11.2.3 Contracts to Deliver Health Care Services

Prioritizing profits over patients is incompatible with physicians' ethical obligations. No part of the health care system that supports or delivers patient care should place profits over such care. Physicians have a fundamental ethical obligation to put the welfare of patients ahead of other considerations, including personal financial interests. This obligation requires that before entering into contracts to deliver health care services, physicians consider carefully the proposed contract to assure themselves that its terms and conditions do not create untenable conflicts of interest or compromise their ability to fulfill their ethical and professional obligations to patients. Those physicians who enter into contracts with corporate entities, such as private equity firms, management service organizations, professional services corporations, insurance companies, or pharmaceutical benefit managers, who act within their capacity as a physician, even as administrators or intermediaries, also have a duty to uphold the ethical obligations of the medical profession.

Ongoing evolution in the health care system continues to bring changes to medicine, including changes in reimbursement mechanisms, models for health care delivery, restrictions on referral and use of services, clinical practice guidelines, and limitations on benefits packages. While these changes are intended to enhance quality, efficiency, and safety in health care, they can also put at risk physicians' ability to uphold professional ethical standards and can impede physicians' freedom to exercise independent professional judgment and tailor care to meet the needs of individual patients.

As physicians seek capital to support their practices or enter into various differently structured contracts to deliver health care services—with group practices, hospitals, health plans,

investment firms, or other entities—they should be mindful that while some arrangements have the potential to promote desired improvements in care, other arrangements have the potential to put patients' interests at risk and to interfere with physician autonomy.

When contracting with entities, or having a representative do so on their behalf, to provide health care services, physicians should:

(a) Carefully review the terms of proposed contracts, preferably with the advice of legal and ethics counsel, to assure themselves that the arrangement:

  (i) minimizes conflict of interest with respect to proposed reimbursement mechanisms, financial or performance incentives, restrictions on care, or other mechanisms intended to influence physicians' treatment recommendations or direct what care patients receive, in keeping with ethics guidance;

  (ii) does not compromise the physician's own financial well-being or ability to provide high-quality care through unrealistic expectations regarding utilization of services or terms that expose the physician to excessive financial risk;

  (iii) ensures the physician can appropriately exercise professional judgment;

  (iv) includes a mechanism to address grievances and supports advocacy on behalf of individual patients;

  (v) is transparent and permits disclosure to patients;

(vi) enables physicians to have significant influence on, or preferably outright control of, decisions that impact practice staffing;

(vii) prohibits the corporate practice of medicine.

(b) Negotiate modification or removal of any terms that unduly compromise physicians' ability to uphold ethical or professional standards.

When entering into contracts as employees, preferably with the advice of legal and ethics counsel, physicians should:

(c) Advocate for contract provisions to specifically address and uphold physician ethics and professionalism.

(d) Advocate that contract provisions affecting practice align with the professional and ethical obligations of physicians and negotiate to ensure that alignment.

(e) Advocate that contracts do not require the physician to practice beyond their professional capacity and provide contractual avenues for addressing concerns related to good practice, including burnout or related issues.

(f) Not enter into any contract that would require the physician to violate their professional ethical obligations.
When contracted by a corporate entity involved in the delivery of health care services, physicians should:

(g) Terminate any contract that requires the physician to violate their professional ethical obligations and report any known or suspected ethical violations through the appropriate oversight mechanisms

AMA Principles of Medical Ethics: I,II,III,V,VI,VIII,IX

Opinion 11.2.3 Contracts to Deliver Health Care Services reorganizes guidance from multiple sources as follows:

CEJA Report 5-A-25 Protecting Physicians Who Engage in Contracts to Deliver Health Care Services

CEJA Report 3-I-05 Physician pay-for-performance programs

CEJA Report 2-I-03 Professionalism and contractual relations

CEJA Report 7-A-02 Managed Care, *Amendment*

CEJA Report 5-A-02 Restrictions on Disclosure in Managed Care Contracts, *Amendment*

CEJA Report 4-A-97 Ethical implications of capitation

CEJA Report 1-A-96 Restrictions on disclosure in managed care contracts

CEJA Report 13-A-94 Ethical issues in managed care

REPORT 05 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (A-25)
"Protecting Physicians Who Engage in Contracts to Deliver Health Care Services"
(D-140.951)

EXECUTIVE SUMMARY

Policy D-140.951, "Establishing Ethical Principles for Physicians Involved in Private Equity Owned Practices," asks that the Council on Ethical and Judicial Affairs (CEJA) to "study and clarify the ethical challenges and considerations regarding physician professionalism raised by the advent and expansion of private equity ownership".

Increasing investments by private equity firms in health care raise ethical concerns regarding dual loyalties of physicians and competing interests between profits and patients. The ethical concerns raised by private equity firms' incursion into health care warrant extreme caution. To respond to these issues, CEJA recommends amending Opinion 11.2.3, "Contracts to Deliver Health Care Services" to more clearly encompass partnerships with private equity firms and the ethical dilemmas and obligations that they raise for both physicians seeking capital to support their private practice as well as physicians entering into employment contracts with private equity-owned health care entities.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 05-A-25

Subject: Protecting Physicians Who Engage in Contracts to Deliver Health Care Services

Presented by: Jeremy A. Lazarus, MD, Chair

Referred to: Reference Committee on Ethics and Bylaws

Policy D-140.951, "Establishing Ethical Principles for Physicians Involved in Private Equity Owned Practices," asks our American Medical Association (AMA) to "study and clarify the ethical challenges and considerations regarding physician professionalism raised by the advent and expansion of private equity ownership", the Council on Ethical and Judicial Affairs (CEJA) presented Report 02-A-23, Report 03-A-24, and Report 02-I-24, which offered recommendations on amending Opinion 11.2.3, "Contracts to Deliver Health Care Services." The last report was referred back to CEJA at the 2024 Interim Meeting, with testimony expressing a desire that a stronger stance be taken against private equity's (PE) involvement in health care, noting that the report placed too high of a bar on physicians contracting with private equity and needs stronger language to guide physicians working for private equity investors. CEJA acknowledges that private equity investment in health care raises pressing, complex issues, which will ultimately require multiple avenues to address, such as the related Council on Medical Service report (CMS 03-A-25) on private equity and the corporate practice of medicine as well as work currently being done by our AMA's Advocacy unit to promote physician-led care and reduce burnout. The present report has been revised in light of the valuable comments proffered at the last meeting, and offers specific ethics analysis and guidance for physicians impacted by private equity's involvement in medicine.

BACKGROUND

The past several decades have seen an increase in the corporatization, financialization, and commercialization of health care [1,2]. Since 2018, more physicians now work as employees of hospitals or health care systems rather than in private practice [3,4]. Our AMA reports that this trend is continuing: "[e]mployed physicians were 50.2 percent of all patient care physicians in 2020, up from 47.4 percent in 2018 and 41.8 percent in 2012. In contrast, self-employed physicians were 44 percent of all patient care physicians in 2020, down from 45.9 percent in 2018 and 53.2 percent in 2012" [4]. A major factor in these trends has been the incursion of private equity into health care. It is estimated that private equity capital investment between 2000 and 2018 grew from $5 billion to $100 billion [1]. Between 2016 and 2017 alone, the global value of private equity deals in health care increased 17 percent, with health care deals compromising 18 percent of all private equity deals in 2017 [5].

Private equity firms use capital from institutional investors to purchase private practices, typically utilizing a leveraged buy-out model that finances the majority of the purchase through loans for

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Reference Committee on Ethics and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

which the physician practice serves as security, with the goal of selling the investment within three to seven years and yielding a return of 20-30 percent [1,5,6]. However, private equity investment broadly encompasses many types of investors and strategies, including venture capital firms that primarily invest in early-stage companies for a minority ownership, growth equity firms that tend to partner with promising later-stage ventures, and traditional private equity firms that borrow money through a leveraged buyout to take a controlling stake of mature companies [7]. Private equity firms represent a unique business model within health care due to their primary focus, not on goods or services, but on quick returns on financial investment, emphasis on fulfilling promises to investors, and treatment of health care entities as not substantially different from non-health related investments.

When ownership shifts from physicians to private equity firms, the firms typically seek to invest resources to expand market share, increase revenue, and decrease costs to make the practice more profitable before selling it to a large health care system, insurance company, another private equity firm (as a secondary buyout), or the public via an initial public offering (IPO) [8]. To expand market share, private equity typically employs a "platform and add-on" or "roll-up" approach in which smaller add-ons are acquired after the initial purchase of a large, established practice, allowing private equity firms to gain market power in a specific health care segment or sub-segment [1,9]. These practices by private equity appear to be driving mergers and acquisitions within health care, significantly contributing to the consolidation of the health care industry that has dramatically increased over the past decade [9].

Proponents of private equity investments in health care claim that private equity provides access to capital infusions, which may facilitate practice innovation and aid in the adoption of new technological infrastructure [6,8]. Proponents also advocate that private equity can bring "valuable managerial expertise, reduce operational inefficiencies, leverage economies of scale, and increase healthcare access by synergistically aligning profit incentives with high quality care provision" [10].

Critics argue that private equity's focus on generating large, short-term profits likely establishes an emphasis on profitability over patient care, which creates dual loyalties for physicians working as employees at private equity-owned practices [5,6]. Critics further assert that prioritizing profits likely jeopardizes patient outcomes, overburdens health care companies with debt, leads to an over-emphasis on profitable services, limits access to care for certain patient populations (such as uninsured individuals or individuals with lower rates of reimbursement such as Medicaid or Medicare patients), and fundamentally limits physician control over the practice and clinical decision making [5,8,10].

While more empirical research is needed on the impacts of private equity investment in health care, there is a growing accumulation of evidence that private equity investment results in negative outcomes, including increases in costs, decreases in the quality of patient care, and decreases in patient satisfaction [10-13]. This is particularly worrisome as private equity firms are emerging to be major employers of physicians. Currently, it is estimated that 8 percent of all private hospitals in the U.S. and 22 percent of all proprietary for-profit hospitals are owned by private equity firms [14].

Relevant Laws

Fuse Brown and Hall write that despite the market consolidation that results from private equity acquisitions within health care, these acquisitions generally go unreported and unreviewed since they do not exceed the mandatory reporting threshold under the Hart-Scott-Rodino (HSR) Act and

that there are currently no legal guidelines for assessing the collective market effects of add-on acquisitions. However, they do note:

> Under Section 7 of the Clayton Act, federal antitrust authorities—the Federal Trade Commission (FTC) and the Department of Justice —can sue to block mergers and acquisitions where the effect of the transaction may be "substantially to lessen competition, or to tend to create a monopoly." To determine whether a transaction may threaten competition, antitrust agencies analyze whether the transaction will enhance the market power of the transacting parties in a given geographic and product market. […] Typically, the FTC oversees health care acquisitions (other than insurance).[1]

To protect patients from harmful billing practices, the federal government has passed the No Surprise Act, the False Claims Act, Anti-Kickback Statute, and Stark Law. Additionally, most states have similar laws, such as those barring fee-splitting and self-referral, and several states have passed laws regulating or restricting the use of gag clauses in physician contracts [1]. In 2024, the FTC also issued a final rule banning noncompete clauses in all employment contracts; while a district court issued an order stopping the FTC from enforcing the rule, the FTC has appealed that decision [15].

The federal Emergency Medical Treatment and Labor Act ensures that hospitals with an emergency department provide all patients access to emergency services regardless of their ability to pay. Similarly, federal law requires nonprofit hospitals, which account for 58 percent of community hospitals, provide some level of charity care as a condition for their tax-exempt status, which the Internal Revenue Service defines as "free or discounted health services provided to persons who meet the organization's eligibility criteria for financial assistance and are unable to pay for all or a portion of the services" [16].

While there is no federal law banning the corporate practice of medicine (CPOM), most states do have CPOM laws that prohibit corporations from owning or operating medical practices. However, these state laws typically include exceptions that allow corporate investors, such as private equity firms, to invest in health care entities through a physician management company or management services organization, and which also provide potential avenues for corporate investors to circumvent stringent limits on their operational authority.

Relevant AMA Policy Provisions

Council on Medical Service Report 11-A-19 reviewed the scope and impact of private equity and venture capital investment in health care, and its recommendations were adopted as Policy H-160.891, "Corporate Investors." This policy delineates 11 factors that physicians should consider before entering into partnership with corporate investors, including alignment of mission, vision, and goals; the degree to which corporate partners may require physicians to cede control over practice decision making; process for staff representation on the board of directors and medical leadership selection; and retaining medical authority in patient care and supervision of nonphysician practitioners.

Our AMA further developed and published materials to assist physicians contemplating partnering with private equity and venture capital firms:

- Venture Capital and Private Equity: How to Evaluate Contractual Agreements
- Model Checklist: Venture Capital and Private Equity Investments
- Snapshot: Venture Capital and Private Equity Investments

Policy H-310.901, "The Impact of Private Equity on Medical Training," encourages GME training institutions and programs to "demonstrate transparency on mergers and closures, especially as it relates to private equity acquisition" and asserts that our AMA will "[s]upport publicly funded independent research on the impact that private equity has on graduate medical education."

Policy H-385.926, "Physician Choice of Practice," states that "[o]ur AMA supports the freedom of physicians to choose their method of earning a living (fee-for-service, salary, capitation, etc.)." While this policy upholds physician autonomy and supports the freedom of physicians to choose where and how they practice, the right to choose a method of earning a living is not unbounded, as the policy also states that physicians should charge their patients fair fees and provide "adequate fee information prior to the provision of services" whenever possible.

Additionally, policy H-215.981, "Corporate Practice of Medicine," states, "[o]ur AMA opposes the corporate practice of medicine and supports the restriction of ownership and operational authority of physician medical practices to physicians or physician-owned groups." This policy recognizes the attendant risks that the corporate practice of medicine represents to both patients and the practice of medicine.

Relevant AMA *Code Provisions*

Opinion 10.1.1, "Ethical Obligations of Medical Directors," states that physicians in administrative positions must uphold their core professional obligations to patients. The opinion mandates that physicians in their role as medical directors should help develop guidelines and policies that are fair and equitable, and that they should always "[p]ut patient interests over personal interests (financial or other) created by the nonclinical role."

Opinion 11.2.1, "Professionalism in Health Care Systems," acknowledges that "[p]ayment models and financial incentives can create conflicts of interest among patients, health care organizations, and physicians" and offers recommendations for physicians within leadership positions regarding the ethical use of payment models that influence where and by whom care is delivered. Key elements include the need for transparency, fairness, a primary commitment to patient care, and avoiding overreliance on financial incentives that may undermine physician professionalism.

Opinion 11.2.2, "Conflicts of Interest in Patient Care," clearly states: "[t]he primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. […] When the economic interests of the hospital, health care organization, or other entity are in conflict with patient welfare, patient welfare takes priority."

Opinion 11.2.3, "Contracts to Deliver Health Care Services," stipulates that physicians' fundamental ethical obligation to patient welfare requires physicians to carefully consider any contract to deliver health care services they may enter into to ensure they do not create untenable conflicts of interest. The opinion states that physicians should negotiate or remove "any terms that unduly compromise physicians' ability to uphold ethical standards." However, it should be acknowledged that physicians have little leverage in changing entire payment structures or reimbursement mechanisms when negotiating their contracts with hospitals. Similarly, physicians in private practice often feel that they have little leverage in negotiating the sale of their practice; they simply receive an offer and are told they can take it or leave it.

Opinion 11.2.3.1, "Restrictive Covenants," states: "[c]ovenants-not-to-compete restrict competition, can disrupt patient care, and may limit access to care" and that physicians should not enter into covenants that "[u]nreasonably restrict the right of a physician to practice medicine for a

specified period of time or in a specified geographic area on termination of a contractual relationship". However, many hospitals and hospital systems today now routinely include noncompete clauses as part of their physician contracts. These clauses put physicians at risk of violation of professional obligations and their widespread use has the potential to undermine the integrity of the profession as a whole. While the FTC issued a rule in April 2024 banning most noncompete agreements, a Texas District Judge issued a preliminary injunction on July 3, 2024, halting the enforcement of the ban.

ETHICAL ANALYSIS

The increasing corporatization and financialization of health care have generated legitimate concerns over ethical dilemmas they raise regarding a focus on profits at the expense of patient care. Prioritizing profits over patients is incompatible with physicians' ethical obligations. In other words, because it is unethical for physicians to place profit motives above commitments to patient care and well-being, when private equity firms invest in health care, their business model is prima facie ethically problematic for physicians. Private equity's primary objective of fast profit-making in order to uphold their promises to investors is at odds with physicians' primary obligation of acting in the patient's best interest.

However, although private equity-owned health care entities are different in their ownership structure and oversight compared to other traditional health care investors, private equity-acquired health care entities may not be substantively different from other for-profit and non-profit health care entities in terms of their stated goals of both solvency and patient care. Zhu and Polsky argue that private equity is not inherently unethical and that there are likely good and bad actors as is the case in many sectors [6]. They add: "physicians should be aware that private equity's growth is emblematic of broader disruptions in the physician-practice ecosystem and is a symptom of medicine's transformation into a corporate enterprise" [6].

The corporatization of medicine comes with ethical and professional risks that are perhaps best exemplified by private equity but are not unique to private equity alone. One only needs to turn to the systemic failure of nonprofit hospitals to provide adequate charity care or how for-profit hospitals often reduce access to care (particularly for Medicaid recipients) to see examples of how the corporatization and financialization of medicine has increasingly come to treat health care as a mere commodity [17,18]. This is despite the fact that health care is inherently different from normal market goods because the demand for health care is substantially inelastic and nonfungible, and medical knowledge is a social good collectively produced by the work of generations of physicians, researchers, and patients. The real problem with private equity's involvement in health care is that it blatantly reveals that as a society, we have increasingly moved towards treating health care as a commodity when as a profession, we know this should not be the case.

While business ethics and medical ethics are not inherently antithetical, differences do clearly exist [19]. Many physicians are thus justly concerned about any removal of professional control that may accompany the increasing commercialization of the physician's role. Veatch points out that paradoxically, despite being open to the profit motive in the practice of medicine, the profession as a whole has shown strong resistance to the commercialization of medical practice. For Veatch, the crux of the issue is whether people perceive health care as a fundamental right or a commodity like any other, adding that the notion of health care as a right jeopardizes any profit motive in health care including traditional private practitioner fee-for-service models [19].

Pellegrino offers a similar analysis, arguing that health care is not a commodity but rather a human good that society has an obligation to provide in some measure to all citizens [20]. Pellegrino

argues that health care is substantively different from traditional market goods—it is not fungible, cannot be proprietary because medical knowledge is possible only due to collective achievements, is realized in part through the patient's own body, and requires an intensely personal relationship—and thus cannot be a commodity. Pellegrino warns that the commodification of health and medicine turns any interaction between the patient and physician into a commercial transaction subject to the laws and ethics of business rather than to medical and professional ethics. "In this view," Pellegrino writes, "inequities are unfortunate but not unjust […]. In this view of health care, physicians and patients become commodities too" [20].

As health care has become increasingly commodified, the ethical risks to patients and physicians are being realized as physicians find themselves increasingly working as employees and worrying about the impact commercial enterprises—such as private equity investments—may be having on patients.

Private equity represents the latest and most extreme form of health care commercialization that has escalated over the past few decades. This is the very reason why private equity firms became interested in health care in the first place—they recognized that health care as a market was already ripe for investment and future profitability. Private equity firms use the same investment models in health care that they do in other industries—invest in fragmented markets, acquire the most promising targets as a platform, expand through add-on acquisitions, and exit the market once a significant consolidation of market share can secure a sale, secondary buyout, or IPO [9]. Each individual acquisition is typically too small to require review by anti-trust regulators at the FTC; at the same time, however, this practice is driving the trend of mergers and acquisitions in the health care sector [9].

Fuse Brown and Hall explain, "[private equity] functions as a divining rod for finding market failures—where PE has penetrated, there is likely a profit motive ripe for exploitation" [1]. They continue that private equity investments pose three primary risks:

> First, PE investment spurs health care consolidation, which increases prices and potentially reduces quality and access. Second, the pressure from PE investors to increase revenue can lead to exploitation of billing loopholes, overutilization, upcoding, aggressive risk-coding, harming patients through unnecessary care, excessive bills, and increasing overall health spending. Third, physicians acquired by PE companies may be subject to onerous employment terms and lose autonomy over clinical decisions [1].

While the profit motive of private equity firms may drive them to take part in less than scrupulous practices, such as private equity's exploitation of out-of-network surprise billing, there is also potential for private equity to play a more positive role in transforming health care practices [1,21]. Powers et al write:

> Ultimately, private equity—a financing mechanism—is not inherently good or bad. Instead, it acts to amplify the response to extant financial incentives. Within a fee-for-service construct, this is intrinsically problematic. But value-based payment models can serve as an important guardrail, helping to ensure that financial return to private equity investors are appropriately aligned with system goals of access, quality, equity, and affordability [21].

Private equity firms could help accelerate changes in health care payment and delivery towards value-based models. With such models, where financial performance is tied to quality and value, private equity may be incentivized to invest in changes that support better health and lower costs [21].

While more research is needed on the impacts of private equity investments in health care and on de-investment, when private equity firms ultimately pull out of a health care sector, private equity firms' involvement in health care does not appear to be exceptional within the current corporate transformation of the profession. As Fuse Brown and Hall point out, "PE investment in health care is just the latest manifestation of the long trend of increasing commercialization of medicine. And so long as the U.S. treats health care as a market commodity, profit-seeking will persist" [1]. Any financing model of health care that ignores patient care or puts profits over patient care should be considered unethical by physicians and the public.

Concerns over private equity's incursion into health care are clearly warranted. However, the financial and investment landscape of health care continues to evolve, and while private equity may be the latest trend it will not be the last version that emerges within the health care marketplace. Health care spending in the US continues to rise each year, with health spending increasing by 4.1 percent in 2022 for a total of $4.5 trillion and accounting for roughly 17 percent of total GDP [22]. With so much money involved in health care, it is bound to draw in investors; the involvement of investors from outside of health care, who may treat it as merely a market commodity and do not share physicians' overriding commitment to patient care and well-being, should be concerning. Such involvement by outside investors is likely to further transform health care, driving consolidation, commercialization, and de-professionalization.

In a practical approach to the current financial health care landscape, Ikrum et al offer some realistic recommendations for partnering with private equity in health care:

> While PE involvement in health care delivery invokes inherent concerns, it has provided much-needed capital for many primary care practices to mitigate the effects of the pandemic and to potentially undertake care delivery innovations such as population health management under value-based payment models. To make partnerships with private investors work, providers need to select the right investors, establish strategies upfront to address misaligned objectives, and define a successful partnership by setting goals for and transparently reporting on indicators that reflect both financial and clinical performance. Safeguards and regulations on sales may also protect patients and providers [7].

While private equity's overriding profit motive may be unethical in many instances, the reality is that private equity is already a large player in health care and physicians urgently need guidance on how to interact with private equity firms and private equity-owned health care entities. Keeping within its purview, the *Code* should offer guidance to physicians and to the practice of medicine on how to best interact with private equity and other outside forces that increasingly impact health care today. To support physicians as private equity continues to increase its market share of health care entities, practical guidance is needed related to both the sale of physician-owned practices to private equity as well as to those seeking employment by private equity-owned health care entities to help physicians navigate today's evolving financial health care landscape. Guidance is also needed for physicians employed by corporate entities that interact with the health care profession, including by private equity firms, management service organizations (MSOs), professional services corporations (PCs), insurance companies, and pharmaceutical benefit managers (PBMs).

CONCLUSION

The ethical concerns raised by private equity investments in health care are not unique but instead represent ethical dilemmas that exist due to the very nature of treating health care as a commodity. As highlighted by policy H-215.981, "Corporate Practice of Medicine," it is not some corporate practices but all corporate practices of medicine that create the potential for ethical dilemmas and

so should be avoided. Any decision to pursue financial incentives over and above patient care is unethical, and physicians' concerns regarding private equity's focus on short-term profits at the expense of patients' and their own well-being are justly warranted. Due to such concerns, physicians should strongly consider whether they can sell their practice to private equity investors while also upholding their ethical and professional obligations to patients and to the profession as a whole. Such reflection is also warranted for any physician considering employment by a corporate entity, such as a private equity firm, MSO, PC, insurance company, or PBM.

It is therefore crucial that policy guidelines be developed to ensure that private equity-acquired hospitals, hospital systems, and physician practices function in an ethical manner that prioritizes patients and patient care over profits. Policies that require greater transparency and disclosure of data on private equity ownership, greater state regulatory control over private equity acquisitions, closing payment and billing loopholes, rules requiring an independent clinical director on the Board of private equity firms engaged in health care, and means for physicians to help set goals and measure outcomes to ensure the alignment of corporate and clinical values should be considered [7]. The growth of private equity investment within the health care marketplace is clearly concerning and is an urgent issue that needs greater regulatory oversight. Beyond established ethical and professional norms, new regulations must be developed to prevent private equity from negatively impacting patient care and the medical profession [6]. A new Senate Budget Committee Bipartisan Staff Report, released in January 2025, calls for greater oversight, transparency, and restrictions of private equity involvement in health care [23]. While the report acknowledges that "not every PE firm operates in an identical fashion, the evidence highlights systemic issues with PE in investment in health care," and goes on to conclude, "the findings of the investigation call into question the compatibility of private equity's profit-driven model with the essential role hospitals play in public health. The consequences of this ownership model—reduced services, compromised patient care, and even complete hospital closures—potentially pose a threat to the nation's health care infrastructure, particularly in underserved and rural areas" [23].

Because the private equity business model creates serious potential risks and conflicts of interest for the practice of medicine, it is essential for physicians considering entering into partnership with private equity firms to first reflect on their ethical and professional obligations. If they do decide to proceed, however, physicians have a duty to evaluate their contracts and require that the agreements are consistent with the norms of medical ethics. Likewise, physicians considering entering into a contractual relation as an employee—whether with a private equity-owned hospital or otherwise—should ensure that their contract does not place them in an untenable conflict of interest or compromise their ability to fulfill their ethical and professional obligations to patients [8]. While we must acknowledge that physicians often have little power in contract negotiations, their ethical obligation remains nonetheless to try to negotiate when contractual agreements are likely to lead to ethical dilemmas. If a contract would prevent a physician from upholding their professional ethical obligations, the contract should not be entered into.

The Preamble to the *Code* stipulates that "[o]pinions of the AMA Council on Ethical and Judicial Affairs lay out the ethical responsibilities of physicians as members of the profession of medicine." Although some areas of concern therefore extend beyond what the *Code* may speak to, CEJA is currently studying the ethical obligations of health care entities that interact with physicians and is considering entering a report in the near future regarding the potential need for a new opinion to address additional stakeholders involved in our evolving health care landscape. CEJA recognizes that private equity investment raises concerns for physicians and for the practice of medicine but also acknowledges the *Code* is unable to speak to the totality of the issues raised by such investment practices. This is why it is crucial that multiple AMA units, such as the Council on

Medical Service's related report on private equity, work in tandem to address the complexity of the many issues raised by private equity firms' investment in health care entities.

It is the conclusion of the Council on Ethical and Judicial Affairs that increasing investment by private equity firms in health care raises ethical concerns regarding dual loyalties of physicians and competing interests between profits and patients. To respond to these issues, CEJA recommends amending Opinion 11.2.3, "Contracts to Deliver Health Care Services," to more clearly address concerns raised by entering into partnerships with private equity firms, physicians employed by corporate entities (including private equity firms, MSOs, insurance companies, and PBMs), and the ethical risks that may arise for both physicians seeking capital to support their private practice as well as physicians entering into employment contracts with private equity-owned health care entities.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that Opinion 11.2.3, "Contracts to Deliver Health Care Services," be amended by addition and deletion as follows and the remainder of this report be filed:

> Prioritizing profits over patients is incompatible with physicians' ethical obligations. No part of the health care system that supports or delivers patient care should place profits over such care. Physicians have a fundamental ethical obligation to put the welfare of patients ahead of other considerations, including personal financial interests. This obligation requires ~~them to~~ that before entering into contracts to deliver health care services, physicians consider carefully the proposed contract to assure themselves that its terms and conditions ~~of contracts to deliver health care services before entering into such contracts to ensure that those contracts~~ do not create untenable conflicts of interest or compromise their ability to fulfill their ethical and professional obligations to patients. Those physicians who enter into contracts with corporate entities, such as private equity firms, management service organizations, professional services corporations, insurance companies, or pharmaceutical benefit managers, who act within their capacity as a physician, even as administrators or intermediaries, also have a duty to uphold the ethical obligations of the medical profession.
>
> Ongoing evolution in the health care system continues to bring changes to medicine, including changes in reimbursement mechanisms, models for health care delivery, restrictions on referral and use of services, clinical practice guidelines, and limitations on benefits packages. While these changes are intended to enhance quality, efficiency, and safety in health care, they can also put at risk physicians' ability to uphold professional ethical standards ~~of informed consent and fidelity to patients~~ and can impede physicians' freedom to exercise independent professional judgment and tailor care to meet the needs of individual patients.
>
> As physicians seek capital to support their practices or enter into various differently structured contracts to deliver health care services—with group practices, hospitals, health plans, investment firms, or other entities—they should be mindful that while ~~many~~ some arrangements have the potential to promote desired improvements in care, ~~some~~ other arrangements ~~also~~ have the potential to ~~impede~~ put patients' interests at risk and to interfere with physician autonomy.
>
> When contracting with entities, or having a representative do so on their behalf, to provide health care services, physicians should:

(a) Carefully review the terms of proposed contracts, preferably with the advice of legal and ethics counsel, ~~or have a representative do so on their behalf~~ to assure themselves that the arrangement:

(i) minimizes conflict of interest with respect to proposed reimbursement mechanisms, financial or performance incentives, restrictions on care, or other mechanisms intended to influence physicians' treatment recommendations or direct what care patients receive, in keeping with ethics guidance;

(ii) does not compromise the physician's own financial well-being or ability to provide high-quality care through unrealistic expectations regarding utilization of services or terms that expose the physician to excessive financial risk;

(iii) ~~allows~~ ensures the physician can ~~to~~ appropriately exercise professional judgment;

(iv) includes a mechanism to address grievances and supports advocacy on behalf of individual patients;

(v) is transparent and permits disclosure to patients~~.~~;

(vi) enables physicians to have significant influence on, or preferably outright control of, decisions that impact practice staffing;

(vii) prohibits the corporate practice of medicine.

(b) Negotiate modification or removal of any terms that unduly compromise physicians' ability to uphold ethical or professional standards.

When entering into contracts as employees, preferably with the advice of legal and ethics counsel, physicians should:

(c) Advocate for contract provisions to specifically address and uphold physician ethics and professionalism.

(d) Advocate that contract provisions affecting practice align with the professional and ethical obligations of physicians and negotiate to ensure that alignment.

(e) Advocate that contracts do not require the physician to practice beyond their professional capacity and provide contractual avenues for addressing concerns related to good practice, including burnout or related issues.

(f) Not enter into any contract that would require the physician to violate their professional ethical obligations.

When contracted by a corporate entity involved in the delivery of health care services, physicians should:

(g) Terminate any contract that requires the physician to violate their professional ethical obligations and report any known or suspected ethical violations through the appropriate oversight mechanisms.

1 (Modify HOD/CEJA Policy)

Fiscal Note: Less than $500

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8. Programs regarding various aspects of health care are commonly televised; therefore, physicians should recognize that their patients may have preformed expectations from public broadcasts that may need to be addressed. (I, IV, VII, VIII)

Issued December 2001 based on the report "Filming Patients in Health Care Settings," adopted June 2001; updated November 2005.

(References pertaining to Report 2 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)

3. PHYSICIAN PAY-FOR-PERFORMANCE PROGRAMS

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

Physician pay-for-performance (PFP) compensation arrangements attempt to provide an economic incentive to improve health care quality by linking remuneration to measures of individual, group or organizational performance. These programs typically offer bonus payments to physicians who either meet, or demonstrate improvement in meeting, pre-established standards of performance measures.

The American Medical Association has issued a set of principles and guidelines that advocate for acceptable parameters. The AMA states that PFP programs should strive to: ensure the quality of care; foster the patient/physician relationship; offer voluntary physician participation; use accurate and fair data reporting; and provide fair and equitable program incentives. Many of these principles are closely related to core concepts of medical ethics and professionalism, including patient autonomy, conflicts of interest and trust, as well as fairness and justice. Accordingly, this report examines the tensions that may arise from physicians' participation in PFP programs and offers guidance to physicians striving to practice ethically in the face of performance-based incentive arrangements.

BACKGROUND

The past decade has been marked by an emerging quality movement in medicine, prompted by the Institute of Medicine's health care quality initiative, "Crossing the Quality Chasm," which proposed a new quality construct based upon safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. To achieve these objectives, key health care leaders have emphasized the role of evidence-based guidelines.

In turn, this has led to the establishment of market-based quality improvement mechanisms that link compensation to measurements of patient safety and clinical outcomes. Among these, pay-for-performance programs provide participants with monetary bonuses to reward the achievement of predetermined quality or efficiency benchmarks.

To measure performance, PFP programs must collect data on health care process and outcomes, including patient safety indicators and patient satisfaction. These data are then incorporated into payment mechanisms for hospitals or physicians. Physicians or physician groups, upon meeting a given program's performance criteria, are rewarded with modest financial bonuses that may constitute up to 5% of the total revenue received from a given health plan.

ETHICAL RESPONSIBILITIES OF PHYSICIANS

Physicians are ethically obligated to provide competent, patient-centered care to each of their patients, as codified within Principles I and VIII of the *Code of Medical Ethics*. Physicians must also assume central roles in promoting patient safety by participating in the identification, reduction, and prevention of medical errors (see Opinion E-8.121, "Ethical Responsibility to Study and Prevent Error and Harm," AMA Policy Database). Stemming from these obligations, physicians and the medical profession assume a duty to improve the safety and effectiveness of the health care that patients receive.

Designing Appropriate Physician Incentive Programs

Compensation policies that are designed to promote optimal patient care, such as the incentives offered through PFP programs, represent one of many measures intended to help physicians improve health care quality. However, the establishment of financial incentives may also create unintended tensions for participating physicians, as well as for physicians in leadership positions.

Most notably, the presence of economic incentives risks establishing a conflict between physicians' financial interests and the fulfillment of their professional obligations. Physicians' commitment to patient-centered care must supersede incentives offered by various compensation arrangements (see Opinion E-8.03, "Conflicts of Interest: Guidelines," and Opinion E-8.054, "Financial Incentives and the Practice of Medicine"). Yet, all reimbursement systems, including fee-for-service (FFS), capitation, and salary arrangements, establish various incentives that may adversely influence the quality of patient care.

In fee-for-service (FFS), physicians are paid for each procedure or service that they provide to the patient. Physicians have great latitude in providing necessary services, such as diagnostic tests or preventive services. Some may provide more services than are medically necessary, thereby promoting the overutilization of medical resources.

Capitation plans pay physicians a fixed amount per patient over a given period of time, regardless of the quality or quantity of services rendered. While capitation has the potential to mitigate overutilization, it creates an economic disincentive for the provision of expensive or complicated care, thus promoting underutilization.

Salaried arrangements that pay physicians a fixed sum may similarly contain costs, but also have the potential to lower productivity and discourage treatment of difficult clinical cases.

In view of the shortcomings of all compensation methods, PFP programs may prove beneficial when they recognize and reward physicians who deliver optimal care to their patients. However, practicing physicians and physicians involved in the design and implementation of PFP programs must take appropriate measures to ensure that any incentives used by these programs are consistent with the ethical values of the profession.

Responsibilities of Physicians in Leadership Positions

Physicians with appropriate professional expertise should be integrally involved in the design, implementation, and evaluation of new PFP programs. Accordingly, physicians acting in this capacity should undertake efforts to ensure that any incentives and performance benchmarks established by PFP programs are designed to primarily benefit the patient and improve the quality of their health care, rather than promoting cost-containment (see Opinions E-8.021, "Ethical Obligations of Medical Directors," and E-8.054, "Financial Incentives and the Practice of Medicine").

Responsibilities of Practicing Physicians

Physicians participating in PFP programs should work to ensure that the incentives provided by PFP programs preserve their ability to promote patient well-being. This may require negotiating the removal of any contractual terms that might compromise professional values, impede their ability to act as patient advocates, or obstruct the provision of medically necessary care (see Opinion E-8.0501, "Professionalism and Contractual Relations").

Promoting Evidence-Based Practice and Preserving Patient-Centered Care

All physicians who strive to practice ethically are committed to the provision of competent patient care through the exercise of their professional expertise. However, due to differences in training and practice styles, equally competent and dedicated physicians may provide divergent treatments for like medical conditions. This has led to system-wide variations in the use of medical services, medical expenses, and patient outcomes.

Such inconsistencies in physician practice become ethically problematic when they prevent patients from deriving adequate benefits from medical care. To promote fairness, individual physicians must be sensitive to variations in patient care that are not explained on the basis of medical need (see Opinion E- 2.095, "The Provision of Adequate Health Care).

Collectively, physicians should implement quality improvement activities as a means of ensuring competent medical care and reducing unwarranted variations in patient outcomes. One such approach is the promotion of evidence-based practice guidelines, which define standards for the safe and effective delivery of medical care.

Pay-for-performance arrangements can strive toward this goal by establishing performance incentives incorporating evidence-based practice guidelines. When doing so, the AMA has advised that PFP programs should utilize current peer-reviewed evidence-based performance measures that have been accepted by physicians with appropriate practice expertise.

The benefit of practice guidelines resides in their promise to improve aggregate outcomes at the population-level. However, the adoption of practice guidelines is not intended to eliminate all practice variations. It should be noted that the degree of benefit derived from a given intervention remains variable at the individual-level due to patient-specific factors. Moreover, overreliance upon disease-specific practice guidelines can potentially diminish the quality of care delivered to patients with multiple comorbid conditions. For this reason, physicians must retain the ability to customize care for each individual in order to meet the specific needs of patients when participating in PFP programs.

Responsibilities of Physicians in Leadership Positions

Physicians involved in the design and implementation of PFP programs should contribute their professional expertise to ensure that practice guidelines that are fair and objective, and consistent with the ethical values of the profession (see Opinion E-8.021). Moreover, physicians working in this capacity must also ensure that all practice guidelines allow for sufficient variation to enable physicians to accommodate the specific needs of individual patients (see Policy H-320.949, "Clinical Practice Guidelines and Clinical Quality Improvement Activities").

Once evidence-based practice guidelines have been established, their designers have a responsibility to make these guidelines available to participating physicians, along with an explanation of any intended purposes and uses not related to patient care (see Policy H-410.980, "Principles for the Implementation of Clinical Practice Guidelines at the Local/State/Regional Level"). If possible, PFP program designers should also inform practicing physicians of the expected benefits associated with specific evidence-based recommendations. By doing so, the implementation of clinical guidelines can improve health care quality by helping physicians to select among multiple evidence-based recommendations in order to best benefit the individual patient.

Responsibilities of Practicing Physicians

Practice guidelines are ethically acceptable when they are primarily designed to promote the well-being of patients. Practicing physicians should familiarize themselves with current evidence-based findings and clinical practice guidelines that arise from them. This commitment is consistent with Principle V of the *Code*, which directs physicians to "continue to study, apply and advance scientific knowledge [and] maintain a commitment to medical education" in order to serve patients in accordance with professional standards of excellence.

Physicians also should share this knowledge with their patients in order to better inform patients' medical decision making and to improve their adherence to prescribed treatment (see Opinion E-8.08, "Informed Consent"). Physicians must not allow practice guidelines or performance-based compensation arrangements to create unrealistic expectations among patients (see Opinion E-6.01, "Contingent Physician Fees"). Therefore, physicians should inform patients that evidence-based practice guidelines are based on clinical findings aggregated at the population level, meaning that individual treatment options and outcomes may vary in practice.

Physicians must also ensure that their focus on relevant practice guidelines does not inappropriately infringe upon patients' autonomy. Practicing physicians must inform their patients about the full range of available treatment options, as required by Opinion E-8.053, "Restrictions on Disclosure in Health Care Plan Contracts." Physicians must then provide appropriate services in accordance with their patients' medical needs and personal preferences, even if such treatments conflict with the guidelines used to determine the physicians' performance. However, physicians are not ethically required to cater all patient demands and may decline to deliver medical care that they do not believe has a reasonable chance of benefiting the patient (see Opinion E-2.035, "Futile Care").

MITIGATING POTENTIAL ADVERSE IMPACTS OF PFP PROGRAMS

A potential ethical concern regarding the long-term effects of pay-for-performance programs is the impact that these efforts may have upon patients' access to health care. Should PFP programs publicize performance ratings or link physicians' compensation to patient outcomes without making appropriate case-mix adjustments, some physicians may be motivated to preferentially seek out and treat healthier patients. This practice allows physicians to improve their prospects for achieving pre-determined performance measures by treating only those patients presenting the best anticipated health outcomes. As this occurs, it may become increasingly difficult for some patients to access appropriate health care.

The negative effects of patient selection could be especially problematic for patients belonging to vulnerable population groups. Patients from these groups tend to enter the health care system in more advanced disease states, and may be faced with limited financial and social resources or more severe communication difficulties, which can impede their ability to adhere to treatment recommendations. As a result, treatment outcomes for these patients may be sub-optimal. This may systematically disadvantage physicians who treat patients from such vulnerable populations, because their aggregate performance outcomes may not meet the benchmarks established by PFP programs. As a result, poorly designed PFP incentive structures could dissuade physicians from serving vulnerable patient populations in favor of catering to comparatively healthier patients.

In the face of such pressures, all physicians must uphold the mandates of Principle IX and work to support access to medical care for all people. Practicing physicians can promote equitable access by continuing to treat patients on the basis of need. In addition, physicians participating in the design and implementation of PFP programs should ensure that these programs are structured in a way that does not discourage the treatment of patients belonging to vulnerable population groups. This can be accomplished by avoiding the use of performance benchmarks based upon factors beyond the control of individual physicians, by the incorporation of appropriate risk-adjustment mechanisms, and through the use of risk-pooling strategies. If PFP program administrators choose to make data on physicians' performance publicly available, physicians should advocate for the incorporation of risk-adjusted performance ratings, characterized by adequate review and appeal mechanisms.

CONCLUSION

Physician pay-for-performance programs may benefit patients by improving the effectiveness and safety of medical care. These goals are consistent with physicians' obligations to provide competent patient care. However, physicians participating in these incentive programs must continue to uphold all ethical obligations to their patients and avoid conflicts of interest stemming from PFP arrangements. Participating physicians must ensure that all care is delivered on the basis of patients' individual needs and preferences. Physicians must also continue to treat each of their patients without bias and avoid further disadvantaging vulnerable patient populations. In addition, physicians should work collectively to ensure that the goals and incentives utilized by PFP programs promote patients' best interests.

RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Physician pay-for-performance (PFP) compensation arrangements should be designed to improve health care quality and patient safety by linking remuneration to measures of individual, group, or organizational performance. To uphold their ethical obligations, physicians who are involved with PFP programs must take appropriate measures to promote patients' well-being.

1. Physicians who are involved in the design or implementation of PFP programs should advocate for:

   (a) incentives that are intended to promote health care quality and patient safety, and are not primarily intended to contain costs;

   (b) program flexibility that allows physicians to accommodate the varying needs of individual patients;

(c) adjustment of performance measures by risk and case-mix in order to avoid discouraging the treatment of high-risk individuals and populations; and

(d) processes to make practice guidelines and explanations of their intended purposes and the clinical findings upon which they are based available to participating physicians.

2. Practicing physicians who participate in PFP programs while providing medical services to patients should:

(a) maintain primary responsibility to their patients and provide competent medical care, regardless of financial incentives;

(b) support access to care for all people and avoid selectively treating healthier patients for the purpose of bolstering their individual or group performance outcomes;

(c) be aware of evidence-based practice guidelines and the findings upon which they are based;

(d) always provide care that considers patients' individual needs and preferences, even if that care conflicts with applicable practice guidelines; and

(e) not participate in PFP programs that incorporate incentives that conflict with physicians' professional values or otherwise compromise physicians' abilities to advocate for the interests of individual patients.

(References pertaining to Report 3 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)

REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1-5, were presented by Michael S. Goldrich, MD, Chair:

1. COMMUNICATING PERSONAL BELIEFS TO PATIENTS AND FAMILIES

HOUSE ACTION: REFERRED

At the 1999 Annual Meeting, the Council on Ethical and Judicial Affairs issued Opinion 9.012 "Physicians' Political Communications with Patients and Their Families." Since that time, CEJA has received a number of inquiries regarding the communication of personal beliefs by physicians to patients and their families. Although some of the ethical considerations raised by such communication may be similar to those that are addressed in Opinion 9.012, CEJA recognizes that the ethical concerns inherent in expressing personal beliefs to patients and the families warrant further guidance. The following recommendations offer ethical guidelines to assist physicians in communicating with their patients.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of the report be filed:

> In the clinical setting, conversations between patients and physicians may diverge from clinical pertinence. In a trusting patient-physician relationship, conversations stemming from personal beliefs can be a positive supplement to the therapeutic alliance. However, physicians should use caution in expressing personal beliefs to avoid potential conflicts or misunderstandings that may erode trust and thereby negatively affect the medical care a patient receives. When patients, or their families, initiate a discussion of personal beliefs, physicians should consider whether they are related to the patient's health or welfare; if they are unrelated, greater caution is advised.
>
> Physicians should not allow differences in personal beliefs to interfere with the patient-physician relationship and the quality of medical care. In order to protect the integrity of the patient-physician relationship, physicians may wish to consider whether in certain circumstances, another party would be better suited to discuss personal beliefs with the patient or family, for example a provider of pastoral care or an ethics consultant.
>
> Patients and physicians may feel most comfortable discussing personal beliefs during clinical encounters when they share similar value systems. Although certain personal beliefs may not conflict with those of a patient, physicians should be sensitive to a patient's discomfort or preference not to discuss such beliefs.

2. PROFESSIONALISM AND CONTRACTUAL RELATIONS

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

Resolution 11 (A-02), "AMA's *Principles of Medical Ethics*," called for Principle VI to be amended to add the notion of freedom to contract. However, the Council found that the current language of Principle VI, by referring to free choice of association, implied free choice of contract as did many Opinions of the AMA's Code of Medical Ethics, notably Opinions E-6.11, "Competition," E-9.06, "Free Choice," and E-8.05, "Contractual Relations." These Opinions make clear that physicians could exercise their freedom to choose the conditions within which to practice. This choice generally is expressed by entering into contracts with selected entities including health plans or health care facilities, or directly with patients. Therefore, CEJA Report 11-A-03, "AMA's *Principles of Medical Ethics* (Resolution 11, A-02)," concluded that the proposed amendment did not need to be made, but the Council agreed to continue to address ethical issues that physicians face when entering into various contractual relationships.

CONTRACTUAL RELATIONS--CLINICAL AND BEYOND

Currently, Opinion E-8.05 addresses the various contractual relationships that physicians enter into with group practices or with insurance plans to provide services to patients. The opinion addresses income arrangements and other benefits. More importantly, the opinion states that "physicians should not be subjected to lay interference in professional medical matters and their primary responsibility should be to the patients they serve."

This statement derives from two complementary notions: first, physicians as professionals hold unique obligations to attain expertise in the art and science of medicine and to use their knowledge and skills to provide medical care, a service that is highly valued by society. As professionals, they also are entrusted to self-regulate, in part because others do not hold the necessary knowledge to evaluate their activities. Professional integrity is achieved by fulfilling this mandate and preventing undue interference by government or market force. At the level of individual physicians, lay interference may undermine physicians' professionalism.

The other important notion expressed in the concluding sentence of Opinion E-8.05 echoes Principle VIII, which states that "A physician shall, while caring for a patient, regard responsibility to the patient as paramount." Together, these two notions establish a patient-physician dyad that ought to be protected from extraneous interests.

Apart from their clinical interactions with patients, it is important to recognize that physicians serve many other ancillary functions. Indeed, the AMA's Code of Medical Ethics identifies many other roles that physicians fulfill, which may or may not overlap with their clinical responsibilities, such as educators, research investigators, inventors, administrators, investors in health care facilities, expert witnesses, and peer reviewers.

In many instances, fulfilling these functions will require physicians to enter into contractual agreements with non-health care professionals, including corporate entities. Despite the possibility of some common interests with physicians and/or patients, these third parties may not be bound by the same ethical norms, nor be motivated by the same goals.

Conflict of Interests and Contracts

When patient interests are not clearly aligned with those of the entity with which a physician enters into a contract, the physician may have a conflict of interest. That is to say that the physician's professional judgment about patient welfare stands to be unduly influenced by the interests of the other contracting party, whether financial or otherwise. Many concerns that arise from specific instances of conflicts of interest are addressed by the Code of Medical Ethics.

Concerns regarding conflicts of interest have been particularly intense in the context of managed care, where physicians have complained that reimbursement arrangements and various practice restrictions (such as referrals, prescriptions, hospitalizations, etc.) have prevented them from providing due care to some patients. Therefore, physicians have been cautioned to review these contractual agreements carefully to measure their potential impact on patient care. The medical profession as a whole has sought to modify some managed care arrangements that were found to be detrimental to patient care, and these efforts continue. However, similar caution is warranted whenever physicians enter into contracts to perform functions that are ancillary to patient care, as enumerated above.

CONCLUSION

Before entering into contracts with third parties, physicians should attempt to ascertain the goals or motivations of the other contracting party and determine the possible impact on professionalism, independent clinical judgment, or patient care. Even if a shared goal can be identified, motivations or means to achieve a common goal may present an untenable conflict of interest. If negotiations to address these concerns fail, physicians should reject the contract.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of the report be filed:

> Physicians are free to enter into a wide range of contractual arrangements. However, physicians should not sign contracts containing provisions that tend to undermine their ethical obligation to advocate for patient welfare. Therefore, before entering into contractual agreements to provide services that directly or indirectly impact patient care, physicians should negotiate the removal of any terms, such as financial incentives or administrative conditions, that are known to compromise professional judgment or integrity. Particularly, when contractual compensation varies according to performance (see Opinion E-8.054, "Financial Incentive and the Practice of Medicine"), physicians should beware of incentives that may adversely impact patient care.

3. PHYSICIANS' OBLIGATION TO ACCEPT PERSONAL RISK IN THE PROVISION OF MEDICAL CARE

HOUSE ACTION: REFERRED

The terrorist attacks of 2001 were a reminder that individual and collective safety cannot be taken for granted. Since then, physicians, alongside public health professionals and other health care professionals as well as non-health care personnel, have been developing plans to enhance the protection of public health and the provision of medical care in response to various threats, including acts of terrorism or bioterrorism. Included in those plans are strategies to attend to large numbers of victims and help prevent greater harm to even larger populations.

It is important to recognize that unique responsibilities beyond planning rest on the shoulders of the medical profession. Indeed, irrespective of the cause of harm, physicians are needed to care for victims. In some instances, this will require individual physicians to place their health or their lives at risk. Many physicians have demonstrated their sense of duty and courage by participating in the rescue efforts that followed the events of September 11, 2001, and many were involved in the public health efforts that arose from the anthrax contamination. These and other recent events, such as the debate regarding smallpox vaccination of front-line responders and the SARS epidemic, offer the medical profession and each of its members a unique opportunity to reflect anew on ethical responsibilities that arise in the face of adversity.

A BRIEF HISTORY OF ETHICAL OBLIGATIONS IN THE FACE OF RISKS

Prior to the events of 2001, the most recent profession-wide debate regarding a duty to treat despite personal risks arose when there was limited understanding of HIV transmission. Those who believed there was a duty to treat appeared to rely in part on historical evidence of the role physicians had played during epidemics. However, some historians remained cautious in making any claim that such a duty existed. In fact, they pointed to many instances when physicians had fled in times of the plague, and also showed that physicians who had provided care during epidemics had done so not out of a sense of professional obligation, but either because of religious doctrines, because it was lucrative, or because it could result in fame.

By the time standards of medical ethics became codified, starting in the late 18th Century, a growing sense of the duties owed by professionals had developed. In this vein, the AMA's first code stated that: "When pestilence prevails, it is [physicians'] duty to face the danger, and to continue their labors for the alleviation of the suffering, even at the jeopardy of their own lives." This clear mandate may have been moderated in the 1912 edition of the AMA's code by the introduction of the notion that physicians should be free to choose whom to serve. However, the AIDS epidemic led to a reiteration of the obligation to treat.

Much of the historical analysis regarding physicians' obligation to treat despite personal risk has focused on the treatment of infectious diseases. However, threats to personal safety, health or life come in many different forms, for example when a natural disaster strikes or during armed conflicts. Along the spectrum of threats, all physicians are confronted with the same question: whether the care needed by a patient or a group of patients calls for the assumption of personal risk.

(iii) ~~The~~ Physicians should advocate for the time period over which incentives are determined ~~should~~ to be long enough to accommodate fluctuations in utilization resulting from the random distribution of patients and illnesses. For example, basing incentive payments on an annual analysis of resource utilization is preferable to basing them on monthly review.

(iv) Financial rewards or penalties that are triggered by specific points of utilization may create enormous incentives as a physician's practice approaches the established level. ~~Incentives should therefore~~ Therefore, physicians should advocate that incentives be calculated on a continuum of utilization rather than a bracketed system with tiers of widely varied bonuses or penalties.

(v) ~~A~~ Physicians should ascertain that a stop-loss plan ~~should be~~ is in place to prevent the costs ~~of treating a single patient~~ associated with unusual outliers from significantly impacting the reward or penalty offered to a physician.

3. ~~Incentives should be designed to~~ Physicians also should advocate for incentives that promote efficient practice, but ~~should not be~~ are not designed to realize cost savings beyond those attainable through efficiency. As a counterbalance to the focus on utilization reduction, ~~incentives~~ physicians also should advocate for incentives based ~~upon measures of~~ on quality of care and patient satisfaction.

4. Patients must be informed of financial incentives that could impact the level or type of care they receive. ~~This~~ Although this responsibility should be assumed by the health plan, ~~to ensure that patients are aware of such incentives prior to enrollment Physicians~~ physicians, individually or through their representatives, must be prepared to discuss with patients any financial arrangements that could impact patient care. Physicians should avoid reimbursement systems that, ~~cannot be~~ if disclosed to patients, ~~without negatively affecting~~ could negatively affect the patient-physician relationship. (II, III)

Issued June 1998 based on the report "Financial Incentives and the Practice of Medicine," adopted December 1997; updated June 2002.

7. MANAGED CARE, *AMENDMENT*

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates adopted Resolution 3, "Restrictive Drug Policies in Public Programs such as Medicaid," in response to which the Council on Ethical and Judicial Affairs is amending Opinion 8.135, "Managed Care Cost Containment Involving Prescription Drugs." For the sake of consistency, CEJA proposes that, like Opinion 8.135, other Opinions on managed care in the *Code of Medical Ethics* be extended in scope to cover health care plans in general rather than managed care organizations only and be edited to direct their recommendations to physicians only. Accordingly, CEJA proposes the following amendments to Opinion 8.13, "Managed Care." The revised Opinion will appear in the next edition of the *Code of Medical Ethics*.

8.13 Managed Care

The expansion of managed care has brought a variety of changes to medicine including new and different reimbursement systems for physicians with complex referral restrictions and benefits packages for patients. Some of these changes have raised concerns that a physician's ability to practice ethical medicine will be adversely affected by the modifications in the system. In response to these concerns, the following points were developed to provide physicians with general guidelines that will assist them in fulfilling their ethical responsibilities to patients given the changes heralded by managed care.

1. The duty of patient advocacy is a fundamental element of the ~~physician~~ patient-physician relationship that should not be altered by the system of health care delivery. Physicians must continue to place the interests of their patients first.

2. When ~~managed~~ health care plans place restrictions on the care that physicians in the plan may provide to their patients, physicians should insist that the following principles ~~should~~ be followed:

(a) Any broad allocation guidelines that restrict care and choices--which go beyond the cost/benefit judgments made by physicians as a part of their normal professional responsibilities--should be established at a policy making level so that individual physicians are not asked to engage in bedside rationing.
(b) Regardless of any allocation guidelines or gatekeeper directives, physicians must advocate for any care they believe will materially benefit their patients.
(c) Physicians should be given an active role in contributing their expertise to any allocation process and should advocate for guidelines that are sensitive to differences among patients. ~~Managed~~ Health care plans should create structures similar to hospital medical staffs that allow physicians to have meaningful input into the plan's development of allocation guidelines. Guidelines for allocating health care should be reviewed on a regular basis and updated to reflect advances in medical knowledge and changes in relative costs.
(d) Adequate appellate mechanisms for both patients and physicians should be in place to address disputes regarding medically necessary care. In some circumstances, physicians have an obligation to initiate appeals on behalf of their patients. Cases may arise in which a health plan has an allocation guideline that is generally fair but in particular circumstances results in unfair denials of care, i.e., denial of care that, in the physician's judgment, would materially benefit the patient. In such cases, the physician's duty as patient advocate requires that the physician challenge the denial and argue for the provision of treatment in the specific case. Cases may also arise when a health plan has an allocation guideline that is generally unfair in its operations. In such cases, the physician's duty as patient advocate requires not only a challenge to any denials of treatment from the guideline but also advocacy at the health plan's policy-making level to seek an elimination or modification of the guideline. Physicians should assist patients who wish to seek additional, appropriate care outside the plan when the physician believes the care is in the patient's best interests.
(e) ~~Managed~~ Health care plans must adhere to the requirement of informed consent that patients be given full disclosure of material information. Full disclosure requires that ~~managed~~ health care plans inform potential subscribers of limitations or restrictions on the benefits package when they are considering entering the plan.
(f) Physicians also should continue to promote full disclosure to patients enrolled in ~~managed care organizations~~health care plans. The physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's ~~managed~~ health care plan. Full disclosure includes informing patients of all of their treatment options, even those that may not be covered under the terms of the ~~managed~~ health care plan. Patients may then determine whether an appeal is appropriate, or whether they wish to seek care outside the plan for treatment alternatives that are not covered.
(g) Physicians should not participate in any plan that encourages or requires care below minimum professional standards.

3. When physicians are employed or reimbursed by ~~managed~~ health care plans that offer financial incentives to limit care, serious potential conflicts are created between the physicians' personal financial interests and the needs of their patients. Efforts to contain health care costs should not place patient welfare at risk. Thus, physicians should accept only those financial incentives ~~are permissible only if they~~ that promote the cost-effective delivery of health care and not the withholding of medically necessary care.

(a) ~~Any~~ Physicians should insist that any incentives to limit care ~~must~~ be disclosed fully to patients by plan administrators upon enrollment and at least annually thereafter.
(b) ~~Limits~~ Physicians should advocate that limits be placed on the magnitude of fee withholds, bonuses and other financial incentives to limit care. ~~Calculating~~ and that incentive payments be calculated according to the performance of a sizable group of physicians rather than on an individual basis ~~should be encouraged~~.
(c) ~~Health~~ Physicians should advocate that health care plans or other groups ~~should~~ develop financial incentives based on quality of care. Such incentives should complement ~~financial incentives~~ those based on the quantity of services used.

4. ~~Patients have an individual responsibility to~~ Physicians should encourage both that patients be aware of the benefits and limitations of their health care coverage. ~~Patients should~~ and that they exercise their autonomy by public participation in the formulation of benefits packages and by prudent selection of health care coverage that best suits their needs. (I, II, III, V)

Issued June 1996 based on the report "Ethical Issues in Managed Care," adopted June 1994 (*JAMA*. 1995;273: 330-335); updated June 2002.

8. REFERRAL OF PATIENTS: DISCLOSURE OF LIMITATIONS, *AMENDMENT*

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates adopted Resolution 3, "Restrictive Drug Policies in Public Programs such as Medicaid," in response to which the Council on Ethical and Judicial Affairs is amending Opinion 8.135, "Managed Care Cost Containment Involving Prescription Drugs." For the sake of consistency, CEJA proposes that, like Opinion 8.135, other Opinions on managed care in the *Code of Medical Ethics* be extended in scope to cover health care plans in general rather than managed care organizations only and be edited to direct their recommendations to physicians only. Accordingly, CEJA proposes the following amendments to Opinion 8.132, "Referral of Patients: Disclosure of Limitations." The revised Opinion will appear in the next edition of the *Code of Medical Ethics*.

8.132 Referral of Patients: Disclosure of Limitations

When a physician agrees to provide treatment, he or she thereby enters into a contractual relationship and assumes an ethical obligation to treat the patient to the best of his or her ability. ~~Preferred Provider Organization (PPO) and Health Maintenance Organization (HMO)~~Some health care plans' contracts ~~generally~~ restrict the participating physician's scope of referral to medical specialists, diagnostic laboratories, and hospitals that have contractual arrangements with the ~~PPO and HMO~~health care plan. Some plans also restrict the circumstances under which referrals may be made to contracting medical specialists. If the ~~PPO or HMO~~health care plan does not permit referral to a non-contracting medical specialist or to a diagnostic or treatment facility when the physician believes that the patient's condition requires such services, the physician should so inform the patient so that the patient may decide whether to accept the outside referral at his or her own expense or confine herself or himself to services available within the ~~PPO or HMO~~health care plan. In determining whether treatment or diagnosis requires referral to outside specialty services, the physician should be guided by standards of good medical practice.

Physicians must not deny their patients access to appropriate medical services based upon the promise of personal financial reward, or the avoidance of financial penalties. Because patients must have the necessary information to make informed decisions about their care, physicians have an obligation to assure the disclosure of medically appropriate treatment alternatives, regardless of cost.

Physicians must assure disclosure of any financial inducements that may tend to limit the diagnostic and therapeutic alternatives that are offered to patients or that may tend to limit patients' overall access to care. Physicians may satisfy this obligation by assuring that the ~~managed~~ health care plan makes adequate disclosure to enrolled patients ~~enrolled in the plan~~. Physicians should also promote an effective program of peer review to monitor and evaluate the quality of the patient care services within their practice setting. (II, IV)

Issued June 1986; Updated June 1994 based on the report "Financial Incentives to Limit Care: Ethical Implications for HMOs and IPAs," adopted June 1990; updated June 2002.

3. Stop-loss plans ~~should be in effect to~~ can prevent the potential of catastrophic expenses from influencing physician behavior. Physicians should ~~attempt to~~ ensure that such arrangements are finalized prior to signing an agreement to provide services in a health plan.

4. Physicians must be prepared to discuss with patients any financial arrangements, which could impact patient care. Physicians should avoid reimbursement systems that, if ~~cannot be~~ disclosed to patients, could ~~without~~ negatively affecting the patient-physician relationship. (II, III, VI)

Issued December 1997 based on the report "The Ethical Implications of Capitation," adopted June 1997; updated June 2002.

5. RESTRICTIONS ON DISCLOSURE IN MANAGED CARE CONTRACTS, *AMENDMENT*

HOUSE ACTION: FILED

At the 2001 Annual Meeting, the American Medical Association House of Delegates adopted Resolution 3, "Restrictive Drug Policies in Public Programs such as Medicaid," in response to which the Council on Ethical and Judicial Affairs is amending Opinion 8.135, "Managed Care Cost Containment Involving Prescription Drugs." For the sake of consistency, CEJA proposes that, like Opinion 8.135, other Opinions on managed care in the *Code of Medical Ethics* be extended in scope to cover health care plans in general rather than managed care organizations only and be edited to direct their recommendations to physicians only. Accordingly, CEJA proposes the following amendments to Opinion 8.053, "Restrictions on Disclosure in Managed Care Programs." The revised Opinion will appear in the next edition of the *Code of Medical Ethics*.

8.053 Restrictions on Disclosure in ~~Managed Care~~ Health Care Plan Contracts

Despite ethical requirements demanding full disclosure of treatment options regardless of limitations imposed by plan coverage, some ~~managed care organizations~~ health care plans include clauses in their employment contracts that directly inhibit the ability of physicians to keep their patients fully informed. These types of contract clauses erect inappropriate barriers to necessary communications between physicians and patients, labeled "gag clauses" by some observers. Restrictive clauses of this type impact the ability of physicians to provide information to their patients and to act effectively as a patient advocate. They also threaten to undermine individual and public trust in the profession of medicine.

1. ~~Managed care organizations~~ Health care plans have the right to protect proprietary information, ~~as long as such protection does not~~ However, physicians should oppose any such protection that inhibits them from disclosing relevant information to patients. ~~Contract clauses that could be applied to prevent~~ For this reason, physicians should advocate for the elimination of contract clauses that could prevent them from raising or discussing matters relevant to patients' medical care ~~should be removed to safeguard the health of plan subscribers~~.

2. The right of patients to be informed of all pertinent medical information must be reaffirmed by the medical profession, and individual physicians must continue to uphold their ethical obligation to disclose such information.

3. Physicians, individually or through their representative, should review their contracts carefully to ensure that ~~there is no possibility that the health of their patients will be jeopardized in any way by clauses that inhibit their ability~~ they are able to fulfill their ethical obligations to patients. (II, III, VI)

Issued June 1998 based on the report "Restrictions on Disclosure in Managed Care Contracts," adopted June 1996; updated June 2002.

iv. Financial rewards or penalties that are triggered by specific points of utilization may create enormous incentives as a physician's practice approaches the established level. Incentives should therefore be calculated on a continuum of utilization rather than a bracketed system with tiers of widely varied bonuses or penalties.

v. A stop-loss plan should be in place to prevent the costs of treating a single patient from significantly impacting the reward or penalty offered to a physician.

3. Physicians have an obligation to evaluate incentive programs to ensure that they are not threatening to appropriate medical care. Plans should calculate their incentives on the basis of the expected costs associated with providing necessary care. Incentives should be designed to spur efficient practice, but should not be designed to realize cost savings beyond those attainable through the elimination of waste. As a counterbalance to the focus on utilization reduction, inducements should also be based upon considerations of quality.

4. Patients must be informed of the financial incentives, positive and negative, that could impact the level or type of care they receive. This responsibility should first be assumed by the managed care organization to ensure that patients are aware of the coverage they are purchasing prior to enrollment. An obligation exists on the part of the physician to disclose such incentives if the patient has not been adequately informed. In such circumstances, the physician also has a corresponding obligation to appeal to the plan for more complete disclosure.

(References pertaining to Report 3 of the Council on Ethical and Judicial Affairs are available from the Ethical Standards Division Office.)

4. THE ETHICAL IMPLICATIONS OF CAPITATION

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

Introduction

The systems through which physicians are reimbursed for their services have grown varied and complex. To date, discussion of the actual impact of these changes on the quality of patient care has been limited by a lack of data. However, there is much to be gained from discourse within the profession concerning the potential effects these systems may have. At the Annual Meeting in 1996, the House of Delegates recognized the need for this discourse and adopted Resolution 5, which recommended that:

1. The American Medical Association study the ethical aspects of capitation and its impact on both physicians and their patients; and

2. These ethical concerns and issues be reviewed by the Council on Ethical and Judicial Affairs.

With the intent of responding to this resolution and of contributing to the necessary discussion of capitation, the Council presents the following report.

CAPITATION AND FINANCIAL INCENTIVES

It is crucial to distinguish pure capitation arrangements from other financial incentives as they are traditionally defined. Financial incentives target the monetary interests of physicians and are designed to use the pressure of

potential income variations to encourage certain behaviors. Capitation, on the other hand, is defined simply as the payment of a fixed sum per patient per unit time. If capitated payments are given to individual physicians, the physician's salary will be derived from what remains of the capitated pool, and an inherent financial incentive will be created that could affect the provision of care. Other capitated plans, however, provide payments to a group of physicians whose personal incomes are in turn provided through a wide variety of payment systems ranging from salary to bonuses to fee-for-service. In these plans, the immediate parallels between capitation and other, more direct financial incentives are not so clearly established.

Regardless of how the physician is personally reimbursed, the capitated sum is applied to cover the costs incurred in providing a pre-determined set of services to the pool of capitated patients. Physicians may be expected to apply capitated funds to cover only their own services, or as in the case of some primary care physicians, the pool may also be used to cover the provision of outside laboratory tests, specialty care, hospital stays, and ancillary services. Individual physician income may at least partially be attached to the capitated pool through additional financial incentives, such as bonuses or withholds. An analysis of the ethical merits and conflicts associated with such direct incentives is presented in a different Council report. This report intends to address only the ethical implications of providing care for patients under a fixed budget without attempting to analyze the multifarious reimbursement systems that could be applied as a subset of capitation to influence physician behavior.

Capitation has many of the defining characteristics of other financial incentives. By providing a fixed budget with which to treat patients, physicians are motivated to minimize costs because of the possibility that patients could conceivably find themselves without the resources to obtain treatment if the pool is not managed effectively. Additionally, physicians who practice as a part of a group under capitation typically experience significant pressure to stay within the allotted budget from colleagues who share the resource pool and from insurance companies, employers, and other third party payers. Although it is not clear whether physicians are motivated to be cost-conscious and efficient by the concerns of colleagues, payors, or patients, it seems clear that capitation successfully shifts the mentality of practicing physicians.

ANALYSIS OF THE PHYSICIAN'S ROLE UNDER CAPITATION

Although operating under a fixed budget does not necessarily introduce the clinician's personal income into the patient-physician relationship, it can alter the role of the physician. Medicine has long held that the primary obligation of physicians is to advocate for the interests of each individual patient. In a capitated environment, however, patients covered by the same pool have overlapping interests, and explicitly tying the care of multiple patients to a single, limited funding source bestows upon the physician an additional obligation to consider the potential depletion of that resource when making treatment decisions. The extent to which these duties are in conflict is dependent upon the strength of each component obligation. Physicians practicing under capitation have an individual responsibility to maintain the resource pool, and the degree of pressure they experience to act on that responsibility is inversely related to the number of physicians in the capitated plan. Very small plans therefore make physicians more acutely aware of their responsibility to the capitated pool which may in turn create conflicts with their primary obligation to individual patient care.

Even in large plans, physicians practicing under capitation are encouraged to consider the costs to the plan of different treatment options. It is entirely appropriate for physicians to feel some obligation to safeguard broader health care resources; indeed such an obligation has existed for decades. Adopting dual roles is only cause for concern when the roles are given equal or nearly equal status and the primacy of individual patient care is threatened.

THE PHYSICIAN AS INSURER

When discussing capitation, it is useful to note some of the parallels between physicians under capitation and insurers. While the analogy is by no means perfect, some comparisons are helpful. Insurers receive in the form of a premium a fixed sum from each member of the covered population. With that sum, they are responsible for paying all legitimate claims in order to fulfill the guarantee of protection implied under the term "insurance." Their duty

to their subscribers, therefore, is to manage a global budget against shortfalls. Fulfilling this duty requires that they judge individual claims to determine if they in fact meet criteria for coverage. It also requires that they examine each claim in light of its potential impact on the system's ability to pay future claims. All the descriptions to this point could equally describe the position of physicians practicing under capitation.

Perhaps the primary function of insurers can best be described as making broad-level decisions about plan resource allocation. Recognizing that decisions about the application of limited medical resources may be appropriate, the Council has previously stipulated that any allocation decisions that will affect patient access to care must be decided on a broad (ideally societal) level. Given their unique knowledge of what constitutes acceptable levels of health care, the input of physicians into these global decisions is crucial. It is therefore appropriate for large groups of physicians who accept capitated payments together to take an active role in assessing which services will be covered under their capitated resource. It is imperative, however, that such determinations be disclosed to patients prior to their enrollment in the plan.

As physicians under capitation assume many of the roles traditionally held by insurers, however, these decisions could be brought to the bedside. The uncertainties of clinical practice place inherent limits on the degree of precision specific rules for coverage can be expected to attain, and it is tempting to place the burden of allocating resources on the shoulders of individual physicians. This shift in responsibility can be achieved by capitating single physicians or small groups of physicians and allowing them to establish rules of resource utilization. The Council has previously opposed this form of allocation because it depends upon variable factors in an individual's practice and may lead to standards of provision that are not consistent across different physician practices. Furthermore, because these decisions are based in part on the resource use of a relatively small group of patients, fluctuations in clinical practice may result in standards that are not even consistent within one physician's practice across different time periods.

IMPLICATIONS FOR PATIENT CARE

The effect on patient care of the physician's role as it is defined under capitation ultimately hinges upon the availability of funds to provide treatment. The adequacy of plan resources is affected by a number of factors. First, the efficiency of a physician's practice can impact the availability of resources. By reducing overhead or any unnecessary services, physicians can increase the effective size of the capitated pool.

A second factor is the rate of capitated payment. A capitation rate that is insufficient to fund all necessary care even under circumstances of ideal efficiency could adversely affect the care available to plan patients. Some have argued that setting the capitation rate too low will impact quality and therefore detract from the payor's ability to compete in the medical marketplace. In other words, quality control and patient protection will be provided by market forces. Additionally, it has been argued that medical malpractice claims and liability suits will provide a check against deterioration in the quality of care. The level of protection these safeguards can provide is highly debatable, not least because quality is so hard to assess by any objective available measure. That point notwithstanding, it seems that liability and market forces are tools better suited to preventing a slide below minimal levels of care than to upholding the standards of optimal care.

Regardless of how effective liability and free-market economics may be in protecting patients, the fact remains that as determinants of the capitation rate these issues largely miss the point. Capitation is a means to reduce costs. Its value to the health care system, however, is linked only to its ability to eliminate unnecessary and wasteful practices. In keeping with this goal, the rate of capitation should be determined by the identifiable needs of the covered patients and not by market trends or the probability of legal action. It is difficult for payment rates based on either purely economic or legal premises to reflect the appropriate goals and aims of the profession, including the provision of necessary care and the preservation of ethical practice.

Admittedly, basing capitation payments on a determination of necessary services is difficult given the general lack of consensus even among physicians as to what constitutes optimal care. Debate between professionals concerning specific treatments has long existed and recent data suggest that there are broad differences in practice patterns

across geographic areas. An inadequate supply of definitive outcomes data further complicates attempts to define necessary care for a given population, to say nothing of assessing the appropriate cost of that care. However, even an estimate based on available information is superior to a figure that does not attempt to incorporate the nuances of varying levels of care.

It is imperative that the capitation rate reflect the medical needs of plan patients because a pool that is insufficient to cover necessary care can lead to serious ethical conflicts for the physician. The most obvious of these conflicts arises between patients. If the financial resources are inadequate to the task of providing all necessary care, the physician has no choice but to prioritize individual patients on the basis of relative need. There are a number of implications associated with this process. First and perhaps most troubling, some patients may be denied care that could be of material benefit. For instance, cases of marginal or discretionary need may be targeted for refusal of treatment, or less costly and less effective treatments may be substituted for more expensive but more effective interventions. As marginal need may become too liberally defined under financial constraints, additional necessary care may be denied.

A second concern raised by inadequate capitation rates is that confidence among patients that the physician is in a position to advocate for their individual needs may be severely undermined. Patients engage in treatment relationships on the assumption that physicians act as advocates for individuals. They cannot assume that all requested treatments will be paid for or even provided, but they can rely upon their physicians to act in a manner that is responsive to their particular needs. Encouraging a physician to deny or alter care for one patient on the basis of the competing needs of another patient will have significant and deleterious effects on the trust that lies at the core of the patient-physician relationship.

MITIGATING ETHICAL CONCERNS AT THE LEVEL OF A CAPITATED PLAN

Because the capitation rate is so pivotal in the ethical analysis of the system, the factors that should be considered when evaluating the size of a capitated payment need to be stated. First, the individual medical needs of enrolled patients should be assessed and accommodated in the capitated plan. This can be accomplished in a number of ways. For example, capitated payments made to each physician can be adjusted according to the general characteristics (age, gender, existing chronic conditions) of the patients represented in his or her practice. In this way, physicians with a disproportionate number of sick patients will be given a slightly larger capitated pool from which to provide appropriate care. Even more simply, the expenses generated by a similar patient population in previous years can be used as a benchmark to establish a capitated rate that will facilitate the provision of necessary care.

The uncertainties of clinical practice preclude the establishment of exact capitation figures and while medical factors and parameters of necessary care are indispensable to the process of setting capitation rates, they can lead to only a close approximation of probable costs. These estimates are superior to rates set on the basis of market economics but still result in risks that the pool will be inadequate to provide all required care. For this reason, additional means to protect patients in a capitated system from the potential effects of budgetary shortfalls need to be considered. For instance, the size of the plan can mitigate or prevent fluctuations in costs that will lead to unpredicted but necessary rationing on the part of the physician. The laws of probability dictate that the expenses incurred by a very large patient population over an extended period of time will consistently approximate a definable average. The Health Care Financing Administration has estimated that the expenses incurred by patient populations in excess of 25,000 members do not vary significantly from year to year. It seems then that spreading financial risk by capitating large pools of patients will reduce variations in the available budget and therefore prevent physicians from having to base their treatment decisions on unforeseen or potential budgetary crises. This approach also improves the ability of plans to predict annual expenses and to set the rate of capitation according to the foreseeable use of resources.

Increasing the number of physicians who are capitated as a group will have a similar effect on the level of financial risk as increasing the size of the patient pool. By providing capitated funds to a large physician group, the

effect of any single treatment decision on the pool of resources is diluted, thereby reducing the incentive to consider potentially competing interests of other patients while providing treatment to individuals. Sharing a capitated pool over a group also promotes the mutual assumption of responsibility for treatment decisions, which in turn promotes peer review between group physicians and reduces the element of individual responsibility for allocation decisions.

The time over which capitation rates are calculated will also affect the accuracy of predicted use and will therefore affect the physician's perception of the impact individual clinical decisions may have on the available budget. Increasing the time period over which resource use is measured greatly increases the probability that excessive costs will be counterbalanced by periods of underutilization. This dissipates the immediacy of the cause and effect relationship between one clinical treatment and the ability to provide other interventions in the future.

Even under ideal circumstances, the capitated physician runs the risk that a small number of patients could require a level of care sufficiently extreme to create a conflict with the interests of other patients covered through the same pool of capitated funds. Most plans and physicians recognize the need for protection against such an occurrence and have provided some form of stop-loss plan. Once a set spending limit is reached, these plans pay the vast majority of costs incurred in treating individual patients. The need for these provisions is underscored by the fact that even the possibility of a catastrophic case could seem sufficiently pervasive to encourage physicians to treat their patients too conservatively in order to preserve funds against such an event. It could also lead plans to identify those patients likely to require such catastrophic care and to discourage or prevent their inclusion in a capitated pool. As neither of these options is acceptable, protection against excessive losses resulting from the treatment of a single patient must be implemented.

MITIGATING ETHICAL CONCERNS ON THE LEVEL OF THE PHYSICIAN

Even with safeguards, physicians have an obligation to determine if the rate of payment is sufficient to provide all necessary care. In previous reports, the Council has established an obligation on the part of physicians to appeal denials of coverage for necessary treatments. Capitated physicians have a corresponding responsibility to appeal for a larger budget if established payments are inadequate to the task of providing care. Similarly, physicians have an obligation to ensure that the pool for which capitated payments apply is sufficiently large to compensate for unpredictable variations in the cost of providing services. As a final protection, physicians should be covered through some form of stop-loss plan.

Assessing the rate of capitation as an individual physician is clearly a difficult task. As a general rule, however, payment systems can be judged in part on the basis of whether or not they are appropriate to discuss with patients. Patients have a right to all information that may impact on the care they receive, including the reimbursement plan under which that care is delivered. Physicians should avoid arrangements that cannot be justified to patients and therefore cannot be disclosed without negatively affecting the patient-physician relationship.

CONCLUSION

Appropriately constructed, capitation can be applied to reduce the costs of health care and further the interests of patients, physicians and the health care system in general. Capitation encourages physicians to act on their obligation to the health of more global populations through increased efficiency and attention to necessary allocation decisions. Even under ideal circumstances, however, providing physicians with a fixed budget not only encourages attention to broader obligations, but also requires physicians to recognize and consider potential conflicts that may exist between patients in the course of clinical care. While it is difficult for capitated physicians to ignore the competing demands of the larger group, they must continue to fulfill their primary obligation to act as single-minded advocates for the needs of each individual patient.

If not carefully constructed, systems of capitation can create conflicts which can in turn impact patient care. If physicians have insufficient funds available to provide all necessary care, plan patients will be placed in

competition for plan resources and the physicians may be forced to evaluate patient need on a relative scale with the intent of minimizing expenditures rather than maximizing quality of care. There is also the possibility that inappropriately designed systems may result in discrimination against the sick. The potential for these conflicts to arise is influenced by a number of factors including the rate of capitation, the size of the patient pool covered by capitated payments, the size of the physician group for whom the pool applies, and the time period over which capitated rates are calculated.

RECOMMENDATIONS

The Council recognizes that the application of capitation to physicians' practices can result in the provision of cost-effective, quality medical care. It is important to note, however, that the potential for conflict exists under such systems. In an effort to minimize these conflicts and to ensure that capitation is applied in a manner consistent with the interests of patients, the Council recommends the following:

1. Physicians have an obligation to evaluate a health plan's capitation payments prior to contracting with that plan to ensure that the quality of patient care is not threatened by inadequate rates of capitation. Capitation payments should be calculated primarily on relevant medical factors, available outcomes data, the costs associated with involved providers, and consensus-oriented standards of necessary care. Furthermore, the predictable costs resulting from existing conditions of enrolled patients should be considered when determining the rate of capitation. Different populations of patients have different medical needs and the costs associated with those needs should be reflected in the per member per month payment. Physicians should seek agreements with plans that provide sufficient financial resources for all necessary care and should refuse to sign agreements that fail in this regard.

2. Physicians must not assume inordinate levels of financial risk and should therefore consider a number of factors when deciding whether or not to sign a provider agreement. The size of the plan and the time period over which the rate is figured should be considered by physicians evaluating a plan as well as in determinations of the per member per month payment. The capitation rate for large plans can be calculated more accurately than for smaller plans because of the mitigating influence of probability and the behavior of large systems. Similarly, length of time will influence the predictability of patient expenditures and should be considered accordingly. Capitation rates calculated for large plans over an extended period of time are able to be more accurate and are therefore preferable to those calculated for small groups over a short time period.

3. Stop-loss plans should be in effect to prevent the potential of catastrophic expenses from influencing physician behavior. Physicians should ensure that such arrangements are finalized prior to signing an agreement to provide services in a health plan.

4. Physicians must be prepared to discuss with patients any financial arrangements which could impact patient care. Physicians should avoid reimbursement systems that cannot be disclosed to patients without negatively affecting the patient-physician relationship.

(References pertaining to Report 4 of the Council on Ethical and Judicial Affairs are available from the Ethical Standards Division Office.)

REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1-5, were presented by Charles W. Plows, MD, Chair:

1. RESTRICTIONS ON DISCLOSURE IN MANAGED CARE CONTRACTS

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED:

INTRODUCTION

The changes that have characterized the movement to reform the country's health care system have presented the medical profession with the task of providing guidelines that reaffirm the ethical absolutes of medicine within the context of new and shifting health care delivery structures. One of the most fundamental of these ethical absolutes is the right of patients to complete information concerning their condition and treatment. In a previous report, the Council included this right in its broader discussion of the ethical issues surrounding managed care, writing in part, "Physicians also should continue to promote full disclosure to patients enrolled in managed care organizations." The Council built on that premise, stating, "The physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's managed care plan."

CLAUSES THAT RESTRICT DISCLOSURE

Despite the unambiguous ethical requirements demanding full disclosure, some managed care organizations include clauses in their employment contracts which directly inhibit the ability of physicians to keep their patients fully informed. These contract clauses, labeled "gag clauses" by some observers, are qualitatively different from other confidentiality clauses designed to protect proprietary information from competitors. While these latter clauses legitimately safeguard business interests, "gag clauses" erect inappropriate barriers to necessary communications between physicians and patients.

Probably the most problematic restrictive language in contracts is found in general statements which prohibit physicians from making statements to patients which could negatively impact their perception of the health plan. For example, one HMO included in its contract the following language: "Physician shall agree not to take any action or make any communication which undermines or could undermine the confidence of enrollees, potential enrollees, their employers, their unions, or the public in (HMO) or the quality of (HMO) coverage." Clauses containing general prohibitions such as this can easily be interpreted to encompass disclosure of treatment options not covered by the contracting plan as such disclosure could cause patients to seek an alternative plan more suitably tailored to their health needs. Because complete disclosure could have economic consequences for a plan by contributing to patient attrition, there is an incentive to restrict the ability of physicians to provide patients with certain information. However, contract language which so prioritizes the financial success of a plan over the right of patients to all relevant medical information cannot be reconciled with the fundamental ethical obligation of physicians to advance the interests of their patients. These contracts also violate the ethical guidelines established by the Council, which demand the disclosure of all treatment options regardless of limitations imposed by plan coverage.

Other restrictive clauses are more specific, designating a particular pathway through which information must pass before reaching patients. Although the language may vary from contract to contract, the system described generally involves a process by which treatment proposals are circulated through some form of utilization review before they are presented to the patient. In effect, physicians who are bound by these contracts require authorization to present treatment options to patients. It stands to reason that because this process exists, the contracting plan anticipates that some proposals will not be authorized and thus not presented. As a result, under this system patients

may not be given all the available treatment options from which to choose the best therapeutic course. This failure to disclose all legitimate therapies is paternalistic, deceptive, and cannot be excused by limitations in coverage. Furthermore, standards of informed consent are impossible to uphold when patients are not given information outlining all the possible treatments.

A final category of restrictive clauses prevents physicians from discussing various plan operations including structures of financial reimbursement and utilization review procedures. The Council previously concluded that systems of reimbursement that include incentives to limit care must be disclosed to patients. In general, the financial structure of a plan as well as the mechanism of its quality assurance program could impact the care a patient receives and should therefore be disclosed by the plan prior to enrollment and clarified by the physician thereafter. The exact level of reimbursement, however, constitutes proprietary information and does not need to be disclosed to patients.

ETHICAL CONCERNS COMMON TO CAUSES RESTRICTING COMMUNICATION

The practice of medicine is dependent upon the capacity of patients to trust their physician. Simply stated, patients cannot fully trust a physician who has a contractual obligation to conceal relevant information. Furthermore, society cannot trust that the medical profession is dedicated to the interests of each individual patient when some physicians are bound to agreements which preclude the fulfillment of even the basic duty of disclosure. Public perception often unfairly projects the constraints of some plans onto all managed care providers and ultimately onto all providers. Consequently, even if the majority of physicians have not signed contracts containing disclosure restrictions, the damage to the public trust rendered by the conflicting obligations of the remaining minority will be profound. The danger of undermining society's confidence in medicine demands the profession's vigorous opposition to these clauses and their inappropriate restrictions.

In addition to the loss of public trust resulting from the enforcement of these contracts, the direct impact of these clauses on those patients enrolled in plans employing restrictions on disclosure must be considered. For instance, patients under the care of physicians whose contractual obligations prevent complete disclosure may follow recommendations for treatment without hearing of other, potentially more effective, options. Even if the plan would not cover other options, it is the right of the patient to seek or utilize alternative means to fund therapies outside of the plan. Perhaps more significantly, these patients will surrender unknowingly their right to fully informed consent and will place their faith in a physician-patient relationship formed and maintained under false pretenses. The importance of maintaining the openness and honesty that form the basis of the physician-patient relationship cannot be overstated and requires the rejection of contract clauses which strike at the very heart of that relationship.

CONCLUSION

The Council has previously written, "The duty of patient advocacy is a fundamental element of the physician-patient relationship that should not be altered by the system of health care delivery in which physicians practice. Physicians must continue to place the interests of their patients first." Whatever the societal implications of "gag clauses" may be, their immediate impact on the ability of physicians to provide information to their patients and to act effectively as a patient advocate is deeply disturbing. Violations of individual and public trust in the profession of medicine are detrimental to the health of society and must be resisted.

RECOMMENDATIONS

To facilitate the continued practice of ethical medicine, the Council on Ethical and Judicial Affairs recommends the following:

1. Managed care organizations have the right to protect proprietary information as long as such protection does not inhibit physicians from disclosing relevant information to patients. Contract

clauses which could be applied to prevent physicians from raising or discussing matters relevant to patients' medical care should be removed to safeguard the health of plan subscribers.

2. The right of patients to be informed of all pertinent medical information must be reaffirmed by the medical profession, and individual physicians must continue to uphold their ethical obligation to disclose such information.

3. Physicians should review their contracts carefully to ensure that there is no possibility that the health of their patients will be jeopardized in any way by clauses that inhibit their ability to fulfill their ethical obligations.

2. ETHICAL USE OF PLACEBO CONTROLS IN CLINICAL TRIALS

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

The House of Delegates adopted Resolution 1, Ethical Use of Placebo Controls, at the Annual Meeting in 1995. That resolution, sponsored by the Young Physicians Section, called upon the American Medical Association to "study the ethical use of placebo controls in studies evaluating drug therapies in those conditions for which effective treatment exists." In response to this charge, the Council on Ethical and Judicial Affairs presents the following examination of the use of placebo controls in circumstances where an accepted therapy is available.

CLINICAL RESEARCH

The advancement of scientific knowledge within the medical community is one of the fundamental duties of all physicians. Scientific research has provided physicians with the means to satisfy their enduring commitment both to individual patient health and the collective health of society. However, clinical investigation relies upon participants who are willing to accept a certain level of risk to facilitate the improvement of medical practice. While the risks involved are generally limited, there are cases where negative outcomes have been severe, thus forcing the scientific community to address concerns that the needs of future patients could take priority over the needs of the patient participants in clinical research.

The Council has examined this issue in previous work and has provided ethical guidelines that protect patients participating in research protocols from undue risk and exploitation in the name of some greater benefit to society. Competent study design, careful implementation and conscientious supervision help to ensure that clinical research satisfies its dual obligation to provide verifiable scientific data and to safeguard the rights of participants.

PLACEBO-CONTROLLED TRIALS

One fundamental requirement of clinical investigation is that it must provide scientifically valid data. In the development of new drugs, trials must therefore be designed with a control capable of allowing investigators to discern the effects of the drug under investigation. One of the best means to fulfill this requirement is to compare an experimental therapy with placebo.

Despite the general support of placebo controls within the scientific community, opponents of this research model have voiced objections. A particularly heated debate erupted when, in 1977, the National Institute of Allergy and Infectious Diseases organized a 22-institution study to determine the efficacy of adenine arabinoside (ara-A) in the treatment of herpes simplex encephalitis, a disease then characterized by a mortality rate of 70 percent. Despite

13. ETHICAL ISSUES IN MANAGED CARE

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

A primary concern of medical ethicists for some time has been the absence of any meaningful analysis of the impact of health care delivery market place changes and current legislative reforms on the essential tenets of the physician-patient relationship. Although President Clinton's original reform proposal addressed in broad terms the ethical imperatives supporting universal access, it left virtually unexamined the more fundamental question of the role of the physician in a reformed system where the incentives are dramatically changed and budgets determine the amount of health care spending and services.

In June 1990, the Council issued a report, Financial Incentives to Limit Care: Financial Implications for HMOs and IPAs, which described the financial incentives that managed care plans offer physicians to limit their provision of care (policy 140.978). The report concluded that patient welfare must of course remain the first concern of physicians working in HMOs and IPAs and that physicians must disclose all relevant financial inducements and contractual restrictions that affect the delivery of health care to patients.

With its emphasis on managed care and managed competition, health care reform will greatly increase the ethical concerns raised by managed care. It is therefore essential that the profession and society act now to ensure that managed care techniques are implemented in a way that protects patients and the integrity of the patient-physician relationship.

In this report, the Council reiterates the physician's commitment to patient welfare first and updates its previous recommendations for physicians. This report discusses in greater detail the potential conflicts of interest faced by physicians practicing in the managed care environment. It then recommends measures to preserve the fundamental duty of physicians as patient advocates by reducing the risk of rationing and inappropriate financial incentives.

BACKGROUND

As health care costs have risen, and calls for more cost conscious health care have been made, health care insurers increasingly have adopted principles of managed care. Several different types of managed care arrangements have gained prominence in the American health care system, including group and staff model health maintenance organizations (HMOs), independent practice associations (IPAs) and preferred provider organizations (PPOs). Fee-for-service plans are also using many of the cost-saving techniques of managed care.

Managed care plans use a number of techniques. Some of them are directed at physician behavior. Others are directed at subscribers to the plan. For example, managed care plans typically encourage subscribers to seek health care when it is still possible to prevent the development of illness by covering a broad range of preventive and primary care services. In addition, they restrict subscribers to panels of physicians who have agreed to accept lower reimbursements or who may have exhibited a history of practicing lower cost care. (Recently, even experienced, highly competent physicians have been separated from their patients in large "deselection" actions by many major plans.) Managed care plans can also control their subscribers' behavior by denying access to the services of medical specialists until the subscriber has obtained the approval of a primary care physician.

Managed care plans constrain the costs of participating physician practices in several ways as well. The plans often restrict the ability of physicians to perform certain procedures or to order certain medications or diagnostic tests. For example, a physician may need the approval of a radiologist before ordering a test, or a managed care plan might exclude some expensive drugs from the plan's formulary. Managed care plans aggressively use programs

of utilization review to detect what they consider unnecessarily costly practice patterns. Sometimes their programs become harassing, intimidating and deceptive.

Managed care plans can also reduce costs by creating economies of scale, by coordinating care among physicians and hospitals, by mandating the use of guidelines or parameters of care and by establishing advanced information systems which provide an improved basis on which to measure quality and efficiency.

Managed care plans also encourage physicians to make cost-conscious treatment decisions through the use of financial incentives. The plans often compensate physicians with capitation fees or a salary. In addition, plans typically employ incentives for physicians to limit their use of diagnostic tests, referrals to other physicians, hospital care or other ancillary services. For example, managed care plans often pay bonuses to physicians, with the amount of the bonus increasing as the plans' expenditures for patient care decrease. Or plans often withhold a fixed percentage of their physicians' compensation until the end of the year to cover any shortfalls in the funds budgeted for expenditures on patient care. If there is no shortfall, or the shortfall can be covered by part of the withheld fees, the remaining withheld fees are returned to the physicians.

While efforts to contain costs are critical and while many of the approaches of managed care have an impact, managed care can compromise the quality and integrity of the patient-physician relationship and reduce the quality of care received by patients. In particular, by creating conflicting loyalties for the physician, some of the techniques of managed care can undermine the physician's fundamental obligation to serve as patient advocate. Moreover, in their zeal to control utilization, managed care plans may withhold appropriate diagnostic procedures or treatment modalities for patients.

THE PATIENT-PHYSICIAN RELATIONSHIP

Before discussing the potential impact of managed care on the patient-physician relationship, it is important to consider what is at stake. The foundation of the patient-physician relationship is the trust that physicians are dedicated first and foremost to serving the needs of their patients. In the Oath of Hippocrates, trust is a central element in almost all of the ethical obligations of physicians: physicians must keep patients' private information confidential, avoid mischief and sexual misconduct, and give no harmful or death-causing agent. Patients can expect that physicians will come to their aid even if it means putting the physician's own health at risk, and they can trust that physicians will do everything in their power to help their patients. It is this trust which enables patients to communicate private information and to place their health, and indeed their lives, in the hands of their physicians. Without trust, the success of the healing process would be seriously diminished.

No other party in the health care system is charged with the responsibility of advocating for patients, and no other party can reasonably be expected to assume the responsibility conscientiously. Physicians care for patients directly, are in the best position to know patients' interests, and can advocate within the health care system for patients' needs. Without the commitment that physicians place patients' interests first and be agents for their patients alone, there is no assurance that the patient's health and well-being will be protected.

ETHICAL CONCERNS

Managed care creates at least two conflicting loyalties for the physician. First, physicians are expected to balance the interests of their patients with the interests of other patients. When deciding whether to order a test or procedure for a patient, the physician must consider whether the slot should be saved for another patient or not used at all to conserve the plan's resources. Second, managed care can place the needs of patients in conflict with the financial interests of their physicians. Managed care plans use bonuses and fee withholds to make physicians cost conscious. As a result, when physicians are deciding whether to order a test, they will recognize that it may have an adverse impact on their income.

Some commentators argue that market forces will ensure that patients are protected from undue conflicts of interest. Because subscribers are theoretically free to choose their managed care organization based on quality of coverage, performance record, and other factors, they can theoretically drive those managed care organizations with the least impressive records out of business. However, it is unlikely that these consumer choices alone will ensure high quality managed care organizations. As stated in a recent editorial, "patient satisfaction depends more on visible amenities and personal relations than on the quality and appropriateness of medical services . . ."

The following two sections address the potential conflicts of interest for physicians under managed care.

1. Conflicts Among Patients

While some cost containment can be achieved by eliminating waste and inefficiency, it is also being achieved by limiting the availability of tests or procedures that offer only small or uncertain benefit, or that provide a likely benefit but at great expense. Because managed care plans generally work within a limited budget, and, increasingly, are for profit companies that compete to report favorable results to shareholders, the cost of a service will influence whether the service is offered to patients who might benefit from it. Allocation rules are developed by the plans to deal with this issue.

Managed care plans can make these allocation decisions in a number of ways: by developing guidelines that determine for a physician when the service should be offered, by instructing physicians to provide medically necessary care and delegating to the physicians the allocation decisions, or by some combination of allocation guidelines, physician discretion, and oversight.

An example of an allocation decision might involve the use of high osmolar contrast media (HOCM) and low osmolar contrast media (LOCM) in diagnostic imaging procedures. Both HOCMs and LOCMs produce images of similar quality and both are approved by the FDA as safe and effective. Adverse reactions, including "changes in cardiac performance, alterations in renal functions, depression of the central nervous system, pain at the site of injection, flushing, nausea and vomiting," are somewhat more likely with the use of HOCMs. In addition, fatal adverse reactions with either media are extremely rare and no more likely with HOCMs than LOCMs. However, there is a significant difference in the cost of the two media: LOCMs are considerably more expensive than HOCMs. Where a peripheral arteriography procedure would use about $10 of HOCM, the same procedure would use about $180 of LOCM, an increase of 18 times the HOCM cost.

It is not obvious which contrast medium should be used. In fact, the decision to use HOCM or LOCM is essentially a value judgment about the relative costs and benefits of the two different media. While medical expertise is necessary to determine what benefits and risks are associated with the two media, the weighing of those benefits and risks with financial costs is not simply a medical decision but also a social judgment about the value of spending additional resources to lower health risks in this manner.

A more difficult allocation case involves the use of bone marrow transplants for certain kinds of advanced cancer. The stakes for the patient are high – a prolonged life if successful – but the costs are great and the likelihood of success uncertain. Some plans will restrict or discourage the treatment, others may make it available under some circumstances.

a. Ethical Problems with "Bedside Rationing"

Physicians make cost benefit judgments every day as a part of their professional responsibility in treating patients. It is unethical to knowingly provide unnecessary care or to be wasteful in providing needed care. Except to the extent that the liability system causes them to behave defensively in certain situations, physicians in general make fair and appropriate cost benefit judgments. It has been demonstrated that, even in an exclusively fee-for-service system, physicians overall respond properly to credible information about the effectiveness of their practices. A primary problem has been good data.

Allocation judgments about costs and services that approach a "rationing" decision – the denial of a procedure that benefits a patient – are not part of the physician's traditional role and, indeed, conflict with it. Although physicians have traditionally served as de facto gatekeepers to the health care system, overseeing the public's use of medical care, the cost primacy environment of managed care significantly complicates this role. As Pellegrino has written, "This [gatekeeper] role is morally dubious because it generates a conflict between the responsibilities of the physician as a primary advocate of the patient and as guardian of society's resources." While this responsibility to guard society's resources is an important one, physicians must remain primarily dedicated to the health care needs of their individual patients.

The primary care physician's role in managed care illustrates the ethical problems associated with bedside rationing. The physician-gatekeeper determines whether the patient will be granted further access to the health care system, including referrals to specialists and diagnostic tests. At the same time, the physician is required by rules and encouraged by incentives to be aware of the overall financial limitations of the managed care entity for which he or she works. The physician knows that there are other patients who have subscribed to the managed care plan to whom is owed a certain level of health care. These competing concerns mean that a patient's further treatment depends not only on the physician's judgment about the legitimacy of that patient's present medical need but also on the relative weight of that need in comparison with the organization's need to serve all patients and control costs. Inconsistent and uninformed decisions are inevitable.

The primary care physician has the greatest responsibility within the managed care organization to assess the seriousness of patients' conditions accurately. A keen understanding of common and uncommon health problems is therefore required, as it is of all primary care physicians. However, the pressures of cost containment may encourage some physicians to try to manage cases longer than they should. Physicians may feel compelled to stretch their competence in order to keep patients at the primary care level and conserve resources. Inappropriate treatment and improper or missed diagnoses are potential outcomes of such decisions to delay or deny referral.

b. Preserving the Physician's Role

The physician is obligated to provide or recommend treatment when the physician believes that the treatment will materially benefit the patient and not to withhold the treatment to preserve the plan's resources. Physicians should not engage in bedside rationing.

But many allocation rules are within arguable ranges or grey areas of at least minimally acceptable treatment. There are two steps to reducing physician/patient conflict in these circumstances. First, physicians should contribute their expertise in the development of the guidelines and should advocate for the consideration of differences among patients. For example, it might be advisable for a certain group of patients at high risk to be offered LOCM while others who do not fall in this group to be offered HOCM. Physicians can help to ensure that all medically relevant information is considered and that no group of patients is put at an unfair disadvantage.

Second, and most importantly, even if the use of the LOCM were prohibited by a guideline for all or a particular class of patients, it remains the physician's duty to recommend its use and to advocate for the patient's right to the treatment in any case where material benefit to a particular patient would result.

The structure through which physicians offer their expertise in policy-level decisions is very important. To help define this structure, the American Medical Association recently proposed legislation which would require managed care organizations to establish a medical staff structure, much like that in existence in every hospital in the United States. This proposal includes a governing board for the managed care organization that would include at least three physician members as representatives of participating physicians, and a medical board composed entirely of participating physicians. Physicians on the medical board would be responsible for periodically reviewing restrictions on services to subscribers and other issues related to health care coverage. They would also review quality of care and physician credentialing on a periodic basis and disclose their review criteria to subscribers. The governing board

would be ultimately responsible for the activities of the managed care organization, but participating physicians would have formal mechanisms for input and responsibilities on crucial medical practice issues.

In addition to the physician's role in making rationing decisions, there is an equally critical role for patients. The decision-making process should include some mechanism for taking into account the preferences and values of the people whom the rationing decisions will most directly affect. Accurate and full disclosure is most important. In addition, a managed care organization could use "town meetings" and other mechanisms whereby subscribers could voice their preferences or "vote" on what treatments should be included in their benefits package.

Once guidelines and criteria are developed at the policy level, physicians are free to make clinical decisions based on those guidelines and criteria. For example, if a managed care plan decided to offer LOCM only to patients at high risk for an adverse reaction to HOCM, physicians would decide which patients are at the high risk.

In addition to the development of appropriate procedures for making allocation decisions, there are other steps that must be taken to protect patient welfare when the allocation procedures are implemented. For example, as part of the process of giving patients informed consent to treatment, physicians should disclose all available treatment alternatives, regardless of cost, including those potentially beneficial treatments which are not offered under the terms of the plan. As described in the Council's report on financial incentives to limit care, obligations of disclosure always apply to the physician practicing in managed care. With full understanding of the limitations affecting their treatment, patients will have the opportunity to make alternative arrangements for care that is not available in their health plan.

It is also critical for managed care plans to have a well-structured appeals process through which physicians and patients can challenge the denial of a particular diagnostic test or therapeutic procedure. Such a process should afford the physician an opportunity to advocate on the patient's behalf before the plan's medical board or governing board. Appeals mechanisms for treatment denials are essential because policy-level allocation decisions can never fully account for all contingencies, and will sometimes underserve individual patients. Managed care plans, as institutions, have an ethical responsibility to allow patients to challenge treatment decisions that directly affect their health and well-being.

In some circumstances, as noted above, physicians have an obligation to initiate appeals on behalf of their patients. Cases may arise in which a health plan has an allocation guideline that is generally fair but in particular circumstances results in unfair denials of care, i. e., denial of care that would materially benefit the patient. In such cases, the physician's duty as patient advocate requires that the physician challenge the denial and argue for the provision of treatment in the specific case. Cases may also arise when a health plan has an allocation guideline that is generally unfair in its operation. In such cases, the physician's duty as patient advocate requires not only a challenge to any denials of treatment from the guideline but also advocacy at the health plan's policy-making level to seek an elimination or modification of the guideline.

2. Conflicts Between Physician and Patient

a. Ethical Problems with Financial Incentives to Limit Care

As discussed above, managed care plans encourage physicians to be more cost conscious by using bonuses, fee withholds and other financial incentives to limit care. With these incentives, physicians recognize that they may reduce their income when they order tests, hospitalize patients or provide other services. The incentives are not inherently unethical, but they can be depending on their design and intensity.

There are two important ways in which financial incentives to limit care compromise the physician's duty of loyalty to patient care. First, physicians have an incentive to cut corners in their patient care, by temporizing too

long, eschewing extra diagnostic tests, or refraining from an expensive referral. Several studies have tried to measure the health outcomes of patients in managed care or pre-paid settings against the health outcomes of patients in fee-for-service arrangements. Although disturbing anecdotes abound, these studies have found largely mixed results: harm or inadequate health outcomes have not been conclusively demonstrated in managed care arrangements, though these patients may be at an increased risk of harm. Second, even in the absence of actual patient harm, the incentives may erode patient trust as patients wonder whether they are receiving all necessary care or are being denied care because of the physicians' pecuniary concerns.

Physicians must place patients' interests ahead of their own interests, including financial remuneration. It is true that financial conflicts are inherent in the practice of medicine, regardless of the system of delivery, and that physicians generally have been able to maintain their duty to patient welfare despite those conflicts. However, incentives to limit care are more problematic than incentives to provide care.

First, financial incentives to limit care exploit the financial motive of physicians, making the physician's financial self-interest indispensable for the success of the managed care organization. Second, financial incentives to limit care are less likely than financial incentives created by fee-for-service to coincide with patients' interests, because patients generally prefer the risk of too much care to the risk of too little care. Third, the effects of incentives to limit care are less likely to be noticed by patients. When a physician recommends a course of action under fee-for-service reimbursement, the patient can seek a second opinion. However, when a physician does not offer an intervention under managed care, the patient may have no idea that a treatment option was withheld and therefore not recognize the need for a second opinion.

Not all financial incentives to limit care create the same conflict of interest between the physician's and patient's interests. In general, the greater the strength of the incentive, the more likely it will create a serious conflict of interest which could lead to patient harm. The strength of a financial incentive to limit care can be judged by various factors, including the percentage of the physician's income placed at risk, the frequency with which incentive payments are calculated, and the size of the group of physicians upon which the economic performance is judged.

If the managed care plan places 30 percent of a physician's income at risk, the physician will be much more conscious of costs than if the plan places 5 percent of income at risk. Similarly, if a physician's incentive payments are based solely on his or her treatment decisions, there is a strong incentive to limit services for each patient. When payments are based on the performance of a group of physicians, on the other hand, the incentive is diminished. When physicians are placed at risk together, they have an incentive to ensure that their colleagues are practicing in a cost-effective manner and the incentive payments will be based on costs incurred by a large patient pool. When the patient panel is small, there is a risk that treatment costs will be skewed by an unrepresentative group of patients that have unusually high needs for medical care.

The strength of a financial incentive can also vary with the frequency of incentive payments. If payments are made on a monthly basis rather than a yearly basis, the physician receives rapid feedback on the economic consequences of treatment decisions and is therefore likely to be more sensitive to those consequences. In addition, when incentives are calculated on a monthly basis, there is less of an opportunity for the costs of cases that are above average to be offset by the costs of cases that are below average. Accordingly there is a stronger incentive not to incur unusually high expenses in any one case.

b. Preserving the Physician's Role

The most effective way to eliminate inappropriate conflicts is to create the use of financial incentives based on quality rather than quantity of services. Reimbursement that serves to promote a standard of "appropriate" behavior helps to maintain the goals of professionalism. Unlike incentives based on quantity of services, which punish the provision of both appropriate and inappropriate services, incentives based on quality of care punish only inappropriate services.

Judgments about the quality of a physician's practice should reflect several measures. First, it is essential to consider objective outcomes data, including data about mortality and morbidity, corrected for caseload. Second, because outcomes are often beyond the physician's control, it is important to consider the degree to which the physician adheres to practice guidelines or other standards of care. Third, patient satisfaction should be considered. Although patients are limited in their ability to evaluate physician competence, they are the best judges of one critical quality of physician care, the physician's "bedside manner." In addition, patient satisfaction reflects the extent to which the physician has accommodated the goals of the patient, as required by the patient's right to exercise self-determination in medical care. Fourth, the judgment of a physician's peers generally reflects the best available assessment of quality.

Because measurements of quality are still in the rudimentary stages of development, it is important to ensure that other safeguards are in place to prevent abuse from incentives based on quantity of care. Reasonable limits should be placed on the extent to which a physician's ordering of services can affect his or her income. For example, quantitative financial incentives should be calculated on groups of physicians rather than individual physicians.

PATIENT AUTONOMY AND RESPONSIBILITY

Many commentators argue that managed care threatens patient autonomy because it curtails patients' freedom of choice. Patients are usually limited in their choice of primary care physicians and, to a much greater degree, specialists, and they are sometimes limited in their choice of treatments. Patients may not be able to receive a desired diagnostic test or referral, and their freedom to personally tailor treatment can be thwarted. In addition, continuity of care be may disrupted if a patient is forced, for a variety of reasons, to change physicians in order to keep their health care benefits.

Public participation in the formulation of benefits packages may resolve some of these concerns about limited autonomy. Legislation reasonably protecting patients' rights to be informed and to choose, and protecting physicians' rights to remain professionals, is also essential. Patients can exercise their autonomy by participating in the decisions of their health plan or in government processes that may restrict their choices or their benefits. In addition, patients have a responsibility to learn as much as they can about the choices of plans before them, including the exact nature of the different benefits packages and their limitations. Patients have a responsibility to make sure they know and understand the terms of their own health care plan.

As patient advocates, physicians continue to have duties of disclosure. They must ensure that all treatment alternatives, regardless of cost, are disclosed. They must also ensure that the managed care organization has fulfilled its obligation to disclose the terms of the benefits package, including all limitations and restrictions.

Patient autonomy does not guarantee the right to have all treatment choices funded. Some limits on personal freedom are inevitable in a society which tries to provide all of its members with adequate health care. The desire for accurate diagnosis and use of high tech medical care, no matter how little the benefit, has been cited as a major factor in health care costs in this country. Moreover, patient autonomy entails patient responsibility, including a responsibility to abide by societal decisions to conserve health care and to make an individual effort to use resources wisely and lead a healthy lifestyle.

While physicians must remain patient advocates, patients do not have an unlimited claim to physicians' obligation to provide health care. Physicians should not manipulate or "game" the system in order to answer patients' demands.

In order to fully exercise their autonomy, patients need to be fully informed about the philosophy and goals of managed care. In an earlier report, the Council stated that the physician's responsibilities under managed care include a duty to disclose to the patient conflicts of interest that may affect patient care and medical alternatives that

cannot be offered because of the restrictions of the managed care plan. That report specifically states that physicians have a duty to disclose financial incentives; a duty to disclose contractual agreements restricting referral; and a duty to ensure that the managed care plan makes adequate disclosure of the details of the plan to subscribers.

RECOMMENDATIONS

For the reasons described in this report, the Council on Ethical and Judicial Affairs recommends that the following guidelines be adopted:

1. The duty of patient advocacy is a fundamental element of the physician-patient relationship that should not be altered by the system of health care delivery in which physicians practice. Physicians must continue to place the interests of their patients first.

2. When managed care plans place restrictions on the care that physicians in the plan may provide to their patients, the following principles should be followed:

   (a) Any broad allocation guidelines that restrict care and choices – which go beyond the cost/benefit judgments made by physicians as a part of their normal professional responsibilities – should be established at a policy making level so that individual physicians are not asked to engage in ad hoc bedside rationing.

   (b) Regardless of any allocation guidelines or gatekeeper directives, physicians must advocate for any care they believe will materially benefit their patients.

   (c) Physicians should be given an active role in contributing their expertise to any allocation process and should advocate for guidelines that are sensitive to differences among patients. Managed care plans should create structures similar to hospital medical staffs that allow physicians to have meaningful input into the plan's development of allocation guidelines. Guidelines for allocating health care should be reviewed on a regular basis and updated to reflect advances in medical knowledge and changes in relative costs.

   (d) Adequate appellate mechanisms for both patients and physicians should be in place to address disputes regarding medically necessary care. In some circumstances, physicians have an obligation to initiate appeals on behalf of their patients. Cases may arise in which a health plan has an allocation guideline that is generally fair but in particular circumstances results in unfair denials of care, i. e., denial of care that, in the physician's judgment, would materially benefit the patient. In such cases, the physician's duty as patient advocate requires that the physician challenge the denial and argue for the provision of treatment in the specific case. Cases may also arise when a health plan has an allocation guideline that is generally unfair in its operation. In such cases, the physician's duty as patient advocate requires not only a challenge to any denials of treatment from the guideline but also advocacy at the health plan's policy-making level to seek an elimination or modification of the guideline.

   Physicians should assist patients who wish to seek additional, appropriate care outside the plan when the physician believes the care is in the patient's best interests.

(e) Managed care plans must adhere to the requirement of informed consent that patients be given full disclosure of material information. Full disclosure requires that managed care plans inform potential subscribers of limitations or restrictions on the benefits package when they are considering entering the plan.

(f) Physicians also should continue to promote full disclosure to patients enrolled in managed care organizations. The physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's managed care plan. Full disclosure includes informing patients of all of their treatment options, even those that may not be covered under the terms of the managed care plan. Patients may then determine whether an appeal is appropriate, or whether they wish to seek care outside the plan for treatment alternatives that are not covered.

(g) Physicians should not participate in any plan that encourages or requires care at below minimum professional standards.

3. When physicians are employed or reimbursed by managed care plans that offer financial incentives to limit care, serious potential conflicts are created between the physicians' personal financial interests and the needs of their patients. Efforts to contain health care costs should not place patient welfare at risk. Thus, financial incentives are permissible only if they promote the cost-effective delivery of health care and not the withholding of medically necessary care.

   (a) Any incentives to limit care must be disclosed fully to patients by plan administrators upon enrollment and at least annually thereafter.

   (b) Limits should be placed on the magnitude of fee withholds, bonuses and other financial incentives to limit care. Calculating incentive payments according to the performance of a sizable group of physicians rather than on an individual basis should be encouraged.

   (c) Health plans or other groups should develop financial incentives based on quality of care. Such incentives should complement financial incentives based on the quantity of services used.

4. Patients have an individual responsibility to be aware of the benefits and limitations of their health care coverage. Patients should exercise their autonomy by public participation in the formulation of benefits packages and by prudent selection of health care coverage that best suits their needs.

(References pertaining to Report 13 of the Council on Ethical and Judicial Affairs are available from the Office of the General Counsel.)