unlimited hospitalization. Preventive care is covered that otherwise would not be covered, frequently including: eyeglasses, hearing aids, nutritional counseling, and other healthy lifestyle [services]. By offering efficiencies more benefits can be offered. We think Americans over 65 are capable of making that choice. . . .

Of course, to make those choices Medicare beneficiaries need a lot of information. A lot of information is available now, and HMOs are working very hard to enhance the information that is available to both those under 65 and those over 65 potential members. We have a lot of studies on quality, and many more are in process. There were two national studies, one done by the CDC and one by HFCA, that I found particularly striking. One found very conclusively that Medicare enrollees in HMOs had much better access to screening for cancer. The second study showed that, in fact, cancer screening led to cancers being detected at an earlier stage in HMO members than in traditionally enrolled Medicare members. We need more consumer satisfaction surveys, we need information so that people can judge whether a plan is convenient for them.

So, in closing, we in the industry applaud the direction Medicare is going — joining other segments of the health care market and looking for greater efficiencies and greater accountability. We are very hopeful that the politics of the debate will not result in mandated changes to HMO systems. . . . Thank you.

Questions

1. The question is about CEO salaries. I answer this more frequently than I care to. My position is that we live in a capitalistic society. There are many salaries that many of us may not agree with, including those for sports figures and film stars. However, I maintain that if a company can provide a useful service and provide it at a cost that is equal to or lower than other players in the market, and can do it with demonstrated quality that is good or better than others, and achieve other public policy goals of state and federal government, then I would say that a CEO's salary is an insignificant issue. I would also point out that the public rarely questions millionaires who provide housing and food and other things that are deemed essential to human life, so I think the issue is very overrated.

2. Is any-willing-provider legislation still high on the HMO Conference and the managed care industry's legislative priorities? It is very high on our priority list. We believe that any-willing-provider legislation undermines the very foundation of what has made HMOs successful — limited, selected networks. The point is that if you are managing care, you have the opportunity, and responsibility, to monitor the quality of physicians within your network. You want us, the managed care company, to contract with the high quality physicians. That's why we do credentialing. That's why we do accreditation to make sure that we are doing our best to ensure that the physicians we offer in our network are quality physicians. "Any-willing-provider" legislation flies in the face of that.

Hospital Perspective: **James R. Tallon, Jr.,**
President
United Hospital Fund of New York

In the months ahead, we're going to have a lot of discussions about how the future health care system will be shaped. I, for one, believe that change is needed, and that managed care is an important part of the future. But when we discuss man-

aged care for Medicare beneficiaries, and how their options will change and expand, we should begin by acknowledging that Medicare beneficiaries have more choice in the current system than anyone else, because they have a rather sweeping benefits package and because most health care providers are willing to serve them under the terms of the Medicare program.

". . . we are currently going through a period in which all payer sectors are diving to the bottom in terms of reducing the resources they allocate to the health care system."

We should also acknowledge that some changes going on out there go beyond Medicare and beyond managed care. To begin with, we are currently going through a period in which all payer sectors are diving to the bottom in terms of reducing the resources they allocate to the health care system. When you look at any one of the changes, you are looking at a tree, but you really have to look at all the trees to see the forest: the $270 billion in Medicare cuts, the $180 billion in Medicaid cuts, the demands of the private insurance market for discounts on top of the lowest possible price, and the retreat of local governments around the country from sponsorship and support for health care services. All of these are factors in the debate, and as we look to the future, we must recognize that all sectors, not just Medicare, are talking about pulling some fairly significant resources from the system after the turn of the century.

Another major change is that we as a society are redefining health care from being a public good to being a commodity. We are starting to move from a system that for three decades has been driven by health care providers (although it is only fair to note that providers themselves are more likely to speak of the constraints under which they operated). If you look back at the system that was growing at two or three times the consumer price index and that saw its share of the gross domestic product grow from 8 percent to 14 percent in 30 years, it was hospitals and physicians who were driving the system.

But over the last several years, we have seen a shift to a purchaser-driven model, whether the purchaser is the government under Medicare using managed care intermediaries; the government under Medicaid; or private employers, either directly or using intermediaries. And these purchasers are thinking about health care services in a very different way from the providers. To begin with, in this commodity-defined, purchaser-driven system, absolutely no one is taking responsibility for the almost 50 million Americans who don't have health insurance. This in itself suggests that this debate should not just be about Medicare but about the whole system. Back in the provider-driven system, there were lots of rules of the game: not-for-profit hospitals had certain obligations to their community, and physicians had a professional obligation that many took very seriously to provide care without respect to issues of compensation. In addition, there was cost-shifting, both informal and formal, through the creation of bad debt and charity care pools, to subsidize the cost of caring for those unable to pay. In the purchaser-driven system, these long-standing practices are being questioned.

As we move ahead, we should also pause to question the assumption that Medicare is out of control. I do not think the numbers show that at all. In a recent study, Marilyn Moon et al. at the Urban Institute said that when you hold constant all the things that distinguish Medicare from the private insurance market (growth in the number of beneficiaries, benefits package, beneficiary demographics), the underlying growth rate for the Medicare program is roughly the same as it is for the private health insurance market. Now, that may indicate that we cannot afford to continue to make the same allocation to health care in the future that we are making today, but that is a political decision. That is very different from the assumption that Medicare is out of control.

We should also acknowledge that Medicare managed care in the future will have little to do with the way it is now, and if we try to get there incrementally, we just won't get there. In the current program, for example, there are provisions that allow people to disenroll on a monthly basis. Nobody can run a managed care program that way. In addition, there is currently a set of rules (which are very positive with respect to the consumer) that require managed care plans to return savings either to the federal government or to consumers in the form of enhanced benefits (after allowing for fair administrative costs and a fair profit, of course). Now, a true managed care program does not operate in this way, and the question for the future is whether we are going to achieve the budget savings targets by continuing to give enhanced benefits packages to the people who are enrolled in the Medicare program.

It is precisely because I do not think the future of Medicare managed care can realistically be built on the characteristics of the current system that I think we have to be very careful about the details of how we do the pricing, how we determine the benefits structure, and how we do the enrollment practices. The Medicare managed care of the future will probably look a lot more like the managed care that exists elsewhere within the health care financing system today.

Now, I was asked to give the hospital perspective on this, and even though my role as head of the United Hospital Fund is not to be an advocate or lobbyist for the hospital community, I think I can fairly summarize the hospital point of view on several key issues. One of the major concerns, especially for hospitals in New York, is payment for noncomparable goods, the specific things that are covered in average area per capita costs (AAPCC) (i.e., that vary a lot from county to county and that are not necessarily comparable across hospitals), including disproportionate share payments and medical education payments. These costs are currently included in the initial calculation of managed care plans' premiums, but then managed

care plans are negotiating rates that exclude these costs, arguing that their job is to meet the service needs of their enrollees, not to pick up the costs of the medically indigent or of medical education. Hospitals, not illogically, object to the fact that the number going in is based on a different set of assumptions than the number coming out. Their argument is that the system should be changed so that expenditures for these two items are paid directly based on who is using the service or some other allocation mechanism.

Another issue for hospitals is that of provider-sponsored networks. Hospitals and physicians have basically said that they would like to offer services directly to the Medicare population, rather than going through intermediary plans, because the integrated delivery systems that they are developing do not really need the financial reserves that an HMO does because the money is coming from Medicare. Now, from the point of view of the hospitals, I am going to commit heresy by saying that I think one of the worst things Congress could do would be to create another Employee Retirement Income Security Act (ERISA), which in effect coupled weak federal standards with a prohibition on state regulation of employee benefits, including self-insured health plans. What I read of provider-sponsored networks reminds me of ERISA: at the federal level the talk is of only the most general kinds of standards, which would nonetheless preempt the states from setting any standards of their own. I think there is a good case to be made for states setting different standards for provider-sponsored networks and for HMOs, but preempting or prohibiting the states from jurisdiction would be a bad long-term decision.

Let me close with three points. First, keep a close eye on the debate about long-term care services and the benefits package. If you look at Medicare's current allocation and the growth of expenditures for home care and nursing homes, you will see an expanding benefit that is very important to Medicare beneficiaries. How that gets handled in discussions of the managed care benefits package, whether managed care seeks to eliminate that growth trend — these will be very critical questions.

Second, there is a little virus in this bill [legislation under consideration in the fall of 1995], and that is the medical savings account. The goal of the medical savings account is quite simply to divide Medicare beneficiaries, who are now so politically powerful, to diminish their influence by fragmenting them. Medical savings accounts are essentially catastrophic insurance with a lot of front-end financial incentives to induce beneficiaries not to use the system. If adopted, they would succeed in dividing the pool of Medicare beneficiaries, inserting a wedge between those who don't really need health care services who would take the noncomprehensive insurance benefit, and those who do.

Finally, if we go this way we really have to confront the issue of how to assist people in making choices about health benefit plans for which none of their experience in life has prepared them. Beneficiaries need help, protection, and support on terms that are meaningful to older, often infirm, individuals. Can managed care save Medicare? No. It can be of some benefit in reducing the growth rate, and if done correctly, it can provide comprehensive services in a reasonable way to Medicare beneficiaries. I think that there is a real potential for improvement and that managed care is a positive part of the future, but it is not in and of itself the savior of the program, and we should be sure we go into it with our eyes open.

Consumer Perspective: **Joyce Dubow, Senior Analyst**
American Association of Retired Persons
Public Policy Institute
Washington, DC

**** I took the question that was posed to the panel quite literally: "Can managed care *save* Medicare?" The word "save," as Kathryn said before, is a very strong word and suggests that there is something very wrong with the Medicare program. I would like to take a minute to speak about the Medicare program. It offers enormous choice to Medicare beneficiaries already. It is an extremely popular program. If you look at the Medicare Current Beneficiary Survey you will find that about 90 percent of beneficiaries are satisfied or very satisfied with the Medicare program. Further, when you look at opinion surveys asking the public whether it supports cuts in the Medicare program, there is not generally support for cutting Medicare. Contrary to what was earlier implied, I do not think it is true that during the last thirty years the Medicare program has stood still in time. It has introduced payment innovations, such as prospective payment and the DRG system. Many of the payment practices that the private sector now uses originated in the Medicare program. To imply that Medicare is on the "critical list" is just not accurate.

Interest in doing something about Medicare arises for two main reasons: One is the projected Part A insolvency in about 2002. The projection of insolvency is not a new phenomenon; insolvency has been projected before, and Congress has addressed it in the past, most recently in 1993. But this year, probably because congressional leaders have decided that they want to address the deficit, they have made the impending insolvency of Part A a major crisis. This is not to say that the Medicare program does not need to be looked at. And it is not to say that we do not have to address Medicare's rate of growth. It is just that it is not the crisis that it would seem from reading the newspaper or listening to the news on television. **** The point is that one must look at data. Second, if you ignore the services that are not provided to the same extent in private coverage as in Medicare (like in skilled nursing and home health), you find that the rates of growth in the private sector and Medicare are relatively comparable. In fact, Medicare grew more slowly than the private sector until the early 1990s. **** In summary, we need to be very clear about what we are talking about when we are looking at the Medicare growth rates. Again, this explanation is not to say that we do not have to address the situation in Medicare. Virtually everyone agrees that a 10 percent rate of growth is not sustainable, particularly when you consider the influx of the baby boomers to the program. Medicare, of course, is affected by the same factors that cause spending growth in the private sector, such

as improved technology, excess capacity in the system, and over-specialization.

Now, let us turn to the specific question of whether managed care can make a contribution to the Medicare program. Interest in managed care for Medicare stems from the fact that managed care has grown so rapidly in the private sector, where premium levels have declined in recent years. Many believe that there should be a similar growth of managed care in the Medicare program. But Medicare beneficiaries simply have not had the same opportunities or the range of choices that their private sector counterparts have had. Further, it is not yet clear whether the Medicare program will realize savings from the growth of managed care. The evidence on savings is limited. CBO acknowledges that there is a reduced use of services in the private sector, but that this reduction is not always translated into savings for purchasers or consumers. They point out that this depends on whether the market is a competitive one or not. CBO does suggest that the reduction in use could translate into savings in the Medicare program, but as has been pointed out by earlier speakers, the average area per capita cost [AAPCC] is a flawed methodology, and therefore the federal government does not benefit from the savings that managed care might otherwise generate. However, in some cases, *beneficiaries* do benefit. One of the second-tier issues that is not really considered in the present debate is that the beneficiaries who are living in high cost AAPCC areas and who have "zero" premiums and enhanced benefit packages are going to be in for a rude awakening when a changed payment method is introduced for managed care plans. The opportunity for the plans to provide enhanced benefits and lower cost-sharing and premiums is probably going to be reduced with the revised reimbursement methodology.

The most important thing to remember about Medicare and managed care is that because beneficiaries have not had the same exposure to the ranges of choices of managed care as those in the private sector, there is a huge need for information — for descriptive, objective information that beneficiaries will be able to use when they are confronted with these new choices. Without such information, expanded choice is going to be very confusing to a lot of older persons. They just have not had the exposure to the array of choices that is contemplated. ****

Beneficiaries are going to need information that is easy to understand and clear. We do not know very much about the kinds of information that beneficiaries actually will use in making choices. A good deal of research on this issue has been commissioned by the Health Care Financing Administration (HCFA) and the Agency For Health Policy and Research (AHCPR). HCFA has responsibility to learn what beneficiaries want and need and to provide Medicare beneficiaries this kind of information. ****

An even greater responsibility is for HCFA to act for Medicare beneficiaries the way private employers act on behalf of their employees. HCFA has to act as a prudent purchaser in selecting the proper plans chosen to be offered to beneficiaries. There must be national, uniform standards that apply to all managed care plans. These have to address a range of areas that are important to consumers, such as fiscal solvency, consumer protections like grievance and appeals procedures that are timely and accessible, adequacy of the provider network, quality of care — both internal quality improvement and external review, etc. ****

All that said, we too, see the potential of managed care if it is done "right." Kathryn Allen pointed out studies that report where managed care has been exemplary. It is encouraging to read about these studies. Here is a system that has the potential to work: it can coordinate care and this is crucial to Medicare beneficiaries with chronic conditions. This would be an enormous improvement for them over the fragmented system we have now. But, we have to recognize the potential for the downside as well. We have to be mindful of the consumer satisfaction surveys that show those with chronic illness routinely report higher dissatisfaction levels and reduced access to specialist care than those who are healthier and who make fewer demands of the health care system. ****

Insurance Industry Perspective:

Robert A. Riehle, M.D.
Medical Director
Blue Shield of Northeastern New York

**** The Blues plans provide all types of health plans; they now offer some managed care products, and the Blues provide care through their HMOs across the country. There are 76 Blue HMOs and their combined membership is greater than any other of the HMO plans. ****

My definition of managed care is that it is an intent to coordinate and organize the care that a patient receives with two objectives — to maximize his or her health and to control costs. That concept is really a topic for another conference.

As a physician . . . I have seen a number of seniors who wander through the health care system seeking the appropriate physician for a specific problem. A gynecologist is not the person to evaluate a new onset headache in a 67-year-old women; a urologist is not the person to evaluate increasing leg pain with ambulation in a 74-year-old man. Many seniors have specialists (for instance, many have cardiologists), [who] may not serve all their health needs.

Managed care attempts to organize the way in which people receive care with two objectives: to maximize their health (that may be taking care of them when they are ill or may be providing screening for them to prevent illness) and to control the costs of care.

To achieve cost control, managed care is very good at aligning provider incentives — getting doctors and hospitals going in the same direction to provide quality, cost-effective care. In New York state, we pay hospitals under DRGs, so if a patient is admitted for pneumonia, the hospital gets so much money, whether the stay is four days or twelve days. In contrast, we pay physicians fee-for-service which means every time they examine the patient, see the patient, perform a procedure to the patient, they're paid for that action. Hospitals are

motivated at the moment to increase the number of admissions; physicians really have no motivation not to increase the number of admissions, so we need to motivate them differently. Managed care aligns incentives, so that the reimbursement for the procedure is more structural and coordinated, and it integrates the providers through a network which is judged by its good quality and cost effective care.

From a payor's perspective, managed care is going to offer Medicare beneficiaries "a smorgasbord of benefits," and, hopefully, the elderly will maintain their choice not only of providers but also of their benefits plan. The Blues' point of view is that the elderly . . . should have available to them the same health care system that the working Americans have. That was the idea Medicare began with, and the Blues feel strongly that all new Medicare initiatives should preserve that element of access and choice. The means that there should be a series of benefits plans from which the senior citizens can choose, depending on their own individual needs. Our industry's job is to educate the seniors concerning how these different plans function and which benefits the plans include. The Blues and I believe strongly that there must be some form of oversight so seniors are well informed before they make their choices. Yet there is a narrow line that you have to walk between oversight and monitoring of quality of care and outcomes so that people can make enlightened choices, and overregulation which measures costs. Finally, managed care maximizes the quality of care because it constantly assesses what care is being delivered, what effects it had, and how can improvements be made. Seniors have to get away from the idea that quality of care is synonymous with the quantity of care. It's not. The more care you've received doesn't necessarily mean that it's better care or that it's enhancing your health.

So yes, managed care can save Medicare if we all work together to save and preserve the outstanding quality of U.S. health care while controlling cost.

II. How Will Medicare SELECT and Medicare Risk Unfold in the New York Market?

Moderator: **Hermes Fernandez, Esq.**
Bond, Schoeneck & King
Albany, New York

Managed Care Organization Perspective: **Eugene W. Huang**
Director of Medicine
Oxford Health Plans
Norwalk, Connecticut

**** What I would like to do is just jump right into some of the elements of health care reform. **** Clearly there is a movement from a defined benefit to a defined contribution [approach]. That is probably one of the most significant impacts. . . . What that does is focus consumers on participating in the decision. They are not going to just bounce around the system, they are going to look for value. . . . That's one of the things that managed care brings, value. **** Another thing you will find is an explosion of choice. . . . You will see that it plays out in many different ways, specifically in New York it will lead to more competitors. It will lead to different players in this market place. It will also lead to more products. It will lead to a variety of products, among them point of service products that allow for out of network utilization. . . . It will lead to provider service networks, and the commentary on that from our perspective is that it is overall not a bad thing as long as we can make sure that provider service networks are adequately regulated and adequately capitalized so that we do not have some very significant failures that would make managed care look bad from everyone's perspective. You will also see medical savings accounts (MSA) as an option that will come through the legislative process. I think you have heard some of the pros and cons of medical savings accounts. **** [They are] probably not the best public policy in the short term. In the long term, I think what MSAs do is force people to look at spending their health care dollar. I think that is really a good thing. The problem is in the short term due to a lot of things that were already discussed. In addition, another comment I would make on MSAs is that when people start to look at the first dollar coverage they often short themselves on preventive care. That is, they don't spend money to go to the doctor when they have a cough. It turns into pneumonia, and then they need their catastrophic benefits. . . . We much prefer to spend more on primary care than less on primary care, and MSAs oftentimes force the opposite action. . . .

The payment rate issue: It is probably one of the most significant issues for New York. There are a number of things going on that will have a large impact in New York, and that is downstate as well as upstate. In some senses they are going to be on opposite sides of the issue. There is clearly a shift to rural communities in terms of the payment rates. This is one of the ways to address some of the disparities in payment, although there is quite a lot of debate as to what causes that disparity, whether it is artificial or whether it really costs more to take care of the typical person you see in South Bronx than it does to take care of the typical person you see in Kansas. We would argue that it does. ****

The graduate medical education issue: There is an effort to bring it out of Medicare reimbursement. There will be a big question as to how that will play out because right now in very many respects, HMOs pay higher rates to teaching institutions because of their higher cost structure. Part of that cost structure includes payments for medical education. It is a very big question for this society as to how we're going to pay for graduate medical education and where that money is going to come from. It has a significant effect on New York because of the concentration of teaching institutions in New York City.

**** The managed care issue: [P]eople vote with their feet. People will be very quick to judge quality. . . . I think there will be a very big focus on cost and quality . . . there will also be an opportunity in this environment for people to make

well-educated choices. **** We clearly believe that you judge quality on outcomes, how well we treat our patients. . . . Don't judge on how much we spend on the patient, but judge on how effectively we help them overcome their disease process or how we affect their quality of life. People are very good judges of quality of life. . . . Our members resoundingly say they are better off in our system, otherwise they would leave. . . . There is an incentive for HMOs to deliver value. . . . More procedures do not mean better health care to most of our members. ****

National Consumer Advocate Organization
Perspective: **Joseph Baker**
Associate Director
Medicare Rights Center
[formerly Medicare Beneficiaries Defense Fund]

**** First let me say one thing about choice. . . . [W]hen seniors talk about choice, they mean choice of providers. They want the freedom to go to whatever doctor they . . . would like to go. Now that may be outmoded and not cost-effective but that's what they want. . . . One of their major concerns with HMOs . . . is being limited to the network providers. . . . [T]o the extent that Medicare reform . . . increases costs on the fee-for-service side . . . and medigap premiums spiral upward to reflect increased costs, most seniors will not have much choice. [T]hey will be forced into HMOs because they will not have the economic resources to stay in the fee-for-service program. I think that is something that we have to deal with and recognize right now.

****

I want to discuss some frequently encountered problems . . . I've tried to focus more on problems that we found in the New York market. In the marketing area, New York has not experienced the fraudulent practices that have occurred in some places like Florida and California. I think we have had problems, however, with badly trained marketing and sales staff not really knowing what Medicare fee-for-service provides — what its benefits are, what its advantages and disadvantages are. Basically they have sometimes given wrong information to Medicare beneficiaries when they go to make their choice. I think that's important when you realize that HCFA, while it has made many efforts to provide information to beneficiaries, only recently came out with a small booklet for beneficiaries about managed care. ****

The grievances and appeals process is a real problem within the HMO system, and it is a real problem in the fee-for-service area too. As an aside, I should say that we talk a lot about the problems of HMOs, but there are also problems in the fee-for-service side that we are working on. Appeals within HMOs are protracted, they can take anywhere from either the statutory timelines on them, without being super technical, generally 60 days to much longer than that. A recent GAO report noted that many HMOs take much longer than HCFA standards, contributing to further delays. Some HMOs have been found to take up to 300 days to process an appeal. With regard to the grievance procedure, we find that a lot of HMOs are mischaracterizing grievances, which are reportable to HCFA, as complaints, which are not reportable and just kind of sink into some black hole. If we move to a yearly enrollment and disenrollment option, as opposed to the monthly disenrollment option that people have today, these appeal delays and mischaracterization of grievances will be even more of a problem. After all, if you are denied care by your HMO, you cannot vote with your feet because you have to stay within that network. An expedited appeals process becomes even more crucial in that situation, especially in the HMO context, because you don't have the doctor advocating for you for coverage as you do in the fee-for-service context.

Another matter . . . concerns problems with referrals to specialists. **** That leads into a larger concern that we've touched on a lot — the financial incentives in HMOs to under-treat. There are, of course, a lot of financial incentives in fee-for-services to overtreat, and we've heard about the so-called horrors of overtreatment. Well, under-treatment is the other side of the issue. I guess if I had a choice between the two, I'd choose to be overtreated. **** Karen Davis of the Commonwealth Fund recently testified that about 90 percent of Medicare beneficiaries cost about $1,300 a year in care and about 10 percent cost about $28,000 a year in care. Now if an HMO is receiving an AAPCC of about $4,500 or $4,800 dollars a year from HCFA to care for each Medicare beneficiary, who do you think they're going to market to? And who do you think they have the incentive to keep in the plan? And incentive to dis-enroll from the plan? ****

In New York, one of the other issues is the language barriers. A lot of the plans do not have marketing materials or other explanatory materials in Spanish, for example, let alone in other languages, and do not have adequate interpretation services.

Although we are going to hear about it in the afternoon, I do want to make one point about quality of care. Before we start really providing very stiff incentives to enroll in HMOs we really have to figure out whether we are measuring the quality of care effectively. Everyone agrees that we just do not have a way to measure and evaluate quality of care. Certainly that kind of data is not available to the public. So our chart here can tell you a lot about the cost and whether you get a hearing aid and whether you get eyeglasses or a prescription drug benefit, all of which is important, I agree, for beneficiaries to know when choosing plans, but it does not tell you if they have great doctors, not if the hospitals they contract with are quality institutions, or what their outcomes are. . . . That information is not available in fee-for-service either, and should be. The problem is, however, more acute in the HMO context. Because you are locked into an HMO you cannot vote with your feet in the middle of the year (especially if you have a yearly enrollment or disenrollment) if you feel like you are not getting quality care. Further, HCFA has not been able to do the monitoring and supervision job that it really should and must do, especially if we have higher levels of the population in managed care and annual enrollment/disenrollment.

I wanted to talk a little bit about some of the improvements that we think need to be made. . . . The information gap is really big here, and I think one of the problems is actually getting information out to seniors in a timely manner. ****

We also need information regarding the financial arrangements between doctors and HMOs so that patients know what they are dealing with when they walk into their doctor's office. We need more tracking and reporting of appeal, grievance, and disenrollment information and making that available to the public. ****

The point of service options [are] important. . . . The problem with HCFA's vision of it right now is that it is completely unregulated. The guidelines are very loose, and I think the HMOs are also very concerned about this. Seniors who do not understand HMOs are going to have an even harder time understanding point of service. The HMOs cannot exploit the point of service benefit as a marketing tool. We are concerned that HMOs will construct point of service products which are not really worth a lot but sound like they are (for example, paying only for out-of-network services associated with a particular illness). Further, we are concerned that HMOs will meet criticisms about the quality of their network care with the response that enrollees can "always go out of network." It costs more to go out of the network, so people on low incomes are not going to be accessing the point of service benefit.

We need more of a consumer voice on HMO governing panels. **** The Medicare market is an individual market. HCFA is not doing an adequate job and does not have the resources to protect individual consumers. To the extent other organizations like ours can act as employers do in the group market and the private market, we can protect seniors and get them the information that they need in a way that they understand and from a group that I hope can be more objective about the advantages and disadvantages of HMOs. Thank you very much.

Insurance Perspective:
Gregory V. Serio, Esq.,
First Deputy
Superintendent & General Counsel
New York State Insurance Department

**** [W]hat we are advocating . . . is something along the lines of a point of service program or a Medicare SELECT program, trying to capitalize on some of the options out there . . . so that providers and carriers can offer the services and the products that may be the best for the marketplace going forward. The marketplace is moving much faster than the law in New York, and even in Washington, and so maybe the marketplace will predict and direct some of the law as it goes forward. **** From our perspective, point of service and other plans like that usually provide a balance between the rigidity of managed care and what has become known as perhaps the inefficiency of indemnity or fee for service. ****

Question: I would like to get your perspective from an insurance oversight point of view on the physician-hospital networks.

Answer: From the traditional insurance perspective, we have to watch for solvency — that they will be there not just today when you contract with them but further on down the road. It becomes difficult because they are being regulated both as health care providers by the Health Department and by the Insurance Department as having certain financial responsibilities. **** [W]e have to parcel out what is the Insurance Department's responsibility for financial solvency and what is the Health Department's for quality of care and the adequate provision of services, and see where those two merge. There is already a strong working relationship between the two agencies, and . . . you may see even a more of a melding between the two in the future because this is government following the marketplace. While we do not want to change government or change the apparatus, we need to be responsive to it. If we change the apparatus and the marketplace goes to something else, we will be playing a game of catch-up all the way as opposed to setting certain standards and letting the marketplace operate from there. . . .

III. Assuring Quality of Care for the Medicare Population: Facing Special Challenges

Moderator: **Professor Pamela McKinney**
Albany Law School

Quality of Care Measurement:
Cary Sennett, M.D., Ph.D.
Vice President for Performance Measurement
National Committee for Quality Assurance
Washington, DC

**** NCQA [National Committee for Quality Assurance] is an independent, not-for-profit corporation that is primarily in the business of evaluating quality of care. . . . We were organized in 1979 originally as part of the managed care industry but became independent in 1990 and have been operating with a broadly based board of directors that represents consumers, purchasers, health plans and significant others related to managed care since 1990. [One of] our goals is . . . to foster the development and the strengthening of the medical management systems upon which users of managed care systems depend. We do this significantly through assessing the quality of the medical management systems that managed care firms use. We also do this through development of statistical measures of performance that give users of managed care firms objective information about the results the plans achieve. So we are fundamentally in the business of producing information, information that we hope will be used by consumers and by purchasers to direct their choice of health plans. Fundamentally, we believe there is an opportunity for meaningful competition in the market for health care services and if people have the information that they need in order to make good choices, they will make informed choices. **** Our

information really flows from two streams. Our accreditation program is a summary evaluation of the strength of the core medical management processes that underlie health plan operations. In addition, we have a performance measurement set. ****

Our accreditation program . . . is probably one of the best instruments available in the marketplace to provide information to potential users of managed care firms about the quality. What accreditation means is that a health plan has the infrastructure and the processes necessary to provide care that meets the needs of its membership. . . . Accreditation is a floor, that is, there may be, among the plans that are accredited, significant differences in quality. It is intended to be a floor, though, and not a ceiling, and as we move forward we have taken advantage of the opportunity to raise the bar, to improve the standards over time in a way that we think drives the industry towards increasingly higher performance.

Let me summarize very briefly how our accreditation process works. There is a long period of preparation by the health plan and the preparation of documents that will inform a review team. This review team is typically three to five individuals (primarily physicians knowledgeable about managed care along with one full-time NCQA staff). [The team] visits the plan and evaluates through review of documents and interviews how the plan is organized, how the plan operates, and whether it operates in a way that assures that the fundamental needs of its membership will be met. ****

Our process is rigorous, and most plans do not achieve full success — full success meaning a certificate of accreditation, which is good for three years. **** [T]ypically only 10 - 15 percent of plans fail outright. Second, there are a substantial number of health plans that have not yet undergone the process. We think that willingness to step up to the plate, to invite NCQA in for accreditation, is actually a marker of something.

Now, as a complement to our accreditation program, we have developed and are working to enhance quite substantially a set of performance measures that would give purchasers, consumers, and beneficiaries more . . . detailed and results-focused information about what the health plan actually is able to accomplish. The acronym that has been associated with this is HEDIS, which is short for the Health Plan Employer Data and Information Set. HEDIS was first developed outside of NCQA but came to NCQA in 1992. It has two primary objectives. The first is to provide a tool that purchasers and eventually consumers can use to evaluate health plans. There is, however, also tremendous value to the health plans associated with creating a standardized set of information. . . . So HEDIS is a set of highly standardized statistics that focuses on the aspects of care that matter to purchasers and consumers.

**** The content of HEDIS is organized around the basic areas in which purchasers and consumers want information. Probably the most important of these relates to the quality of care — the technical aspects or the outcomes associated with care provided. The accessibility or the ability to access care and the satisfaction with care, however, are also clearly important issues about which we need standard measures. Corporate purchasers have a desire for information about the membership of the plan and the utilization of services in the plan, for information about the financial performance of the plan and the plan's financial stability. Finally, there is a category of general descriptive information about the structure of plan.

The current set of HEDIS quality measures focuses primarily on preventive care, an area which has always been one of emphasis in the managed care industry but also an area where measurement is relatively easy. Given the pace with which HEDIS was built there was a strong inclination to focus in areas where returns were felt to be relatively great and could be obtained relatively quickly. There are necessarily issues that are of great significance to the Medicare population. Although rates of mammography undoubtedly are significant, there are additional outcomes measures that look at how effectively preventive care is delivered and how effectively acute and chronic care is delivered to women with breast cancer.

**** [O]ne of the things we are learning through this measurement process is how much variation there is. I do not think the consumers of care — Medicare beneficiaries and others — realize how variable care is. . . .

What I have described in very brief is HEDIS 2.0, the information set that was developed in 1992 and released in November of 1993. The limitations of HEDIS 2.0 are well known; we have made a commitment to move forward and have recently begun the process of developing the next fundamentally different version of HEDIS, which is 3.0. It will attend to some of the issues that I have discussed: in particular, it will extend the measurement work to the publicly insured populations, both Medicaid and Medicare. This work is being informed by a committee that draws upon an expert subcommittee that we put together specifically to bring the Medicare program and the voices of the Medicare beneficiaries to that discussion.

HMO Association

Perspective: **Sandra Harmon-Weiss, M.D.**
Vice President and Medical Director
U.S. Healthcare
Blue Bell, Pennsylvania

By way of a very brief thumbnail sketch, U.S. Healthcare is a publicly held company operational as an IPA or an Independent Practice Model HMO in twelve states and Washington D.C. These states are located in the Northeastern, Middle Atlantic, Southeastern United States and Washington D.C. U.S. Healthcare has 2.4 million members in our programs. A subset of these includes 100,000 U.S. Healthcare Medicare members, who are all Medicare beneficiaries, and 78,000 Medicaid recipients enrolled in the U.S. Healthcare FamilyCare plan.

Today I want to talk to you from the viewpoint of the private sector on Medicare managed care. Caring for the Medicare beneficiaries in managed care is the greatest chal-

lenge for managed care. Frankly, it is the newest frontier in the delivery of health care services, for there is no more care-needy population in the world than the Medicare population. It takes special skills and resources to provide comprehensive quality care for the elderly and disabled patients who are Medicare beneficiaries. This is done effectively through case management with nurses and social workers added to the team of typical health care providers. It takes a great deal of resources to really pay attention to the special needs of this patient population.

At U.S. Healthcare we have very special programs, which we term "safety net programs," developed to encapsulate Medicare beneficiaries in the health care system and to keep them from going off track or falling by the wayside. These programs are particularly important for chronic conditions such as congestive heart failure, chronic obstructive pulmonary disease, joint replacements, such as hip and knee replacements, and other common health problems for this group of patients. Finally, more is not always better, and in managed care we decrease the time that seniors stay in the hospital. Efforts are directed towards keeping patients functional and community-dwelling.

Cary Sennett has talked about the development of quality measures that will be directed specifically to the Medicare population. While we, at U.S. Healthcare, were waiting for the development of these Medicare-specific quality measures, we thought it was very important to try to develop and implement some quality measures for the senior population. At U.S. Healthcare, we've moved ahead to develop a Medicare Quality Report Card, and I will share with you some of the approach to collecting quality information for this patient population. We are very invested in preventive care which we think is of utmost importance to the senior population. We have active programs to make sure seniors receive their influenza immunization and mammography. The measurement of process of care allows us to develop quality improvement goals.

Today in quality measurement, we still say, "In God We Trust," but anyone else needs data. Currently our data demands are paramount. In medicine and in health care we can no longer use narrative descriptions or anecdotes or stories about the last patient we saw in the office. We need data, we need scorable, quantifiable outcomes and findings. It is the challenge for today and for the future.

In Medicare managed care, plans are exposed to a significant amount of regulatory oversight and quality review. Quality reviews include the following: NCQA (National Committee for Quality Assurance), HEDIS (Health Plan Employer Data and Information Set), HCFA (Health Care Financing Administration) and the PROs (Peer Review Organizations). NCQA is a private accreditation organization. Plans, such as U.S. Healthcare, can apply for NCQA accreditation and experience an in-depth review every three years and achieve full accreditation if stringent review criteria are met. Approximately 30 percent of plans that submit to this review meet these standards for full accreditation.

In creating the HEDIS version of 2.5, NCQA has taken the lead in developing a standardized tool for health plan performance measurement. HEDIS 2.5, however, focuses only on the commercial population up to age 65 and includes measures such as childhood immunization and prenatal care. The Medicare population, with multiple chronic diseases, is much different from the commercial population; it has many special needs.

Representatives from the Health Care Financing Administration review every operational area of the Medicare plan and Medicare risk contracting. The review is arduous but a good learning process.

"We need data, we need scorable, quantifiable outcomes and findings. It is the challenge for today and for the future."

There is PRO review to measure the quality of services to Medicare beneficiaries. The PROs are quality review agencies that contract with HCFA on a state by state basis. The PROs review health care services provided to Medicare beneficiaries in the fee-for-service sector and managed care sector. The review that was conducted until recently was a tedious medical record review of each service. A new quality improvement initiative has been started at HCFA's direction to have PROs and HMOs work collaboratively on special projects in geriatric care. A number of these projects focus on ambulatory medical care, a most important aspect of the ongoing care for Medicare beneficiaries.

At the present time there is a project called the Medicare Diabetes Project or the Health Care Quality Improvement Project, which is specifically focused at looking at Medicare beneficiaries enrolled in managed care who have diabetes. The Medicare Diabetes Project includes 23 Medicare HMO health plans in five states. U.S. Healthcare is a participating plan in this project.

To fill the void in health plan performance measurements for its Medicare enrollees, U.S. Healthcare and U.S. Quality Algorithms, Inc. (USQA) have used their expertise in performance measurement to develop the Medicare Quality Report Card. 1994 represents the second calendar year for which performance has been measured.

USQA developed the Medicare Quality Report Card to evaluate the quality of care provided to U.S. Healthcare members enrolled in the HMO plan. The USQA Medicare Quality Report Card is population-based and divided into several sections, including quality of care measures, access, and satisfaction measures.

The question was asked today, "What do you use as benchmarks for seniors?" Those of us who are geriatricians and have looked into the literature find very little in the medical literature about what an appropriate benchmark is for seniors. Therefore, it is necessary to go to an available resource, the Healthy People 2000. In this source, the defined goal was, by the year 2000, to have 60 percent of the seniors immunized against influenza on a yearly basis. At U.S. Healthcare, we've collected data in 1993 to compare with 1994 and we have immunized 65.5 percent of our Medicare population in 1994. We have measured, by way of outcomes, the decrease in acute hospital care days as a result of influenza immunization for our population and found a significant decrease in that utilization.

". . . we really want to make sure that our patient population is happy with the plan, and we need to know what their perceptions of care are."

Mammography screening is very, very important. **** At U.S. Healthcare, we have had an active program, for more than ten years, to make sure that all of our members receive their mammography screening when appropriate. The results of this program are that 73.5 percent of our patient population have received their mammography within the past two years. The benchmark for this cancer screen from Healthy People 2000 is, for women age 55 and older, to achieve a 60 percent rate of mammography on two-year basis by the year 2000. The present experience in fee-for-service Medicare is that about 40 percent of women in the senior group are receiving their mammography on a two-yearly basis.

Acute and chronic disease is a very important part of caring for the elderly. We have taken a look at the care of our diabetic patients. In order to do that, first we had to decide who our diabetic patients are. In our patient population, we found that 15 percent of our patients were diabetics. That is a very high proportion of the patient population. In the younger age group, younger than 65, the fraction of the population is about 3 or 4 percent with diabetes. We wanted to look at some measure of long-term diabetic control, and we also wanted to make sure our physicians were ordering eye exams (the retinal exams), for patients with diabetes. This would detect early eye changes and prevent blindness, because we know that diabetes is the leading cause of blindness in the country.

In comparing the rate of diabetic retinal eye exams from 1993 with that of 1994, there is a marked improvement in this performance measure for the U.S. Healthcare Medicare population. This is because, once we established our baseline in 1993, we were not very happy with it. The next step was to say: "What can we do to improve this? What can we do to further educate our primary care physicians and our specialists and our patients?" To answer these concerns, we started a focused campaign to reach out to all of these people to bring them together so that we can have more of these appropriate examinations done and hope that we can bring better care to our diabetics.

The other measures included in acute and chronic disease are simply a way of taking a look at the experience of the patient population with problems that cause patients to go to the hospital frequently. Congestive heart failure is the leading cause of admission to the hospital, bar none. We want to know what proportion of our population goes to the hospital with congestive heart failure but further, we want to know how many patients return to the hospital during a one-year time period. When patients are readmitted to the hospital it means they are not doing well. Once they are treated for their condition, hopefully, we can keep them community-dwelling and functioning better. Looking at this measure, we feel that it will give us a baseline for developing some projects to constantly improve performance. There is a little change from year to year, but I cannot really detect whether it is statistically significant. However, this lets us know where the problems are and then if we address them we should be able to measure the changes.

We find the same pattern with chronic obstructive pulmonary disease. After many years of smoking, our seniors have a great burden of illness with chronic obstructive pulmonary disease. We hope to change that in the future, but we find that many of our seniors go to the hospital because of lung disease. Again, we feel it is important to pilot this performance measure as an area that causes a lot of morbidity and loss of function with our seniors. Hopefully we can improve our performance on that.

We put a mental health parameter into our report card to mimic a similar parameter in the HEDIS-type reporting. We felt that if our patients were admitted to the hospital with a major depression, we would want to make sure that they have adequate follow-up after their hospitalization. That includes going back to see the physician, the psychiatrist or the primary care physician, within thirty days. However, because our patient populations could be frail, we also added that they could be seen by a visiting nurse in the home. We found a very high percentage of follow-up after this acute care episode. We feel that will be able to enhance the probability of continuity of care and improvement following the acute care therapy.

Well, while we are doing all these interventions we really want to make sure that our patient population is happy with the plan, and we need to know what their perceptions of care are. We also need to know whether they are going for care. We've looked at access measures. We survey our members on a yearly basis. We send out about a million to a million and a half surveys each year. The Medicare members respond to our surveys much more rapidly and efficiently than all our other members. Sixty-six percent of our Medicare members send back our surveys. We asked whether our patients are going to see their primary care physicians and 95.8 percent are going to see their primary care physician at least once during the year. However, a subset of that, 42 percent, actually had gone to

visit their physician 5 or more times during the year. That makes us very happy since it means that they are seeing the primary care physician early and often, enhancing the opportunity for early detection and treatment of conditions. We asked the patients' perception of their medical care; was it good, very good or excellent? A very high percentage, 98.8 percent, ranked it good, very good, or excellent. We feel good about that. Important to us, we asked if enrollees would recommend their primary care physician to a friend or family member. We had a very high response rate of 96.9 percent. Lastly we need to know, would members recommend U.S. Healthcare to a friend or family member. Ninety-nine percent responded that they would recommend U.S. Healthcare to a friend or family member.

In closing one of the things we have recognized in our work with Medicare Managed Care, as well as Medicaid Managed Care, is something that has been briefly alluded to today, the need for more coordinated quality monitoring, so perhaps all these organizations that are monitoring quality can get together and have something closer to a single report in the future. . . . We would like to streamline data collection so that we can learn more about a larger proportion of our patients. We are very much in favor of using administrative data so that we do not isolate our quality improvement activities to just looking at a few charts as representative of the patient population. We would much rather look at the information gleaned from the experience of the entire population. Finally, we want to do quality improvement projects. They are fun. Lastly, we see the immense growth of Medicare managed care coming in the future. . . . The challenge for the future includes new and different market areas. Particularly, we've heard some reference to moving into the rural areas with Medicare managed care. Finally, new quality programs based on chronic disease and outcomes will be on our agenda moving forward.

Questions:

1. Dr. Weiss, how will the HMOs handle rare diseases?

Answer: At the present time HMOs handle rare diseases by necessity. Everyone who is a Medicare beneficiary is allowed to sign up for a Medicare managed care plan with only two exceptions. If you have pre-existing end-stage renal disease and have not been a member of a commercial based HMO, or if you are already on the Hospice program, you are not permitted to join. But all other Medicare beneficiaries can enroll in managed care plans and we take care of them.

2. Suppose a person has a rare disease, and it has taken six years for the medical community even to put a name on that disease, how would that be handled?

Answer: We have a special program called medical excellence. If a person has a rare disease that requires special care outside the existing specialist network, then we will fly the person and a family member anywhere around the country or in the world to get that special treatment. In this manner, we provide coverage for those very special, unusual situations.

3. I get very concerned about a quality assurance system that depends on what is and has been instead of what should be, for example, I haven't heard very much about home care talked about here today. One in 20 people over the age of 65 is homebound.

Response: At the present time U.S. Healthcare within the 100,000 Medicare beneficiaries has 285 institutionalized patients who have regular care by a primary care physicians as well as specialists. In addition to that, we encourage our physicians to do home visits, and many of them do home visits on a regular basis to their homebound members. We encourage it and make sure that they physicians can receive additional compensation for doing so. ****

Consumer Advocate Organization Perspective:

Donna L. Wagner, Ph.D.
Vice President for Research and Development
The National Council on the Aging, Inc.
Washington, DC

**** The National Council on the Aging is a national nonprofit advocacy organization that has, since 1950, worked to enhance the quality of life of older people. We do this through education, training and service to our members who are the professionals in the home and community-based care systems around the country — and by knocking on a lot of doors in Washington.

Let me begin by saying that many of the concerns that we have about managed care and health care in general are really related to how we provide and finance health care in this country, that is, the division between acute care and long-term care. Older people and persons with disabilities share one thing in common — they are managing one or more chronic illnesses, and the key to their quality of life and health is the effective management of these chronic illnesses. From a provider's perspective, effective management means a reduction of the cost of health care. By separating the long-term care from acute care as we have done historically in this country, we have a set of rather perverse incentives — in managed care and in other forms of health care provision. I am concerned about what these incentives mean for the older people who are affected by them as we learn how to provide managed care to older people. We heard today about the Health Plan Employer Data and Information Set (HEDIS) and the fact that there really is nothing in the HEDIS which addresses health care needs of older persons with disabilities. Outcome measures which are appropriate for this population are still needed. We also heard from some managed care providers about the quality improvements they would like to make and the fact that they are not sure how to do it and need better outcome measures as well. We are all making this up as we go along. In order to ensure that we do not have too many victims along the way, we need to always keep in mind the incentives that are present for providing good care or for providing bad care. As long as a managed care organization is not ultimately responsible for that long-term care bill at the end, there are going to be a rather perverse set of

incentives. These will have to be overcome. And, certainly, the Health Care Financing Administration (HCFA) and the other watchdogs in the country will have an important role to play as we experience the learning curve of managed care and Medicare.

What do we know about quality of care for older people? You have heard others say we're not sure what this means — we all are searching for the ultimate indicator that could provide us guidance. We do, however, know a few things. We know that, for an older population and for a disabled population, a non-medical service can be as important, if not more important, to keeping that person out of a hospital as a visit to a doctor. We are hoping to see more of these non-medical services being included in managed care programs. I know that some managed care providers are planning or implementing what might be called value-added services from a consumer's perspective. That is, doing some house calls and assessments in-home and exploring non-medical services. But, we cannot lose sight of the fact that managed care was developed and tested on a young, healthy population and the existing outcome measures associated with managed care relate to this population — not an older, chronically ill population. We also know that health and wellness programs have positive effects for persons of all ages and are increasingly embraced by older people. But, we have not convinced everyone that these programs can save money in the long run. More research in this area is needed. Many managed care organizations are including health and wellness programs in their services. But adding a wellness program is not enough to adequately serve an elderly population — significantly more services will be needed if we are to hope for successful managed care/Medicare programs.

One of the biggest issues for managed care today is the health care personnel within the organization. We do not have enough geriatricians in this country today. We still have an unacceptably high rate of iatrogenic disease killing older people in this country and until we can ensure that whatever quality standards or outcomes assessments are in use include professional training, this will continue. A monthly in-service will not be enough — we need professionally prepared and trained geriatric health care professionals who are managing the care in the managed care organizations. With perhaps 30 million older Americans in managed care, we're going to need many more trained professionals working in these organizations. Being a nurse practitioner is not enough — we will need geriatric nurse practitioners. We know there is a special science and a special art to dealing with issues that confront people in late life and we have not adequately dealt with this need in managed care to date.

Another important issue is making sure that managed care works for *everyone*. This will involve enhancing consumer direction and choice within a managed care system. We've heard the word "choice" all day today, but it has been used only to describe the choice an older person has about their managed care organization or the choice of "fee-for-service." I am speaking about choice after you get into a program. One of the important lessons that we have learned from the disability and independent living movement is that not only do people do better when they are managing their care, are the masters of their own destiny, but that this approach can be more cost-effective in the long run. I think that older people are not really good candidates for being "managed" by others. They have done things their own way for 80 years or so and they're not about to give up control that they may want. When I talk to our members, the service providers, they refer to this as a problem of "service resistant" elders. When I talk to physicians, they call it non-compliance. Whatever it is called, older people can be tough to "manage," so if we put them in a system that does not give them choice and control over things, we are going to have some trouble on our hands. **** The movement towards more control and direction is being fueled by two trends — the aging of the disabled population who are not prepared to give up their control just because they become old and are put into a different care system and increasing numbers of highly educated older people who are entering late life.

Finally, I would like to end with the reiteration of something we heard this morning which is, and it is daunting to think about, that we are changing our health care from a public benefit into a purchaser-driven system. It is extremely important for the quality of health care available for older people that the Medicare beneficiary population be kept together for the purposes of purchasing this health care. HCFA or some other public organization needs to ensure that Medicare beneficiaries get the best health care "deals" just as our employers are doing for us in the commercial product area. We want HCFA to have a budget adequate to go out there and be more prescriptive about what managed care programs should look like for older people. We want them to be out there in the field and in the trenches, not just relying upon disenrollment as the "canary in the coal mine." That is not good enough, it has to be something more proactive for older people — and ourselves when we reach old age.

Medical Association Perspective:

Edward B. Hirshfield, Esq.
Vice President and Associate General Counsel for Health Law
American Medical Association
Chicago, Illinois

**** The American Medical Association (AMA) supports the House Medicare reform bill that is being debated in Congress [in the fall of 1995]. I came prepared to explain why. All of you read the newspapers and there were reports last week that made it appear that the AMA support for the bill had been bought with a promise of higher Medicare payment for physicians. Certainly interest groups negotiate with Congress over issues such as Medicare payment, and we engage in that process too. That is not the reason why we are backing the House bill. The AMA probably could have done better on the payment issue if it had joined with those claiming that the bill will destroy the Medicare program. The AMA name does have credibility in the quality care area, and AMA claims that the

bill would harm quality could have helped derail Medicare reform. The AMA chose not to take that tack.

The reason why is that the AMA believes that the costs of the Medicare program must be brought under control. If the program continues on its present course, taxes will have to be increased substantially to pay for it or some kind of queuing system, such as is being experienced in Canada, will have to be implemented. The AMA made a substantial proposal to Congress about ways to bring costs under control. The AMA believes that using market forces to reduce expenditures is the best way to reform Medicare to control costs. The use of market forces has worked well in the private sector. The drafters of the House bill adopted many of our proposals and that is why we support the bill.

The part of the House bill that is important to us is the provision for provider sponsored organizations (PSOs), which would be held plans owned and managed by providers. The AMA first began to advance proposals for PSOs several years ago. Recently, the AMA has been joined by the American Hospital Association (AHA) in advancing this proposal. In fact, the current version of PSOs in the House bill more closely resembles the AHA vision that the AMA's original version.

Originally, the AMA asked Congress to reduce legal barriers that inhibit the formation of provider sponsored health care delivery networks and health plans. Most laws that bear on the formation and operation of provider sponsored networks and health plans were designed in the era of fee-for-service medicine, and are no longer appropriate for the kind of activity that is taking place in the market. In this regard, our chief concern was facilitating the growth of networks that could evolve into health plans, as it is difficult for physicians and other providers to assemble the capital and management necessary to form and operate a full-fledged health plan. Providers need to crawl before they try to walk, and to walk before they try to run. However, the drafters of the House bill rejected the concept of facilitating the development of networks, probably because they wanted to promote the growth of provider sponsored organizations that would take full responsibility for underwriting the cost of providing care to Medicare beneficiaries. As a result, in the House bill, PSOs are health plans that underwrite the risk of providing services for the entire Medicare benefits package to an enrolled population.

There has been a lot of hyperbole about PSOs. They have been called "sweeteners" in the House bill for physicians, and other interest groups have complained that it is unfair to favor one type of health plan over another. However, the only real difference between the PSOs and the other health plans that could be selected by Medicare beneficiaries under the House bill related to solvency standards. Further, it is not clear just what the differences in solvency standards will be — that is left to the rule-making process. The reality is that few providers are in a good position to develop a PSO, and if the bill is passed, it is not likely that many PSOs will be organized in the short run.

With regard to solvency standards, the issue is whether standards such as minimum net worth, minimum reserve levels, and other solvency protections should be less for PSOs than other health plans. The AMA believes that there are good grounds for there to be differences. Most health plans, such as HMOs, are financial intermediaries, meaning that they accept a premium from beneficiaries and use it to buy medical services from providers as such services are needed by the beneficiaries. To regulate the solvency of a financial intermediary, it is necessary to be sure that they have enough cash on hand to pay for medical services in the event that they have unanticipated claims. PSOs are different. They are not financial intermediaries, they actually deliver health care with their own assets. The PSOs do not hold a lot of cash, they have their money invested in assets for health care delivery. The important aspect to look at in maintaining the solvency of a PSO is its capacity to deliver care. If a PSO receives more claims than are anticipated, it will deliver the care instead of buying the services. Therefore, a PSO must have enough health care delivery capacity to provide an unexpectedly large amount of care.

"The important aspect to look at in maintaining the solvency of a PSO is its capacity to deliver care."

The AMA also believes that managed care has substantial promise for those of us that do not feel the pain that occurs as it forces provider payment down, causes physicians to lose their practices, hospitals to close their doors, and patients to lose freedom of choice over providers and the services that they receive. If you can look past that pain, there is a tremendous medical revolution taking place in the science of medicine. The entire realm of medicine is being reassessed to determine what medical services are beneficial to patients and what parts of it provide little or no benefit. From a scientific point of view, this is an extraordinary event. This should ultimately result in the improvement of care because physicians will have assessed what really helps patients and weeded out the good from the useless.

In addition, the coordination of care that occurs with managed care can be a real benefit. I have been in the hospital within the past ten years and I experienced what it was like to steer my own way through that maze. It is a good thing that I was conscious the whole time and that I was out of the operating room. When you have an experience like that, you gain a sense of what benefits can occur with coordinated care. Having someone who really understands health care quarterback the delivery of services to you has extraordinary promise.

There is, however, a dark side to managed care. It is under-treatment, or withholding of necessary services. There have been newspaper exposés about incidents of withholding of necessary medical care. ****

To realize the promise of managed care we have to prevent the dark side from happening. How do we go about doing that? Well, as you have already heard about today, we need standards and we need information based on consistent and scientifically correct methods of measuring outcomes. We, the patients, need information based on those standards and outcomes measures. To give you an idea of the kind of information that we need, imagine what it would be like to buy stock in companies without the kind of financial information about them that we have today. Suppose that you received financial reports from various companies in which different assumptions or standards were used so that you could not compare one to the other, or even be sure that you understood the true financial situation of any of them.

Can you imagine comparing outcomes information between health plans or providers where one health plan assumes that a 50 percent return to full function is an excellent outcome while another health plan assumes that a 70 percent return to full function is excellent? That is the kind of problem that we could have. That is why we have to develop information based on consistent and scientifically proper standards.

How do we go about creating standards? The AMA is creating standards, and so are others. You have heard from some of them today. The federal government is creating them, the National Committee for Quality Assurance (NCQA) is creating standards, U.S. Healthcare is creating them, and many other organizations are creating them. Unfortunately no one is coordinating the production of all of these standards. All of these organizations are following their own paths. If we really want to develop the consistent and scientifically correct standards that we need, these efforts will have to be coordinated.

Therefore, the AMA has made a proposal for the establishment of a partnership for Health Care Value. This would be a council with representatives from the various organizations that are involved in developing standards, including representatives from the federal government. These representatives would sit down and work out a course of action. The AMA proposed that the federal government take the lead in organizing this partnership, and that the private organizations offer their standard-setting initiatives as resources in the development of standards.

There are a lot of resources in the private sector that could be used in such a coordinated effort. You have just heard about the NCQA's system. The AMA also has standard setting initiatives. The easiest way to understand this system is to follow a physician through the education and training process. A student starts by attending a medical school accredited by the Liaison Committee on Medical Education, which is a privately operated entity managed by the AMA and the American Association of Medical Colleges. After graduating from medical school, the student goes to a residency program which is accredited by the Accreditation Council for Graduate Medical Education. That is a privately operated entity of which the AMA and other associations are parents. After residency, the next step is board certification, most of which is handled by the American Board of Medical Specialties, again a private organization in which the AMA participates. Once physicians are in practice, they are peer reviewed by the medical staffs of their hospitals, a process that is privately operated by volunteer physicians who are usually not paid for this work.

Think what could happen if all of the privately operated processes for standard setting could accomplish if they were organized and coordinated to managed the extraordinary revolution that is occurring in medicine right now. As I have already said, the AMA made proposals for such an effort. **** While the proposal is not being taken up by the government now, the AMA hopes that it will be viable in the future.

You might ask why the private organizations do not organize it on their own, and not wait for government leadership. The unfortunate reality is that we have experienced several years of hard, full-tilt lobbying over President Bush's health care reform proposals, President Clinton's proposal, and now over the Medicare reform proposals. Different health care interest groups are taking different positions. The result is that the health care industry has become something like Bosnia. At this point, a guiding force like the federal government may be necessary to restore the sense of trust and cooperation necessary to establish and operate a Partnership for Health Care Value.

IV. Emerging Legal Issues in Managed Care

Moderator: **Peter J. Millock, Esq.**
Nixon, Hargrave, Devans & Doyle
Albany, New York

Academic Perspective: **Professor Dale L. Moore**
Albany Law School

**** I approach this subject with some skepticism about the enthusiasm with which we seem to have embraced managed care. I think there are some issues that should be considered carefully, and obviously that's what a conference like this is about.

In your materials, I've outlined some of the roles physicians have played historically, such as "healer" and "advocate." By the way, I listed "informant" meaning "provider of information," not "squealer." "Confidante" and "friend" also are roles physicians have played. Finally, even in the days when, at least on the East Coast, managed care was nothing more than a gleam in somebody's eye, physicians functioned as rationers of care. For example, physicians, and nurses as well, made decisions about how to allocate resources, such as intensive care unit beds, among those in need.

Today, with the impact of managed care, the contours of the physician-patient relationship have changed, creating new questions in areas such as liability, disclosure, and informed consent. The physician-patient relationship traditionally was very much more of a two-party relationship; today, even

though it may still be a two-party relationship, the autonomy of that two-party relationship has been significantly eroded.

One aspect of that erosion concerns tort law, that is, the rules governing malpractice liability. The liability rules that presently exist developed out of the cases in which somebody was injured, creating disappointment about the outcome of a health-care encounter. These traditional liability rules are modeled on . . . an anachronistic view of the doctor-patient relationship. When I think of the relationship on which our liability rules are modeled I think of somebody like Dr. Welby or maybe Joe Gannon or Hawkeye Pierce — the kind of doctor-patient relationship in which the physician is viewed as having only the patient's interests and concerns in mind. The introduction of "managers" into this relationship has to change the way the relationship works and ultimately will have implications for issues of liability. Historically, the standard of care that has been imposed on physicians for purposes of liability rules has been that of a "reasonably prudent physician under the circumstances." That concept of reasonableness historically has not included any cost component. That is, reasonable physicians have not been required to consider things like "how much does this procedure cost?," "how many of these can I provide for my patients?," and so on. In fact, I think that during the time these liability rules were developing many physicians were really clueless about the cost of various treatment or diagnostic procedures. If we want the liability rules to be consistent with the realities of the relationship today, we have to acknowledge that the standard of care of "reasonable" physicians includes an economic component. That does not mean cost should be the only measure of reasonableness, but rather an aspect of reasonableness.

In the last 30 years or so some interesting institutional liability rules have developed. By "institutions," I mean primarily hospitals because most of these rules have developed in the hospital setting. Those rules are perhaps a little bit more susceptible of application in the managed care setting because they expressly acknowledge the influence of the third party, (the hospital) on what goes on in the doctor-patient relationship. To some extent those rules might lend themselves to being applied in the managed care setting not only with regard to physicians, but with regard to the relevant institutions, such as the health maintenance organization or other manager of care. Some significant questions have been raised about whether the Employee Retirement Income Security Act will preempt common law development of rules in this area. I think preemption would be unfortunate unless we entirely change our thoughts about injured parties' entitlement to recover for damages caused by their health care encounters.

Another area where I think managed care is problematic is in the disclosure of information in the physician-patient relationship. Traditional approaches toward disclosure of information ("informed consent" cases) evaluate the scope of disclosure by one of two general standards: (1) what a reasonably prudent physician under the circumstances would disclose or (2) what a reasonably prudent patient would consider "material" to a decision. Under either standard of disclosure, the nature of the information concerns risks, benefits, alternatives — what are the probable consequences of a particular treatment encounter? In certain circumstances, physicians have not been required to disclose information to their patients prior to treatment. Those situations include emergencies, where the person simply can't provide consent or listen to information because of exigent circumstances. Over time, these two standards (the prudent physician and the prudent patient) have collapsed into each other, such that today what the prudent physician would disclose is what the prudent patient would want to know. Then, however, we have this additional dimension created by the managed care setting, which may change what the prudent physician should disclose and what the prudent patient needs to know. Probably there are more things that the patient needs to know and the physician needs to disclose, including: the existence of the "manager" of care and the economic incentives created by managed care; and during specific encounters, how the manager's decision affects available alternatives. It seems to me the proper approach to all these three is very easy. All such information should be disclosed to the person who is signing on for this type of care, particularly those who have grown up in an entirely different type of system. For example, most current Medicare beneficiaries did not grow up in this kind of setting and are not familiar with the kinds of incentives that managed care might create, nor are they accustomed to the presence of a manager mediating their health care encounters. Finally, a remaining question is: should the manager's decisions be challenged and by whom? Clearly under some circumstances they should be challenged, and often only the physician will know there is any basis for challenging them. Obviously requiring the physician to be the one to make the challenge may put the physician in a difficult position in some circumstances. Since these potential conflicts of interest may arise for physicians in managed care, they should be disclosed to prospective patients. Disclosure will not cure everything, but it is a good start.

Another issue I want to mention briefly . . . is protection of the confidentiality of patient information. We all know that lots of information about all of us is lurking out there now in people's databases, retrievable and subject to dissemination. We've always had to agree to let third-party payers have access to information if we want them to pay for our care, but managed care creates new and greater interests in our private information — for example, to keep track of outcomes and to measure the costs and benefits of treatments. It strikes me that the potential for intrusiveness and loss of privacy is much greater today, making even more important the development of means to protect confidentiality.

A final issue that I outlined is selection and retention of physicians and other individual providers. A great deal has been written about this topic in connection with institutions such as hospitals, and we are beginning to see more discussions of selection and retention of individual health-care providers by HMOs as well. What should influence these decisions? Should they be controlled or regulated? I think that is another area that may well be affected by the Employee Retirement Income Security Income Act. Now I have men-

tioned that Act twice, and I usually try never to mention it because I know very little about it so I'm going to leave it to the next speaker, who does know a good deal about it.

Case in Point:
***Travelers v. Cuomo*[2]:** **Jeffrey J. Sherrin, Esq.**
Sherrin & Glasel
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**** The theme of what I want to talk about is: as the health system moves more and more into managed care, and Medicare and other consumers are more and more covered by managed care programs, will the system become less and less subject to state regulation over areas traditionally subject to state regulation, i.e., quality of care and the cost of care. That's really what the *Travelers* case is about. ****

"The question really in any ERISA preemption case is does a state law relate to an ERISA plan?"

Travelers has to do with the Employee Retirement Income Security Act (ERISA). ERISA has a very unusual provision; it's called the "preemption clause" and it basically says that any state law that relates to an employee benefit plan is void or at least void insofar as it relates to that plan. This is the question that Jim Tallon mentioned. The federal government is setting broad standards, not specific ones, and then telling the states, you have to stay out of it and you cannot set more specific standards. . . . One other provision of ERISA that I want to bring to your attention is after the preemption clause — the clause that says that any state law that relates to an ERISA plan or an employee benefit plan is unenforceable. There is what's called a "savings clause" which says "but," and the "but" is that if the state law regulates insurance, it is not unenforceable or it is not preempted. These are very important provisions in the *Travelers* case. The question really in any ERISA preemption case is does a state law relate to an ERISA plan? The law in *Travelers* was the state law that determines how hospitals are reimbursed for their services. The question really relates to a specific component of New York's hospital reimbursement system that had different rates of payment for certain payers such as Blue Cross plans versus other payers such as commercial insurance companies. The question was whether this system was unenforceable or void because it caused ERISA plans to pay more money if they took certain options. In fact, the statute was found to encourage plans to insure through Blue Cross plans as opposed to managed care or commercial insurers. Was that encouragement of how plans were to operate something that made the statute illegal or void because it related to employee benefit plans?

Well, the Supreme Court said "no," it is not preempted. The basic reason for [the Court's] decision was that it is not enough that it might cost an HMO or a commercial insurer or an ERISA plan more money to operate. The mere fact that the statute may cost [the insurer] more money does not mean it relates to the plan. The Court also said it is very important what Congress intended, and we do not think Congress intended to intrude that heavily into how states traditionally regulate health care. If you are going to say that any time the state passes a law that increases the cost to ERISA plans or employee benefit plans, it is illegal, that would not be consistent with what Congress has traditionally done in encouraging states to regulate quality and regulate costs. That is really what *Travelers* is about, and what is so significant about it is that it really reversed a whole trend of cases that more and more had been finding that traditional state practices in the regulation of health care were preempted. Since *Travelers*, there have been a number of other decisions that have now gone the other way and validated things that had previously been invalidated in lower federal court decisions.

This brings us to the two questions that Peter said I would talk about. I raise these not to resolve the issues but to bring out to you what I think are two emerging issues in ERISA preemption and managed care. The first involves any-willing-provider or freedom-of-choice laws, and you are probably all familiar with those. They, basically, would require HMOs or traditional indemnity plans to open up their policies for participation to any provider who was willing and capable of meeting the qualifications to participate. Freedom-of-choice laws allow a patient to pick his or her provider of choice, and you heard Ms. Allen say that a major legislative objective of the managed care industry is to defeat those laws.

Well, the question whether any-willing-provider laws are preempted, or in other words if the state enacts those are they going to be unenforceable because they relate to employee benefit plans, has come up in a couple of cases, but they are all pre-*Travelers* cases. The argument is that if you are telling an insurer or the plan which physicians must be [allowed] to provide services under the plan, then you are obviously "relating to" the plan, you are relating to some of the very key decisions that plans make, like who is going to provide medical services, or who is going to provide laboratory services. Now, the interesting thing is that in the two cases that I mentioned in my outline, different results were reached. In the first case, *Cigna*,[3] the Court said "yes," this statute definitely relates to an ERISA plan because it is basically telling the plan to open its provider network up to any physician who is willing to participate and who can meet the terms. In the *Cigna* case, the Court said the law was not "saved" under the savings clause, meaning that it was not really the regulation of business of insurance. So, in this jurisdiction, which was Louisiana, the any-willing-provider law was preempted.

Two years earlier, there was a another case out of Virginia called *Stuart Circle*,[4] that also had to do with an any-willing-provider law. The statute basically said that PPOs cannot discriminate among the providers who do want to participate in the PPO, and the court also said that this statute relates to ERISA plans for the same reason — telling plans how to structure who provides medical services. But in this case, the court

said the statute is saved by the savings clause, i.e., it does involve the regulation of insurance. So, a similar statute in Virginia was held not to be preempted. Both of these cases were before *Travelers*. In two jurisdictions, one was saying the any-willing-provider law is enforceable and the other jurisdiction was saying that it is not enforceable.

Any-willing-provider laws are now a major focus of legislative activity at the federal and state levels. More and more states have adopted any-willing-provider laws, and therefore I think you're going to see more and more of these challenges and this may ultimately go up to the Supreme Court also. I think this is a tougher case actually than the *Travelers* case but my prediction is that if as any-willing-provider law applies to an entity, such as a Blue Cross plan or an HMO, that is not owned and operated by an ERISA plan or is a self-insured ERISA plan, but is a plan that is open to a community in general and targets as well ERISA plans for its membership, the statute will not be preempted on the ground that it is determining who the insurance company must contract with, not that the ERISA plan must contract with that insurance company. That is my prediction for any-willing-provider laws. I think it's a very tough question.

The other issue that I plan to bring to your attention is medical malpractice actions, and you have heard a fair amount about those already today. It is not that infrequent that when a patient who is under the care of an HMO suffers a bad result, the patient sues the doctor and may also sue the HMO. In many situations, the HMO is not the employer of the doctor, but rather an IPA situation is present. The argument is that the HMO is responsible for the physician's negligence on a principal-agent theory, just like you generally sue an employer as well as an employee who hurts you. Those cases have also gone both ways and there are in fact some post-*Travelers* decisions in medical malpractice cases. In one, the *Pacificare* case,[5] which is a 1995 post-*Travelers* decision case, though it does not mention *Travelers* at all and I don't understand that, the Court held that the malpractice claim against the HMO is not preempted. The Court says that the issue really was simply did the doctor act negligently or not. If the doctor did act negligently, can we hold the employer or the principal, in this case the HMO, responsible for that on a principal-agent theory? Now, the Court says this is just looking at a simple question whether physicians met generally accepted standards of care, i.e., reasonable care under the circumstances, and it doesn't require one to look specifically at the terms and conditions of the ERISA plan. Just as many courts have held similar malpractice actions not to be preempted as have held them to be preempted. The theory as to why they are preempted is that when you are suing the plan, you are actually saying the plan did not provide me the quality and level of benefits that I am entitled to under the plan. You provided me with something different or something less, and so the courts are saying that this requires the court to read the plan and understand what the plan's requirements are. If you do that, then automatically that [lawsuit] "relates to" the plan, because it depends upon the terms of the plan for its very existence. Sherrin's prediction? I think that such claims will be held not to be preempted if they end up going to the Supreme Court because it is not a question in my mind of what the specific benefits are under the plan, so much as whether the doctor was meeting accepted standards of care in the medical community as a whole. Now I say that with a *caveat* because there are a number of cases that do require review of the plan itself. For example, there is a case in which the utilization review company that provided services to an HMO was sued on the same theory. The court said that the claim was preempted, and probably rightly so, because a utilization review determines what the benefits are in the plan and what the patient or the subscriber is entitled to under that plan. This was a case in which the patient's doctor felt the patient required an extended hospitalization and the utilization reviewer refused to approve that. The utilization reviewer was held not to be subject to a lawsuit because the reviewer simply determined what benefits were available under the plan. The question was not whether the doctor followed accepted practices in the community. So when you get to the question of malpractice liability of an HMO that is providing services for an ERISA plan, issue will turn on whether we are looking at generally accepted medical standards in the community or whether a specific benefit that is in the plan was provided or not provided or some other criterion of the plan is or is not being met. This I think will be another one of the emerging areas in managed care liability, and somewhere along the line we will have final resolution. Thank you very much.

A Practice Perspective on National Legal Trends:

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**** I am going to focus on legal issues pertaining to antitrust, the anti-kickback statutes, and the Stark regulations that have recently emerged. Now, each of these topics actually constitutes a day and a half seminar for lawyers. So I shall just try to hit some of the highlights, and particularly as they relate to the topic of the day, managed care and Medicare managed care organizations. The antitrust issues arise in the context of the component providers in any managed care organization: the physicians, the hospitals, or the joint venture entities that are created by physicians and hospitals. They also relate to the size of the managed care organization, the contracting issues, pricing and the presence of exclusivity in these arrangements. The initial questions that arise are who are the parties that are coming together? Are they competitive physicians or physicians' groups? Are they hospitals that have been competing with each other previously? Or are they a combination of physicians and their hospitals?

Secondly, what percentage of physicians and/or the providers from a given area is included in the managed care organization? This necessitates a definition of the term "market." A very important consideration in antitrust law, particularly in the analysis of antitrust violations according to the rule of reason, is the determination of two markets, the geographic market and the product market. Clearly, the providers seek a rather expansive interpretation of what the market is, whereas the lawyers from the antitrust division of the Department of

Justice and from the Federal Trade Commission seek a rather more restrictive definition. For example, with respect to the product market, are providers of pediatric services just pediatricians, or could it be family physicians, internists, or all of the above?

With respect to questions that arise as to contracting, there are many terms that could be interpreted to be restraints of trade. For example, in physician/provider contracts, terms prohibiting physicians from contracting with an entity other than the managed care organization, preventing the physicians and providers from interacting with or contracting with any payer other than that with whom the managed care organization is contracting, restricting the number of physicians or providers in the managed care organization, may all be interpreted as unlawful restraints of trade.

"For physicians who have traditionally worked mainly in solo practice or small groups, the concept of coming together into larger groups raises a host of issues."

With respect to pricing, there is the issue of setting fees. Potential antitrust liability varies with the degree of integration and the extent of the assumption of financial risk by the participants. For physicians who have traditionally worked mainly in solo practice or small groups, the concept of coming together into larger groups raises a host of issues. There is a whole spectrum of associations of physicians, from the traditional solo private practices and small groups all the way over to the large, fully integrated, multispecialty group such as the Cleveland Clinic, which has over 400 physicians.

Physicians who are just organizing into groups want to test the water, to get their toe wet and check the temperature of the water before they become fully integrated. If they want to do any managed care contracting, they are faced with issues related to pricing. If a physician group is less than fully integrated, the antitrust liability can be minimized by sharing financial risk. Several techniques or arrangements have been identified that can limit the antitrust liability in pricing and which are relevant to sharing financial risk. Capitated contracting is one. Another is establishing fee schedules with withholds where there are requirements to meet cost containment or utilization targets. The Department of Justice and the Federal Trade Commission issued enforcement statements in 1993 pertaining to antitrust in the health care industry. Of relevance to us is one statement that focuses on physician networks, and the enforcement statement states that agencies will not challenge a physician network joint venture that has 20 percent or less of the physicians in each specialty who practice in the relevant geographic market and share risk. Compliance with this can be easily achieved in a large metropolitan area, but it might be very difficult in a smaller community, let alone in a rural community. To qualify for the antitrust safety zone, the physicians in the joint venture must share substantial financial risk. The enforcement statement states that risk does exist in capitated payment systems and in discounted fee schedules with withholds. The enforcement statement then identifies what a rule of reason analysis consists of. It can involve defining the relevant market, evaluating the competitive effects of the joint venture, evaluating the impact of the pro-competitive efficiencies arising from the joint venture, and also evaluating ancillary agreements.

Two recent cases illustrate this. The antitrust division challenged the operation of two Physician Hospital Organizations (PHOs), one in Danbury Connecticut and the other in St. Joseph, Missouri, under the federal antitrust laws. In Danbury the defendants were the Danbury Hospital, which is a 450-bed acute care facility and the only hospital in the area, the Danbury area IPA, which included over 98 percent of the hospital's medical staff, and the Health Care Partners, which was a PHO that was formed by the hospital and the IPA. The complaint alleged that the hospital together with the IPA and the PHO conspired to unreasonably restrain competition by directing managed care payers to the PHO as the designated joint bargaining agent for the hospital and the IPA, negotiating fees and other competitive terms on behalf of the hospital and competing doctors through the PHO, and taking steps to require that each member of the hospital's medical staff perform at least 30 percent of the doctor's outpatient procedures at the hospital's facility as opposed to a local competing outpatient surgery center that was independent of the hospital. The anticompetitive effects of the acts, according to the complaint by the Department of Justice, were that: they unreasonably restrained the price and other forms of competition among physicians in the Danbury area, leading to increased prices; they deprived the managed care payers of the ability to control and decrease unnecessary hospital and physician utilization; they hindered the development of innovative health care financing and delivery systems; and, they deprived employers and individual consumers of the benefits of free and open competition in the purchase of health care services. There were similar allegations made in the St. Joseph, Missouri case.

The defendant parties in both cases entered into consent decrees that were intended to prevent these organizations from engaging in any activity that unreasonably restrained competition among the physicians, outpatient service providers, or managed care plans. The consent decrees introduced a new term called "Qualified Managed Care Plan" (QMCP). A QMCP is defined as a network of physicians who share substantial risk and contain less than 30 percent of the physicians in a relevant physician market if the plan is non-exclusive or less than 20 percent if the plan is exclusive. The definition parallels the antitrust safety zone for physician joint ventures established by the FTC and the Department of Justice in the enforcement statements referred to before. The consent decrees clarify how the government defines a relevant physician market and also introduce the concept of subcontracting physicians, distinguishing physicians who have ownership

interest in the managed care organization from those who do not.

There is a lot more one can say about the antitrust issues . . . [b]ut I want to move quickly to the Medicare/Medicaid antikickback statutes. These are statutes in the Social Security Act that prohibit providers of covered services or goods from knowingly and willfully (and those are two key terms), soliciting, receiving or providing any remuneration, directly or indirectly, in cash or in kind, in exchange for either referring individuals or furnishing or arranging a good or service for which payment may be made under the programs. Some health care attorneys have said, "If it makes good business sense, it's probably illegal." The Federal Fraud and Abuse Laws also prohibit providers from knowingly or willfully making or causing to be made any false statements or representations of material fact on a program claim and prohibit incentive payments that would cause a reduction in medical services. The latter statute prohibits organizations from operating a physician incentive plan in which any compensation arrangement between the organization and the physician either directly or indirectly has the effect of reducing or eliminating services provided to individuals enrolled with the organization, unless there is no specific payment made directly or indirectly under the plan to a physician as an inducement to reduce or limit medically necessary services provided with respect to individuals enrolled with the organization. I think you can see the relevance of that to the managed care organizations that would be providing services to the Medicare population. The antikickback statutes that are applicable to Medicare/Medicaid do not apply to nongovernmental plans.

It is important to note that the anti-kickback statute is a criminal statute. Violations are felonies and are punishable by imprisonment for up to five years, fines up to $25,000 per violation, or both. People have been known to go to jail for violations. Additionally, violations can lead to exclusion from Medicare or Medicaid programs. This can in effect put someone out of business. The violations do not lead to civil money penalties or private causes of action.

In applying the anti-kickback statute, definitions are very important. One of the important definitions pertains to "remuneration." Remuneration is very broadly interpreted to include anything of value such as gifts, discounts, furnishings, supplies, equipment, payments of cash, or waivers. Another important definition is that of "inducement." There is a line of cases . . . in which different appellate courts gave rather expansive definitions of what constitutes a violation of the statute. Basically a violation exists when *one* purpose, not necessarily *the primary* purpose, of a payment is to induce referrals. The operative word there is *induce*.

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There are other issues that pertain to the anti-kickback regulation with respect to whether the returns on investment to physician-investors are excessive and whether the physician-investors are precluded from using other facilities or services. An additional issue related to the criminal nature of the anti-kickback statutes. The Office of the Inspector General of the Department of Health and Human Services (DHHS) had no authority to prosecute under it. Rather, all prosecutions had to be done by the Justice Department. Since DOJ had a heavy caseload in other areas, relatively few violations were prosecuted. Consequently, Congress provided the Office of the Inspector General of DHHS the authority to prosecute these violations. This authority was accompanied by a requirement that the Office of Inspector General identify what are termed "safe harbors." Thus far about 13 safe harbors have been identified. The purpose of the safe harbors was to identify arrangements that will not be subject to prosecution under the anti-kickback regulation. They are very narrowly drawn and generally provide very little protection. But a number of them are relevant to managed care organizations. ****

In the last minute I want to make reference to the anti-referral statutes, Stark I and Stark II. They were enacted initially as part of the Omnibus Budget Reconciliation Act of 1989 and focused solely on clinical laboratory services. They were then expanded in Stark II to nine additional designated health services. **** Suffice it to say the anti-referral legislation was intended to curb abuses that have already been discussed today, where physicians were reportedly reaping windfall profits by referring patients to facilities that they owned and were driving up the costs with unnecessary services.

When one goes from a traditional fee-for-service into a risk contracting mode, particularly if one gets into capitated contracting, one has undertaken a 180-degree paradigm shift. Clearly, the incentive to generate increased costs from self-referral totally disappears for reasons that were discussed in the last panel. Indeed the incentive and concern in a capitated payment system is that there will be underutilization rather the overutilization of services. There are a number of specific aspects of Stark II that arguably are related to the managed care organizations and their operations under Medicare HMOs and to related health plans. I would venture to say that because of the nature of the incentives this is not going to be a major concern. Instead I think the more important concerns relate to the antitrust issues. Thank you.

Managed Care Perspective:

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**** Let me review what is really going on with this term, PSN. The initials stand for Provider Sponsored or Physician Sponsored Network, depending upon whether you like the term provider or the term physician. All it really is, is an integrated care system that is taking capitation. The most common example is the physician/hospital organization. . . . Now what happens under capitation is that the PHO or the PSN is taking a lump sum, and it is assuming a legal obligation to provide care. The obligation is there even if the money is not sufficient to cover all the costs that the organization may be incurring. What the transaction is really about, if I can put on a lawyer hat

for a moment, is a transfer of risk. Now traditionally the transfer of risk is a transaction that not only has been regulated, but very, very heavily regulated by both the state and federal government. Why is that? For the simple reason that if the insurer (the insurer in the traditional sense) . . . runs out of money, they go belly up and there is no one left to provide the care that is been paid for. The legal term for that is "the business of insurance." The reason this is such a big issue is that we spend a lot of time talking about health care, and delivery systems and coordinated care, but the transfer of risk is an insurance concept, not a health care concept. The reason we have pages and books on statutes and regulation governing insurance is to protect consumers when a plan becomes insolvent. . . . The regulation that exists for these things right now falls into five areas.

The first is solvency, which you've heard about. The second is character and competence. The third is grievance procedures. The fourth is quality, and the fifth has to do with access. **** Why are there a number of organizations that have been pushing to get these things authorized? The reason is that basically the medical delivery side has recognized that if they want to participate, they themselves need to form some networks.. . .

**** [F]rom the perspective of managed care organizations, we for the most part support the notion that PSNs should be allowed to operate; should they be formed, we welcome competition. The issue is, though, should they be allowed to function essentially deregulated when everything else in the system is regulated? I want to come back to the issue of solvency to tell you why we think that is such an important issue. We have heard a lot today about the potential for underutilization that exists with managed care. Well, the potential for underutilization does not have as much to do with managed care as it does with capitation. Any system that is taking capitation in theory has some sort of potential for under-utilization and it really does not matter if you're a provider-based system or some other type of system like an HMO or an insurer managed care system. HMOs and insurers have to meet some solvency requirements, and what does that mean? It means they have to have "reserves," and reserves are nothing more than a savings account against basically a rainy day. If you have excessive costs that you haven't prepared for, O.K., there's some money in the bank so you can keep paying everybody and stay afloat. If you're a provider-based system and you do not have reserves and you run out of money there are two things that can happen. One is you can go bankrupt, which is hardly good for anybody, especially consumers; the second thing is you can tell all your providers that you are still going to provide care but we will not pay you for it, it is now free and at that point providers do not become real happy, and they start to look for ways in which they can provide less care or not do all the care that should be given. So if anything, without reserve requirements, without solvency protection, there is a very great danger to consumers. It is very important from our view that they have solvency protection.

Let me talk about one other important issue why solvency is very important for provider based systems and that is because, again without being critical, doctors do not always make the best businessmen. **** Dr. Kang mentioned it this morning again where it was the provider-based systems that went belly up sometime ago. There is a particular risk involved in a provider-based system and that is that the providers are wearing two hats. On one hand they are providers of services; . . . on the other hand, they are the owners. . . . Provider-based systems have different challenges from HMOs that are basically contracting with networks to provide the delivery of care. In that relationship the HMO knows what its job is. Its job is to work the business end: that means it must sell the product, take the premiums and do the marketing, watch the quality standards, provide the information, manage the delivery of services, and look out for consumer service. In the delivery system the HMO has a different job. It is supposed to provide the care. When you have a provider-based system, suddenly it gets very tangled because anytime they are dealing with things, do they have their owner hat on or do they have their provider hat on? That said, it is not that it cannot work because . . . we have a number of very good examples of physician-hospital organizations or other provider-based systems that are quite successful. But if anything the challenges are greater, not less, so if anything they need more regulation not less regulation. What Congress is doing . . . is saying we are going to give you no regulation or very little regulation, while we are going to regulate everybody else to the hilt. Congress also is saying, by the way, we do not want the states to regulate either. What that does is create all sorts of very weird incentives in the competitive marketplace, it is not good for consumers because they have less protection when, if anything, they need more protection. It is not good for government because government does need to have some standards. . . . Frankly, in some ways it is not good for providers because they are put at times in difficult situations. The thing that the provider-based systems are going to end up wanting, I predict, is they are going to want the regulation, because the regulation is going to end up being sort of a quality assurance measure that says yes, we are regulated and we are meeting the same standards as everybody else.

Endnotes

1. *See* U.S. General Accounting Office *Medicare Spending: Modern Management Strategies Needed to Cut Billions in Unnecessary Payments*, September 1995 (GAO/HEHS-95-210).
2. 115 S. Ct. 1671 (1995).
3. *CIGNA Health Plan of Louisiana v. State of Louisiana*, 883 F. Supp. 94 (M.D. La. 1995).
4. *Stuart Circle Hospital v. Aetna Life Ins. Co*., 995 F.2d 500 (4th Cir.), *cert. denied*, 114 S. Ct. 579 (1993).
5. *Pacificare of Oklahoma v. Burrage*, 59 F.3d 151 (10th Cir. 1995).

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Physician-Assisted Suicide: Current Legal Developments*

by Dale L. Moore**

Over the last several years, the topic of physician-assisted suicide has generated a great deal of writing in the popular as well as the scholarly literature. Two remarkable federal appellate court decisions issued earlier this year, however, have sparked even more fervent interest in the issue. The history leading to these decisions, as well as the decisions' implications, are the subjects of this article.

First, it is important to define the practice with which the term "physician-assisted suicide" has come to be associated: a physician's providing medication or other interventions — but usually medication — to a patient, with the understanding that the patient intends to use that medication to end his or her own life. Medications such as barbiturates are examples of the sort that might be used. With that in mind, consider the history of this practice, the legislation and litigation that have developed surrounding it, and some of the potential future developments in the area.

The history: how did this come to be such a high-profile issue? Physician-assisted suicide received significant public attention in 1988, when the *Journal of the American Medical Association* published a very brief essay, written by a resident physician.[1] During a night on call, this physician administered a large dose of morphine to a 20-year-old woman who was dying of ovarian cancer. The essay, "It's Over, Debbie," described the resident's brief encounter with the patient, her somewhat enigmatic statement ("Let's get this over with") that led the resident to believe she was ready for her life and her suffering to end, and the resident's administering 20 milligrams of morphine to her.

Several points should be emphasized about this case. First, the dosage of morphine was on the high side but still could have been enough simply to supply pain relief for some patients. On the other hand, the strong implication of the essay is that the resident meant to supply more than pain relief. The poignant description of the patient's condition makes clear that she was suffering greatly and *in extremis*. Second, the resident apparently did not know the patient at all, indeed had never met her before being summoned by a nurse to provide the patient with some relief. Third, this incident occurred in the middle of the night, when fewer caregivers are available and when things might look bleaker to a patient in this young woman's circumstances. But if this resident really did administer the morphine with the intent to cause the patient's death, then in fact the resident was engaging in the practice of "euthanasia," as that term has come to be used today, rather than physician-assisted suicide. The reason is that most people using the term "physician-assisted suicide" intend to refer to situations in which the *patient* is the one who takes the actual final step of administering the drug. The principal question in the "It's Over, Debbie" case, however, dealt not with the label to be given to the physician's conduct but rather with "voluntariness" — that is, whether a lethal dose of medication was really what the patient wanted.

The publication of this essay sparked a great deal of discussion and debate. Ultimately, as has been the case in many of the discussions about Dr. Kevorkian, procedural criticisms concerning the resident's conduct came to dominate the discussion. It seemed that less attention was devoted to the purely substantive issue of the scope of a patient's right to physician assistance with suicide.

In 1990, two years after "It's Over, Debbie" was published, Dr. Kevorkian began his novel work — or at least began to make it known to the public. Since 1990 he has admitted helping over 30 people to die. He has been acquitted by several juries thus far.[2] Certainly Dr. Kevorkian has been much criticized by the medical community and others on procedural grounds, including the following: his medical specialty is pathology, and generally pathologists seldom deal directly with living patients; he has no underlying relationship with his "patients" at all, they are people who seek him out solely for the purpose of obtaining assistance with suicide; his evaluation of their mental capacity seems open to question, at least in some of the cases; it is not clear whether some of his patients have relinquished hope without knowing all of the possible alternatives that might be available to relieve their suffering without causing death; and finally, the deaths he offers do not seem very dignified, occurring as they occasionally have in the back of a van and perhaps without the attendance of loved ones.

But Dr. Kevorkian has been acquitted by several different juries. In his own defense in these cases he has described his intention as an intention to end suffering. The unfortunate consequences of his actions taken to end suffering are that the patients have died, but his primary intention, as he characterizes it, is to end their suffering. The juries must be believing him.

After Dr. Kevorkian started to publicize his work, he received a great deal of attention in the press. Much public discussion took place and, as noted earlier, much of the criticism was on procedural grounds. Then, in March of 1991, Dr. Timothy Quill published his remarkable and very moving essay in the *New England Journal of Medicine*.[3] It tells the story of a patient to whom Dr. Quill referred as Diane, a woman in her forties who had been diagnosed as suffering from acute leukemia. After learning her diagnosis and her treatment options, Diane decided to reject chemotherapy and any other aggressive treatment. Dr. Quill described his discussions with Diane about treatment and other matters. Ultimately she came to the view that she wanted to have control over her own dying process. She sought Dr. Quill's help.

Although the essay is not very long, it gives some detail about the procedural care with which Dr. Quill approached this

case. Diane was evaluated by a psychologist whom she had seen in earlier years. She was fully aware of her options, including the availability of hospice care. She was not depressed, and she used her remaining time to be with family and other loved ones. Dr. Quill did provide her with a prescription for barbiturates, knowing that she might use them at some point to control the timing of her own death. Apparently she felt very strongly that she did not wish to spend her remaining time in a clouded, drugged state, being so sedated by narcotics and other medications that she would lose control. Eventually she apparently did take the barbiturates, all alone. She asked her husband and her son to leave her because she did not want them to be implicated in any way in her death. Dr. Quill signed her death certificate stating as her cause of death "acute leukemia." He did this, knowing that most likely she had taken the barbiturates, because he did not wish to trigger an investigation into her death.

Dr. Quill then published his essay in the *New England Journal of Medicine*, identifying the patient only as "Diane." Initially, some people thought that this was not a real case but rather a hypothetical or composite account that Dr. Quill had written to provoke debate about the topic. No doubt it was true that Dr. Quill wanted to provoke debate, but it was soon revealed that the account was by no means hypothetical. An anonymous tip of some sort led to the discovery of Diane's body in the Monroe Community College nursing lab, where it was scheduled to be used as a cadaver for teaching student nurses. An autopsy revealed that Diane had indeed died of an overdose of barbiturates. At that point the district attorney initiated a grand jury proceeding. Dr. Quill testified before the grand jury, without immunity. He was not indicted.

Dr. Quill also underwent scrutiny by the Board for Professional Medical Conduct ("BPMC"), the state agency charged with the responsibility for investigating complaints against physicians and for recommending the appropriate penalties (if any), such as loss of licensure, to which they should be subjected. The BPMC concluded that under these circumstances Dr. Quill had not violated the ethical and legal standards to which physicians are held.

Dr. Quill took a terrific risk in publicly "confessing" to his conduct. My own view is that he acted very courageously. No matter our individual views concerning physician-assisted suicide, we all owe Dr. Quill our gratitude. Because his procedures in this case were above reproach, he forced us to confront directly the substantive issue: that is, should a patient ever be able to obtain a physician's assistance with suicide? Dr. Quill took away the possibility of our avoiding this issue by focusing on procedural matters. He took all of the cautionary steps that could have been taken: making sure that Diane was fully informed of all alternatives, making sure that she was evaluated by a mental health professional to be certain that her judgment was not impaired by depression, being certain that she was not ambivalent by having numerous discussions with her over time. In all respects his behavior was so different from that of Dr. Kevorkian that it became essential to take him seriously.

And, in fact, shortly after Dr. Quill underwent the grand jury's and the BPMC's scrutiny, the New York State Task Force on Life and the Law took up the issue of physician-assisted suicide. The Task Force's report, titled *When Death is Sought*, is quite thorough, well researched and well written.[4] The report's conclusion is that there should be no change in the law, in other words that physician-assisted suicide should not be expressly "decriminalized." Whether one agrees or disagrees with that conclusion, the report is certainly worth reading and is in some respects quite persuasive.

It is important to keep in mind throughout all this discussion that we know that other physicians have helped their patients to die. No one knows for sure how often this occurs because the behavior is generally secretive, with both physicians and families exposing themselves to some risks by their conduct. Dr. Quill forced us to look at it openly.

In November 1994 the citizens of Oregon enacted by referendum the Death with Dignity Act.[5] That statute allows competent, terminally ill adults to receive physician assistance with suicide without criminal or other penalties for the physician or any other health-care provider involved in the case.[6] Quite a few procedural protections are built into the Oregon statute. The patient must be at least 18 years old and must be terminally ill, which is defined as having a prognosis of death within six months. The patient must voluntarily make an oral request to a physician. That request triggers a 15-day waiting period during which the attending physician evaluates the patient's diagnosis, prognosis, and decision-making capacity. The physician is obligated to inform the patient fully about all other options, in line with the view that physician-assisted suicide should be a last-resort, not a first-resort, alternative. The attending physician also must consult another physician, who then engages in an evaluation of the same diagnostic, prognostic, and decisional-capacity criteria. The two physicians must concur that the patient meets all eligibility criteria (age, terminal illness, etc.). After these two evaluations, and after the expiration of the 15-day waiting period, the patient must sign a written requested that is witnessed by two other people. Finally, the patient must make a second oral request for physician assistance with suicide.

Throughout this process, at different times, the attending physician is required to advise the patient that the request may be withdrawn at any time. Of course, this entire scheme contemplates the patient's ultimately administering the medication him- or herself in any event. No sooner than 15 days after the first oral request and 48 hours after the written request may the patient receive a prescription for medication to end his or her own life.[7]

Aside from the Dr. Kevorkian litigation, almost all of which has occurred in Michigan's criminal courts, there have been two very recent decisions by federal courts of appeal on the issue of physician-assisted suicide. The decision in the first of these cases was made public on March 6, in *Compassion in Dying v. State of Washington*.[8] The lawsuit was initiated by an organization called Compassion in Dying, which provides assistance of various kinds to the terminally ill. Other plaintiffs

were physicians who wished to provide assistance to their patients but feared the criminal penalties that might follow. Several terminally ill individuals were plaintiffs as well. They were seeking a declaration by the judge that the Washington statute that criminalizes the behavior of those who assist another with suicide violated their federal constitutional rights.

Initially, a federal district court judge declared the Washington statute unconstitutional. The state of Washington appealed, and a three-judge panel of the Ninth Circuit appellate court reversed the district judge's decision, saying that the statute is indeed constitutional. The plaintiffs sought rehearing *en banc*; their request was granted and the case was reargued before an 11-judge panel of the Ninth Circuit.[9] The 11 judges who reheard the case reached a conclusion different from that of the original three-judge panel. They decided, in fact, to affirm the original district court decision, saying: "We hold that insofar as the Washington statute prohibits physicians from prescribing life-ending medication for use by terminally ill, competent adults who wish to hasten their own deaths, it violates the Due Process Clause of the 14th Amendment."[10] The court dealt with only one small piece of the Washington statute, the verb "aids." The Washington statute says that someone who "aids" another person to commit suicide is guilty of a crime. It also says that someone who "causes" another person to commit suicide is guilty of a crime. The court saw no constitutional problem with the legislative conclusion that "causing" another person to commit suicide is criminal. But the case of a physician who "aids" another person to commit suicide is quite different.[11]

The Ninth Circuit made clear that the state of Washington is entitled to regulate the process by which physicians assist their patients with suicide. It is not, however, entitled to prohibit that behavior entirely. The court declined to find a violation of the federal constitution's Equal Protection clause, but the language of the opinion strongly suggests that the court could have been persuaded that such a violation also existed. Officially, however, the decision was based on the Due Process Clause: "We hold that a liberty interest exists in the choice of how and when one dies, and that the provision of the Washington statute banning assisted suicide, as applied to competent, terminally ill adults who wish to hasten their deaths by obtaining medication prescribed by their doctors, violates the Due Process Clause."[12]

Subsequent to the 11-judge panel decision, an attempt was made to obtain another rehearing, this time including all 23 of the Ninth Circuit's judges. That request was denied.[13] The United States Supreme Court has issued an order staying the effectiveness of the Ninth Circuit ruling; on October 1, the Supreme Court granted Washington's petition for *certiorari*.[14]

The Second Circuit case is *Quill v. Vacco*.[15] It was decided about a month after *Compassion in Dying*, in early April of this year. The Second Circuit relied on a different rationale in coming to its conclusion that the New York statutory ban on physician-assisted suicide is also unconstitutional. This court, in an opinion written by Judge Miner, found a violation of the federal Equal Protection clause. The court said that to the extent that the New York statutes at issue "prohibit a physician from prescribing medications to be self-administered by a mentally competent, terminally ill person in the final stages of his terminal illness, they are not rationally related to any legitimate state interest."[16]

The Second Circuit focused on exactly the same population of patients as the Ninth Circuit: competent, terminally ill adults who will self-administer medication prescribed by a physician. The Second Circuit also leaves open the opportunity for New York to regulate this practice.[17] On April 17, about two weeks after its initial decision, the Second Circuit stayed the effectiveness of its ruling to allow the state of New York to file a petition for *certiorari* with the United States Supreme Court. That petition was granted on October 1.

What are the potential future developments in this area? Since both courts left open the possibility of regulation, and since the Supreme Court may do so as well, it is appropriate to consider the forms of regulation that might be desirable as well as the sources from which they might come. One source certainly might be professional ethical standards that physicians themselves would develop and enforce in their private organizations. Physicians have developed such standards and guidelines in many areas of practice (e.g., the appropriateness of cardiac surgery or chemotherapy; the diagnostic procedures that should be undertaken in light of particular symptoms, etc.). Indeed, physicians have already demonstrated their interest in contributing in this manner.[18]

Even if private regulation takes place, however, it is doubtful that legislatures and the public will consider this sufficient. Even institutional standards probably will not be enough. So what form might the legislation take? Start with the assumption that the focus will be on the regulation of a willing physician's supplying of assistance to a patient.[19]

One issue is patient eligibility. Undoubtedly, access will be limited to certain populations. A number of eligibility criteria should be considered. One is age, and whether access to physician-assisted suicide should be an "adults-only" opportunity. Certainly the two court decisions spoke only to adults. But what about children, who can suffer every bit as much as adults during a terminal illness?

Another eligibility criterion would deal with health status. The Oregon statute requires that the patient have a "terminal illness." This is open to debate, however; some would argue that a larger group of people should be entitled to physician assistance with suicide. For example, what about someone with an incurable condition that is not presently terminal but causes great suffering (e.g., multiple sclerosis, amyotrophic lateral sclerosis [Lou Gehrig's disease])? One proposal would establish eligibility criteria that would encompass, in addition to the terminally ill, those who have incurable conditions that are causing great suffering but are not presently terminal.[20] Interestingly enough, a survey of physicians in the state of Washington, which inquired about requests for assisted suicide and euthanasia, revealed that quite a few came from people with very serious, debilitating neurological conditions that

would not have been terminal within six months.[21] These results suggest that a serious issue of expanded eligibility needs to be explored.

The court decisions limited the eligibility to individuals who are able to self-administer the needed medication. Whether this limitation creates a satisfactory classification, however, is open to question. For example, some people who could meet all other eligibility criteria may be too frail physically to administer medication to themselves. Certainly, the easiest case is the one on which the two appellate courts focused — the competent, terminally ill adult who can self-administer the medication, who takes the final act him- or herself. But it is not at all clear why a physically frail or physically incapacitated person who is competent and terminally ill should be denied the assistance of a physician under these circumstances.

Issues of physician eligibility need to be addressed, along with the nature of the physician-patient relationship that should exist. Certainly the Dr. Quill-Diane relationship would seem to be the ideal. It was a very supportive and strong relationship in which Dr. Quill knew the patient very well and could be very confident in his conclusions about her reasoning process, her judgment, and her lack of depression. But theirs is not the "norm" of physician-patient relationships, and limiting this opportunity in such a fashion would substantially limit access. That leads to the question whether assistance with suicide should be a specialty or a subspecialty in medicine. The idea sounds somewhat unappealing, perhaps because Dr. Kevorkian has proposed something of the sort. The fact is, however, that this is not a skill taught in medical school. Medical students do not learn, as part of their education, how to help people commit suicide. In fact, in a survey of Michigan physicians, some expressed great uncertainty about what medications or dosages to prescribe.[22]

Other procedures and formalities associated with physician-assisted suicide are very important as well. One procedural issue involves the means by which patient eligibility should be evaluated. That is, who makes the determination? How many opinions must be sought, for example, about the diagnosis, the prognosis, and the patient's decisional capacity? The northern territory of Australia, which has recently enacted physician-assisted suicide legislation, would require a psychiatrist or other mental health professional to evaluate the patient.[23] Requiring that kind of evaluation would certainly impede access for some people. Moreover, primary care physicians are very capable of assessing whether a patient has decisional capacity. In any event, however, legislation must address the issue of determining eligibility. Finally, what would happen if a consultant disagrees with a primary physician's conclusion? Will this possibility lead to forum shopping? Legislators should at least consider whether means can be created to discourage forum shopping, as well as *pro forma* determinations by consultants, in these cases.

The types and amounts of information provided to patients must be defined. It would seem clear that a patient must be fully informed of all the alternatives, as was the case with Dr. Quill's patient. Moreover, the request must be truly voluntary. The patient must be told that a change of mind is permitted. It should go without saying that coercion will not be tolerated.

There is something of an interesting flip side to this policy of non-coercion: that is, is it incumbent on a physician to inform a person who is terminally ill that he or she has the right to request physician assistance with suicide? In addition, should patients' bills of rights address this issue explicitly? Such bills of rights are posted in health-care facilities, and they advise patients of their right to refuse treatment. If they have the right to request assistance with suicide, perhaps they should be told about that as well. It is somewhat unpleasant to contemplate including such information in signs posted in hospitals, but the question should be raised and decided.

How many requests for assistance must a patient make? Must they be in writing, or may they be oral? How long a waiting period should there be between requests? All of these kinds of things are intended to ensure that the patient's request is an enduring one, something that the patient has carefully considered. This decision should not be the product of whimsy or ambivalence. So, most of the proposals create waiting periods, call for more than one request, and have generally tried to be confident that there is no vacillation.

What about revocability? Obviously these requests should be revocable, and certainly if the right is limited to those who can self-administer medication, revocation is achieved by not taking the medication. Nonetheless, it is important to tell people of their right to revoke and that their caregivers will not be disappointed in them if they change their minds.

Privacy and confidentiality are two important issues implicated here as well. Clearly, patients contemplating assisted suicide are entitled to have their privacy protected. Under the Oregon plan, one of the things physicians must do is encourage their patients to talk with their families. Making this a requirement, however, could prove very violative of a patient's right to privacy. Accordingly, although a patient can be encouraged to discuss this decision with others, including family members, such a discussion cannot be forced.

What about confidentiality? Implementation of the various procedural protections means that a number of people will be made aware of a particular patient's desire to have physician assistance with suicide. All of the caregivers and others involved with this practice must be required to treat this kind of information with the same respect that they treat other medical information by keeping it confidential.

Most proposals also deal with official governmental record keeping. They create a method for reporting to a state health department or some other agency charged with monitoring the frequency with which physician assisted-suicide is administered, what kinds of individuals are seeking it, and that sort of thing. One suggestion that has been made about this kind of reporting is that all information should be reported essentially anonymously, perhaps with one coded identifier that could, under exigent circumstances, link the information to the patient.

Protections for physicians and other health care providers are essential, including pharmacists filling prescriptions as well as nurses and others who might be present at the time the patient administers self-medication. Most of the proposals create immunity from liability for those who act in good faith according to the procedures set up in the statute. Such provisions may not really be necessary because the whole existence of the statutory scheme would mean that people who act according to the statute have done nothing wrong. But given the tradition of putting immunity provisions into virtually every piece of this sort of legislation, it is more than likely that health care providers would demand them here as well.

What about institutional conscience objections? These kinds of provisions have cropped up in other types of legislation. Certainly individuals are entitled to their conscience objections and may refuse to participate on moral, religious, or other grounds if that is their wish. For example, a physician can simply say no and refer the patient to someone else. I am more dubious, however about institutions' being entitled to prohibit certain practices within their walls. After all, having a conscience is a human attribute, not an institutional one. Nonetheless, I suspect institutional conscience provisions will be included. If so, the institutions must be required to provide notice of their policies to health care providers and patients.

In summary, it appears that the debate over physician-assisted suicide will be with us for some time, no matter what the Supreme Court does. Even if the Court reverses the decisions of the Second and Ninth Circuits, the questions will not go away. There are simply too many people who believe that what Doctor Quill did for his patient Diane was a compassionate and courageous act that should not be characterized as criminal.

Endnotes

1. *It's Over, Debbie*, 259 JAMA 272 (1988) (published in the "A Piece of My Mind" column).
2. *See, e.g.*, Jeff Stryker, *A Bedside Manner for Death and Dying*, NEW YORK TIMES, May 19, 1996, at E3.
3. Timothy E. Quill, *Death and Dignity: A Case of Individualized Decision Making*, 324 NEW ENG. J. MED. 691 (1991).
4. New York State Task Force on Life and the Law, *When Death is Sought* (1994).
5. Melinda A. Lee, Heidi D. Nelson, Virginia P. Tilden, Linda Ganzini, Terri A. Schmidt & Susan W. Tolle, *Legalizing Assisted Suicide — Views of Physicians in Oregon*, 334 NEW ENG. J. MED. 310 (1996).
6. Ann Alpers & Bernard Lo, *Physician-Assisted Suicide in Oregon: A Bold Experiment*, 274 JAMA 483 (1995).
7. Shortly after the Death with Dignity Act was enacted, efforts were undertaken to prevent its going into effect. A lawsuit filed in a federal district court resulted in a declaration of the Act's unconstitutionality. *Lee v. State of Oregon*, 891 F. Supp. 1429 (D. Or. 1995). In light of the decision in *Compassion in Dying v. State of Washington*, 79 F.3d 790 (9th Cir. 1996), which will be discussed below, the result in *Lee* is highly susceptible to reversal on appeal. Arguments were heard by a three-judge panel of the Ninth Circuit on July 9, 1996, during which one of the judges reportedly "made clear that the judges were interested in whether the lawsuit should have even gone forward" (presumably in light of the *Compassion in Dying* ruling). *See* (on the Internet): http://www.islandnet.com/deathnet/ergo_news12.html
8. 79 F.3d 790 (9th Cir.) (*en banc*), *rehearing denied*, 1996 WL 315922, *stay granted*, 1996 US LEXIS 3864, 64 USLW 3820 (June 10, 1996), *cert. granted,* 1996 WL 411596 (Oct. 1, 1996).
9. The Ninth Circuit is very large, having 23 full-time judges, and so generally an *en banc* rehearing involves a group larger than three but smaller than the total number of judges.
10. 79 F.3d at 793-94.
11. 79 F.3d at 797-98.
12. 79 F.3d at 838. This talk of a "liberty interest" is derived in part from language in the United States Supreme Court's decision in the case of Nancy Cruzan. In that case, which was decided in 1990, the Supreme Court identified a constitutional liberty interest as the source of the right of competent adults to decline medical treatment. *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990). The Ninth Circuit further developed this concept of a liberty interest in the choice of how and when one dies, ultimately finding, as noted, that the Washington statute banning assisted suicide in some cases would have to yield to this individual liberty interest. The Ninth Circuit's opinion is rich in its discussion of history and precedent.
13. 1996 WL 315922.
14. 1996 US LEXIS 3864, 64 USLW 3820 (June 10, 1996), *cert. granted*, 1996 WL 411596 (Oct. 1, 1996).
15. 80 F.3d 716 (2d Cir. 1996), *cert. granted*, 1996 US LEXIS 4536 (Oct. 1, 1996). Yet another challenge is underway, seeking a ruling that the Florida statute is unconstitutional. *McIver v. Krischer*, CL-96-1504-AF (15th Cir. Palm Beach County). *See* (on the Internet): http://www.islandnet.com/deathnet/McIver.html
16. 80 F.3d at 731.
17. Moreover, the Second Circuit's decision would not affect cases such as the prosecution of George Delury, about which many of you have probably read. He was the man who assisted his wife, who suffered from multiple sclerosis, to commit suicide last summer. The circumstances of this event seemed rather troubling in light of the details Mr. Delury recorded in a diary, describing among other things his frustration with his wife's illness and the burdens she presented for him. *See, e.g.*, Garry Pierre-Pierre, *Man Sentenced to Six Months in Wife's Suicide*, NEW YORK TIMES, May 18, 1996, § 1 at 22, col. 1; Herbert Hendin, *Dying of Resentment*, NEW YORK TIMES, March 21, 1996, A25, col. 1.
18. *See, e.g.*, Timothy E. Quill, Christine Cassel & Diane Meier, *Care of the Hopelessly Ill: Proposed Clinical Criteria for Physician-Assisted Suicide*, 327 NEW ENG. J. MED. 1380 (1996).
19. That is, we are not talking about giving people a right to *demand* that a physician assist them in this manner. Rather, the focus is on a right to receive the assistance of a willing physician. It is doubtful that anyone is ready to talk about forcing physicians to participate in this process.
20. Charles H. Baron, Clyde Bergstresser, Dan W. Brock, Garrick F. Cole, Nancy S. Dorfman, Judith A. Johnson, Lowell E. Schnipper, James Vorenberg & Sidney H. Wanzer, *A Model State Act to Authorize and Regulate Physician-Assisted Suicide*, 33 HARV. J. LEGIS. 1 (1996).
21. Anthony L. Back, Jeffrey I. Wallace, Helene E. Starks & Robert A. Pearlman, *Physician-Assisted Suicide and Euthanasia in Washington State: Patient Requests and Physician Responses*, 275 JAMA 919 (1996).
22. Jerald G. Bachman, Kirsten H. Alcser, David J. Doukas, Richard L. Lichtenstein, Amy D. Corning & Howard Brody, *Attitudes of Michigan Physicians and the Public Toward Legalizing Physician-Assisted Suicide and Voluntary Euthanasia*, 334 NEW ENG. J. MED 202 (1996).
23. Rights of the Terminally Ill Act 1995, Northern Territory of Australia.

** This article is adapted from remarks made on June 4, 1996, at the Warren Anderson Legislative Breakfast Seminar Series sponsored by the Government Law Center of Albany Law School. For a copy of the entire monograph for the 1996 Breakfast Seminar Series, call the Government Law Center at 518-445-2329 (fax: 518-445-2302).*

** **Associate Dean and Professor of Law, Albany Law School.**

From the Committee Chairs: Missions and Accomplishments

Legislation

The mission of the Legislation Committee is to review pending legislation, regulations, and policies which may or do relate to and impact the delivery, administration and regulation of health care services and the persons who provide such services and to submit to governmental and other appropriate bodies such comments and proposals as the Committee deems appropriate.

This year, the Legislation Committee actively monitored pending legislation, including post-NYPHRM and managed care reform legislation and established contacts with a number of state and legislative officials, including Hank Greenberg, General Counsel DOH; Glen Lefebvre, DOH's Office of Government Affairs; and Senator Kemp Hannon's office. The Committee prepared and/or was involved with several legislative reports, including S.6774 (Post-NYPHRM bill) and S.6422 (Anatomical Gifts) and circulated a draft report on Senate Bill 7553 concerning HMOs and managed care organizations. Phil Rosenberg has been appointed to act as liaison with the Publications Committee.

We plan to continue to monitor legislation of interest and to submit legislative reports on bills of particulars importance. The Committee also plans to maintain liaisons with other committees and the Elder Law Section regarding legislative matters. Committee Chair is David Daniels (914) 855-5900.

Biotechnology and the Law

The Committee on Biotechnology and the Law was formed in 1987 to examine the impact of advances on biotechnology on existing laws and constitutional rights. Prior to 1995, the Committee focused primarily on legal issues raised by new reproductive technologies and practices, including surrogacy, in *vitro fertilization* and gamete donation, and issued several influential reports on those topics.

In 1995, the Committee began an intensive consideration of legal and policy issues raised by advance in human genetics, while continuing to comment on reproductive technology issues. At the NYSBA's Annual Meeting in January, 1996, the Committee sponsored a conference on legal issues raised by the topic of genetic advances.

After joining the new Health Law Section in January 1996, the Committee began to review and comment on a series of pending state legislative proposals on genetic information. Those bills addressed issues of discrimination, confidentiality, consent, access to health care and insurance. We were responsible for securing several amendments to the legislation on consent and confidentiality which was just signed by the Governor. The Committee's comments and interaction with Legislative staff have had a definite influence on policy in this area we intend to continue this work in 1996-97. Moreover, the Committee expects to address a broader range of legal and policy issues in genetics, and to undertake new projects as well — such as a study of issues relating to the patenting of new medical procedures. Committee Chair is Robert Swidler (518) 434-2163.

Ethical Issues in the Provision of Health Care

The Committee on Ethical Issues in the Provision of Health Care will examine the ethical and legal issues posed by the medical advances and social concerns relating to health care delivery. It will inform and contribute to the development of recommendations by the Health Law Section and the Bar Association on state law and health care policy. In addition, the Committee will seek to foster dialogue and education with the Association, the legal profession and the broader public about the questions presented by health care delivery. We will welcome opportunities to work with other committees within the Health Law Section and with organizations outside the Bar Association concerned with addressing some of the critical health policy issues posed both by medical advances and the fundamental changes now underway in the delivery of health care.

The Committee has identified several issues that it will explore in the coming year as potential topics for Committee activity. First, it will continue its examination of state legislative initiatives related to genetic testing and screening. We began our work on this issue by commenting on legislation enacted in New York in June 1996 to require informed consent to genetic testing and to protect the confidentiality of genetic information. The Committee will also analyze legislation passed in New York in July 1996 to protect patient and provider rights under managed care, seeking to determine if further legislative or regulatory action would be important. We have discussed other potential issues for Committee consideration, including: the Second and Ninth Circuit court rulings holding that state laws barring assisted suicide are unconstitutional; the issue of the confidentiality of medical information, particularly mental health information; and the increasing reliance on telemedicine and related questions of liability. Committee Chair is Tracy Miller (212) 241-6868.

Payment Issues

Few would disagree that those who provide needed health care services deserve reasonable and adequate compensation. Increasingly, the reimbursement that providers such as doctors, hospitals and nursing homes receive for their services is out of their control — it is dictated by health insurers or government payors such as Medicare and Medicaid. These providers increasingly need skilled legal counsel to assure that insurers and government rate setters recognize economic reality and apply rationally in their reimbursement decisions.

The Committee on Payment Issues of the Health Law Section intends to actively participate in the arena of health care provider reimbursement through gathering and disseminating information, analysis and opinions regarding payment issues to interested attorneys, health care providers, payors, government officials and the public. In so doing, our Committee will seek to promote better understanding of the legal, social, economic, medical and public policy issues that pervade health care reimbursement. Thomas G. Smith, of the Rochester-based firm of Harter, Secrest & Emery, chairs the Committee on Payment Issues and invites anyone interested in the Committee to contact him at (716) 232-6500 or fax (716) 232-2152.

Legal Education

The primary objective of the Legal Education Committee is to provide our members with meaningful educational programs which timely address critical issues affecting the health law practitioner.

The Legal Education Committee recently completed its CLE program on Managed Care, which was attended by over 400 participants throughout the state. This inaugural program, which was chaired by John Franzen and Bob Abrams, consisted of a diverse faculty of respected experts from the public and private sectors.

Philip Rosenberg has coordinated our CLE program for the fall, "A Basic Primer on Health Law." This program was held in New York City, Rochester and Albany. It addressed a multitude of issues including, but not limited to: Fundamentals of Reimbursement; Tax-Exempt Issues; Fraud and Abuse; Antitrust Concerns; Licensure, Accreditation and Credentialing; Forming Managed Care Networks; Contracting with Managed Care Payors; Buying and Selling a Physician Practice; Defending a Medicare/Medicaid Audit; and Professional Disciplinary Actions.

The November 7, 1996, Health Law Section retreat has been planned and sponsored by our Committee. The purpose of this program is to update our general membership concerning Committee activities and to announce special Section projects. This retreat is aimed at providing all members an excellent opportunity to meet with Section leaders, have input regarding Section development and to volunteer to actively participate in activities of interest.

At the New York State Bar Association Annual Meeting, which is held in the last week of January, our Section will present a special program titled "An Insider's View to the Health Care Revolution in New York State." Special attention will be given to federal and state legislative changes in hospital reimbursement, hospital mergers, managed care, and health-care issues affecting senior citizens.

Also at the Association's Annual Meeting, Tracy Miller, Chair of our Committee on Ethical Issues in the Provision of Health Care will co-chair a special program on Assisted Suicide in cooperation with Walter Burke, Chair-Elect of the Elder Law Section.

In late spring of 1997, we plan to present an Update on Long-Term Care. In addition, we would like to present several other programs pursuant to member recommendations and involvement. Committee Chair is Robert Abrams (516) 328-2300.

Health Care Providers

This Committee is something of a successor to the former Health Law Committee. It will serve as a forum for educational presentations and discussion of issues of particular concern to hospitals, clinics, nursing homes, laboratories, physicians and physician groups, and so on. Its focus will be on the economics of and legal issues surrounding managed care and capitation and the impact of rate deregulation; mergers, acquisitions and corporate restructuring; regulatory and regulatory reform issues; the fraud and abuse, anti-kickback, and anti-referral laws; antitrust and tax issues; the effects of Medicare and Medicaid cuts and the possibility of Medicaid block grants to states; ERISA; and other issues relevant to the operation of health care providers in New York.

In conjunction with the Legislation Committee, the Committee on Health Care Providers will review and comment on proposed, pending, or needed legislation affecting health care providers. Committee Chair is Frank Serbaroli (212) 504-6001.

Managed Care Committee

The Committee is exploring the growing movement towards managed care. Included are regulatory issues, patient protection, the rights of health care providers, panel exclusion and questions of liability. The Committee worked with the CLE Committee to present "Managed Care: The New York Perspective," which was held May 31-June 20, 1996 in Albany, Rochester, Uniondale and New York City. That program covered the major issues faced by attorneys in creating or dealing with managed care organizations. Committee Chair is John Franzen (518) 473-7978.

Health Care Delivery Systems

The purpose of the Committee on Health Care Delivery Systems is primarily to evaluate and make recommendations regarding the legal and practical significance of existing and proposed laws and regulations that define, enable and limit the relationships of institutional health care providers to each other and their affiliated organizations and health care professionals. In this start-up year we have thus far tracked, but not formally commented upon, S.7954 and related legislation concerning integrated delivery systems. By the end of the year, the Committee expects to have in place a methodology for identifying, reviewing and commenting upon relevant legislative and regulatory proposals in a timely fashion as they emerge

and progress through the system. Proposals from Committee members for educational sessions or other activities are welcome. Committee Chair is Eric Stonehill (716) 232-4440.

Public Health

The Committee on Public Health is planning to examine a number of issues that impact upon the health of New York residents. Included are domestic violence, infant mortality and smoking as well as other topics. A Committee meeting will be held in the near future. Please attend and bring your thoughts for additional project areas. Committee Chair is Sal Russo (212) 788-3300.

Liaison with the Health Professions

This Committee plans to explore areas of interest common to attorneys and health care professionals. The Medical Society of the State of New York, New York State Psychological Association, New York State Nurses Association, Dental Society of the State of New York, New York State Association of Physician Assistants and New York State Chapter and National Association of Social Workers, have each appointed high level liaisons to our Committee. Committee Chair is Alan Gibofsky, M.D., J.D. (212) 606-1423.

Inhouse Counsel

The Inhouse Counsel Committee was formed to address the issues unique to the note of attorneys employed directly by hospitals, managed care organizations, health insurance companies and other health care entities. Members are encouraged to suggest topics that they would like to cover. Committee Chairs are Jim Horwitz (518) 761-5208 and Nadia Adler (718) 920-6736.

Membership Committee

In these times, when the problems of securing and providing and delivering health care to the public are so troublesome and challenging, the Membership Committee of the Health Law Section is charged with attracting to the ranks of the newly formed Section, attorneys who are interested in the health field, either as private practitioners, government lawyers or as representatives of consumers or the various related health industries. It is our hope and goal to see the Health Law Section constituted of such a wide array of talents as will enable it to make a substantial contribution to the study and solution of current health care problems. Committee Chair is Robert Corcoran (516) 367-3336.

REQUEST FOR ARTICLES

If you have written or have an idea for an article, please contact
Health Law Newsletter Editor

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e-mail dmoor@mail.als.edu

Articles should be submitted on a 3 1/2" floppy disk, preferably in WordPerfect 5.1 along with a printed original and biographical information.

SECTION COMMITTEES & CHAIRS

The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers (listed on the back page) or Committee Chairs for further information about these Committees.

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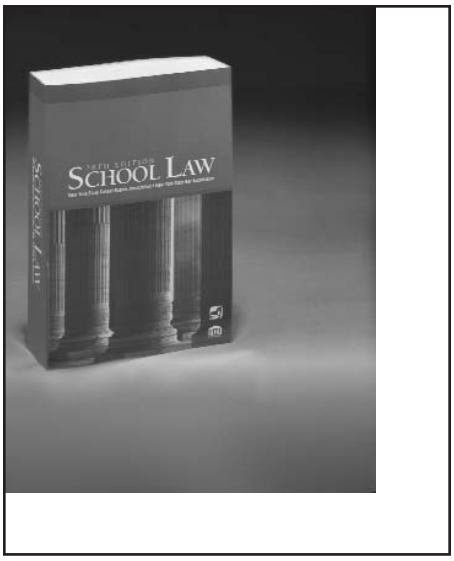

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Health Law Section

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Publication Policy: All articles should be submitted to me and must include a cover letter giving permission for publication in this *Newsletter* We will assume your submission is for the exclusive use of this *Newsletter* unless you advise to the contrary in your letter. Authors will be notified only if articles are rejected. Authors are encouraged to include a brief biography with their submissions.

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Dale L. Moore
Editor

HEALTH LAW Newsletter

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