

11.2.1 Professionalism in Health Care Systems

Containing costs, promoting high-quality care for all patients, and sustaining physician professionalism are important goals. Models for financing and organizing the delivery of health care services often aim to promote patient safety and to improve quality and efficiency. However, they can also pose ethical challenges for physicians that could undermine the trust essential to patient-physician relationships.

Payment models and financial incentives can create conflicts of interest among patients, health care organizations, and physicians. They can encourage undertreatment and overtreatment, as well as dictate goals that are not individualized for the particular patient.

Structures that influence where and by whom care is delivered—such as accountable care organizations, group practices, health maintenance organizations, and other entities that may emerge in the future—can affect patients' choices, the patient-physician relationship, and physicians' relationships with fellow health care professionals.

Formularies, clinical practice guidelines, decision support tools that rely on augmented intelligence, and other mechanisms intended to influence decision making, may impinge on physicians' exercise of professional judgment and ability to advocate effectively for their patients, depending on how they are designed and implemented.

Physicians in leadership positions within health care organizations and the profession should:

- (a) Ensure that decisions to implement practices or tools for organizing the delivery of care are transparent and reflect input from key stakeholders, including physicians and patients.
- (b) Recognize that over reliance on financial incentives or other tools to influence clinical decision making may undermine physician professionalism.
- (c) Ensure that all such tools:
 - (i) are designed in keeping with sound principles and solid scientific evidence.
 - a. Financial incentives should be based on appropriate comparison groups and cost data and adjusted to reflect complexity, case mix, and other factors that affect physician practice profiles.
 - b. Practice guidelines, formularies, and similar tools should be based on best available evidence and developed in keeping with ethics guidance.
 - c. Clinical prediction models, decision support tools, and similar tools such as those that rely on AI technology must rest on the highest-quality data and be independently validated in relevantly similar populations of patients and care settings.
 - (ii) are implemented fairly and do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities;
 - (iii) are implemented in conjunction with the infrastructure and resources needed to support high-value care and physician professionalism;

- (iv) mitigate possible conflicts between physicians' financial interests and patient interests by minimizing the financial impact of patient care decisions and the overall financial risk for individual physicians.
- (d) Encourage, rather than discourage, physicians (and others) to:
 - (i) provide care for patients with difficult to manage medical conditions;
 - (ii) practice at their full capacity, but not beyond.
- (e) Recognize physicians' primary obligation to their patients by enabling physicians to respond to the unique needs of individual patients and providing avenues for meaningful appeal and advocacy on behalf of patients.
- (f) Ensure that the use of financial incentives and other tools is routinely monitored to:
 - (i) identify and address adverse consequences;
 - (ii) identify and encourage dissemination of positive outcomes.

All physicians should:

- (g) Hold physician-leaders accountable to meeting conditions for professionalism in health care systems.
- (h) Advocate for changes in how the delivery of care is organized to promote access to high-quality care for all patients.

AMA Principles of Medical Ethics: I,II III,V

Opinion 11.2.1, Professionalism in Health Care Systems, reorganizes guidance from multiple sources as follows:

CEJA Report 2-N-21 1.2.1, "Professionalism in Health Care Systems"

CEJA Report 5-I-13 Professionalism in health care systems

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

CEJA Report 2-I-03 Professionalism & contractual relations

CEJA Report 3-A-02 Cost Containment Involving Prescription Drugs in Health Care Plans, *Amendment*

CEJA Report 6-A-02 Financial Incentives & the Practice of Medicine, *Amendment*

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

CEJA Report 1-I-97 Financial incentives & the practice of medicine

CEJA Report 4-A-97 Ethical implications of capitation

CEJA Report 2-A-95 Managed care cost containment involving prescription drugs

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

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 02-N-21

Subject: Amendments to Opinions 1.2.11, “Ethical Innovation in Medical Practice”; 11.1.2, “Physician Stewardship of Health Care Resources”; 11.2.1, “Professionalism in Health Care Systems”; and 1.1.6, “Quality”

Presented by: Alexander M. Rosenau, DO, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws

As the Council on Ethical and Judicial Affairs noted in its recent informational report on augmented intelligence (AI) in medicine:

AI systems represent the latest in a long history of innovations in medicine. Like many new technologies before them, AI-based innovations challenge how physicians practice and how they interact with patients at the same time that these innovations offer promises to promote medicine’s Quadruple Aim of enhancing patient experience, improving population health, reducing cost, and improving the work life of health care professionals [1].

At the same time, several characteristics distinguish AI-enabled innovations from other innovations in medicine in important ways. The data-driven machine-learning algorithms that drive clinical AI systems have the potential to replicate bias in the data sets on which they are built and exacerbate inequities in quality of care and patient outcomes. The most powerful, and useful, models are “black boxes” that have the capacity to evolve outside of human observation and independent of human control. Moreover, the design, development, deployment, and oversight diffuse accountability over multiple stakeholders who have differing forms of expertise, understandings of professionalism, and diverging goals.

Published analyses of ethical challenges presented by AI in multiple domains have converged around a core set of goals [2,3,4]:

- Protecting the privacy of data subjects and the confidentiality of personal information
- Ensuring that AI systems are safe for their intended use(s)
- Designing systems of accountability that are sensitive to the roles different stakeholders play in the design, deployment, performance, and outcomes of AI systems
- Maximizing the transparency and explainability of AI systems
- Promoting justice and fairness in the implementation and outcomes of AI systems
- Maintaining meaningful human control of AI technologies
- Accommodating human agency in AI-supported decision making/the use of AI

Realizing these goals for any AI system, in medicine or other domains, will be challenging. As the Gradient Institute notes in its report, Practical Challenge for Ethical AI, AI systems “possess no

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intrinsic moral awareness or social context with which to understand the consequences of their actions. To build ethical AI systems, designers must meet the technical challenge of explicitly integrating moral considerations into the objectives, data and constraints that govern how AI systems make decisions” [5]. Developers must devise mathematical expressions for concepts such as “fairness” and “justice” and specify acceptable balances among competing objectives that will enable an algorithm to approximate human moral reasoning. They must design systems in ways that will align the consequences of the system’s actions with the ethical motivation for deploying the system. And oversight must meaningfully address “the problem of many hands” in ascribing responsibility with respect to AI systems [6].

GUIDANCE IN THE AMA CODE OF MEDICAL ETHICS

Policies adopted by the AMA House of Delegates address issues of thoughtful AI design ([H-480.940](#), “Augmented Intelligence in Health Care”) and matters of oversight, payment and coverage, and liability ([H-480.939](#)). Policy [H-295.857](#) addresses issues of AI in relation to medical education. AMA has further developed a framework for trustworthy AI in medicine that speaks broadly to the primacy of ethics, evidence, and equity as guiding considerations for the design and deployment of AI systems in health care and the interplay of responsibilities among multiple stakeholders [7].

The introduction of AI systems in medicine touches on multiple issues of ethics that are currently addressed in the AMA *Code of Medical Ethics*. These include quality of care, innovation in medical practice, stewardship of health care resources, and professionalism in health care systems, as well as privacy.

The *Code* grounds the professional ethical responsibilities of physicians in medicine’s fundamental commitment of fidelity to patients. As [Opinion 1.1.1](#) notes:

The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians’ ethical responsibility to place patients’ welfare above the physician’s own self-interest or obligations to others, to use sound medical judgment on patients’ behalf, and to advocate for patients’ welfare.

From the perspective of professional ethics, securing this commitment should equally inform medicine’s response to emerging AI-enabled tools for clinical care and health care operations.

Guidance in [Opinion 1.2.11](#), “Ethical Innovation in Medical Practice,” calls on individuals who design and deploy innovations to ensure that they uphold the commitment to fidelity by serving the goals of medicine as a priority. It directs innovators to ensure that their work is scientifically well grounded and prioritizes the interests of patients over the interests of other stakeholders. Opinion 1.2.11 further recognizes that ensuring ethical practice in the design and introduction of innovations does not, indeed cannot, rest with physicians alone; health care institutions and the profession have significant responsibilities to uphold medicine’s defining commitment to patients.

[Opinion 11.2.1](#), “Professionalism in Health Care Systems,” defines the responsibilities of leaders in health care systems to promote physician professionalism and to ensure that mechanisms adopted to influence physician decision making are “designed in keeping with sound principles and solid scientific evidence,” deployed fairly so that they “do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities.” It similarly recognizes that institutional

1 leaders should ensure that when these mechanisms are deployed they are monitored to identify and
2 respond to the effects they have on patient care.

3
4 Individual physicians, and the institutions within in which they practice, have a responsibility to be
5 prudent stewards of the shared societal resources entrusted to them, addressed in [Opinion 11.1.2](#),
6 “Physician Stewardship of Health Care Resources.” Even as they prioritize the needs and welfare
7 of their individual patients, physicians have a responsibility to promote public health and access to
8 care. They fulfill that responsibility by choosing the course of action that will achieve the
9 individual patient’s goals for care in the least resource intensive way feasible.

10
11 Finally, as [Opinion 1.1.6](#), “Quality,” directs, all physicians share a responsibility for promoting and
12 providing care that is “safe, effective, patient centered, timely, efficient, and equitable.” This
13 should be understood to include a responsibility to adopt AI systems that have been demonstrated
14 to improve quality of care and patients’ experience of care.

15
16 For the most part, individual physicians will be consumers of AI systems developed by others. As
17 individual end users, physicians cannot reasonably be expected to have the requisite expertise or
18 opportunity to evaluate AI systems. They must rely on their institutions, or the vendors from whom
19 they purchase AI systems, to ensure that those systems are trustworthy.

20
21 Nonetheless, physicians do have an important role to play in promoting fair, responsible use of
22 well-designed AI systems in keeping with responsibilities already delineated in the AMA *Code of*
23 *Medical Ethics* noted above. Their voice must be heard in helping to hold other stakeholders
24 accountable for ensuring that AI systems, like other tools, support the goals and values that define
25 the medical profession and to which individual practitioners are held. CEJA Report 4-JUN-21
26 outlines the kinds of assurances physicians should be able to expect from their institutions when a
27 given AI system is proposed or implemented.

28 29 CONCLUSION

30
31 AI systems are already a fact of life in medicine and other domains; it would be naïve to imagine
32 there will not be further rapid evolution of these technologies. Fidelity to patients requires that
33 physicians recognize the ways in which AI systems can improve outcomes for their patients and the
34 community and enhance their own practices. They should be willing to be reflective, critical
35 consumers of well-designed AI systems, recognizing both the potential benefits and the potential
36 downsides of using AI-enable tools to deliver clinical care or organize their practices.

37
38 The fact that existing guidance in the AMA *Code of Medical Ethics* already addresses fundamental
39 issues of concern noted above, coupled with the pace and scope of continuing evolution of AI
40 technologies, the council concludes that developing guidance specifically addressing augmented
41 intelligence in health care is not the most effective response. Rather, the council believes that
42 amending existing guidance to more clearly encompass AI will best serve physicians and the
43 patients they care for.

44
45 As the council noted in CEJA Report 4-JUN-21, the implications of AI technologies, and more
46 specifically, the exploitation of “big data” to drive improvements in health care, carries significant
47 implications for patient privacy and confidentiality that warrant separate consideration. The council
48 intends to address those implications separately in future deliberations.

RECOMMENDATION

In light of the foregoing, the Council on Ethical and Judicial Affairs recommend that Opinion 1.2.11, “Ethically Sound Innovation in Medical Practice”; Opinion 11.2.1, “Professionalism in Health Care Systems”; Opinion 11.1.2, “Physician Stewardship of Health Care Resources”; and Opinion 1.1.6, “Quality,” be amended as follows and the remainder of this report be filed:

1. Opinion 1.2.11, Ethically Sound Innovation in Clinical Practice

Innovation in medicine can span a wide range of activities. ~~From~~ It encompasses not only improving an existing intervention, to introducing an innovation in one’s own clinical practice for the first time, to using an existing intervention in a novel way, or translating knowledge from one clinical context into another but also developing or implementing new technologies to enhance diagnosis, treatment, and health care operations. Innovation shares features with both research and patient care, but it is distinct from both.

When physicians participate in developing and disseminating innovative practices, they act in accord with professional responsibilities to advance medical knowledge, improve quality of care, and promote the well-being of individual patients and the larger community. Similarly, these responsibilities are honored when physicians enhance their own practices by expanding the range of tools, techniques, and or interventions they offer to patients employ in providing care.

Individually, physicians who are involved in designing, developing, disseminating, or adopting innovative modalities should:

- (a) Innovate on the basis of sound scientific evidence and appropriate clinical expertise.
- (b) Seek input from colleagues or other medical professionals in advance or as early as possible in the course of innovation.
- (c) Design innovations so as to minimize risks to individual patients and maximize the likelihood of application and benefit for populations of patients.
- (d) Be sensitive to the cost implications of innovation.
- (e) Be aware of influences that may drive the creation and adoption of innovative practices for reasons other than patient or public benefit.

When they offer existing innovative diagnostic or therapeutic services to individual patients, physicians must:

- (f) Base recommendations on patients’ medical needs.
- (g) Refrain from offering such services until they have acquired appropriate knowledge and skills.
- (h) Recognize that in this context informed decision making requires the physician to disclose:
 - (i) how a recommended diagnostic or therapeutic service differs from the standard therapeutic approach if one exists;

- 1 (ii) why the physician is recommending the innovative modality;
- 2
- 3 (iii) what the known or anticipated risks, benefits, and burdens of the recommended therapy
- 4 and alternatives are;
- 5
- 6 (iv) what experience the professional community in general and the physician individually
- 7 has had to date with the innovative therapy;
- 8
- 9 (v) what conflicts of interest the physician may have with respect to the recommended
- 10 therapy.
- 11

- 12 (i) Discontinue any innovative therapies that are not benefiting the patient.
- 13
- 14 (j) Be transparent and share findings from their use of innovative therapies with peers in some
- 15 manner. To promote patient safety and quality, physicians should share both immediate or
- 16 delayed positive and negative outcomes.
- 17

18 To promote responsible innovation, health care institutions and the medical profession should:

- 19
- 20 (k) Ensure that innovative practices or technologies that are made available to physicians meet
- 21 the highest standards for scientifically sound design and clinical value.
- 22
- 23 (kl) Require that physicians who adopt ~~innovative treatment or diagnostic techniques~~
- 24 innovations into their practice have ~~appropriate~~ relevant knowledge and skills.
- 25
- 26 (lm) Provide meaningful professional oversight of innovation in patient care.
- 27
- 28 (mn) Encourage physician-innovators to collect and share information about the resources
- 29 needed to implement their ~~innovative therapies~~ innovations safely, effectively, and
- 30 equitably.
- 31

32 2. Opinion 11.2.1, Professionalism in Health Care Systems

33
34 Containing costs, promoting high-quality care for all patients, and sustaining physician
35 professionalism are important goals. Models for financing and organizing the delivery of health
36 care services often aim to promote patient safety and to improve quality and efficiency.
37 However, they can also pose ethical challenges for physicians that could undermine the trust
38 essential to patient-physician relationships.

39
40 Payment models and financial incentives can create conflicts of interest among patients, health
41 care organizations, and physicians. They can encourage undertreatment and overtreatment, as
42 well as dictate goals that are not individualized for the particular patient.

43
44 Structures that influence where and by whom care is delivered—such as accountable care
45 organizations, group practices, health maintenance organizations, and other entities that may
46 emerge in the future—can affect patients’ choices, the patient-physician relationship, and
47 physicians’ relationships with fellow health care professionals.

48
49 Formularies, clinical practice guidelines, decision support tools that rely on augmented
50 intelligence, and other ~~tools~~ mechanisms intended to influence decision making, may impinge

on physicians' exercise of professional judgment and ability to advocate effectively for their patients, depending on how they are designed and implemented.

Physicians in leadership positions within health care organizations and the profession should ~~ensure that practices for financing and organizing the delivery of care:~~

- (a) Ensure that decisions to implement practices or tools for organizing the delivery of care
~~Are transparent and reflect input from key stakeholders, including physicians and patients.~~
- (b) ~~Reflect input from key stakeholders, including physicians and patients.~~
- (b) Recognize that over reliance on financial incentives or other tools to influence clinical decision making may undermine physician professionalism.
- (c) Ensure ~~ethically acceptable incentives~~ that all such tools:
 - (i) are designed in keeping with sound principles and solid scientific evidence.
 - a. Financial incentives should be based on appropriate comparison groups and cost data and adjusted to reflect complexity, case mix, and other factors that affect physician practice profiles.
 - b. Practice guidelines, formularies, and ~~other~~ similar tools should be based on best available evidence and developed in keeping with ethics guidance.
 - c. Clinical prediction models, decision support tools, and similar tools such as those that rely on AI technology must rest on the highest-quality data and be independently validated in relevantly similar populations of patients and care settings.
 - (ii) are implemented fairly and do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities;
 - (iii) are implemented in conjunction with the infrastructure and resources needed to support high-value care and physician professionalism;
 - (iv) mitigate possible conflicts between physicians' financial interests and patient interests by minimizing the financial impact of patient care decisions and the overall financial risk for individual physicians.
- (d) Encourage, rather than discourage, physicians (and others) to:
 - (i) provide care for patients with difficult to manage medical conditions;
 - (ii) practice at their full capacity, but not beyond.
- (e) Recognize physicians' primary obligation to their patients by enabling physicians to respond to the unique needs of individual patients and providing avenues for meaningful appeal and advocacy on behalf of patients.

1 (f) ~~Are~~ Ensure that the use of financial incentives and other tools is routinely monitored to:

2
3 (i) identify and address adverse consequences;

4
5 (ii) identify and encourage dissemination of positive outcomes.

6
7 All physicians should:

8
9 (g) Hold physician-leaders accountable to meeting conditions for professionalism in health
10 care systems.

11
12 (k) Advocate for changes ~~in health care payment and delivery models~~ how the delivery of care
13 is organized to promote access to high-quality care for all patients.

14
15 3. Opinion 11.1.2, Physician Stewardship of Health Care Resources

16
17 Physicians' primary ethical obligation is to promote the well-being of individual patients.
18 Physicians also have a long-recognized obligation to patients in general to promote public
19 health and access to care. This obligation requires physicians to be prudent stewards of the
20 shared societal resources with which they are entrusted. Managing health care resources
21 responsibly for the benefit of all patients is compatible with physicians' primary obligation to
22 serve the interests of individual patients.

23
24 To fulfill their obligation to be prudent stewards of health care resources, physicians should:

25
26 (a) Base recommendations and decisions on patients' medical needs.

27
28 (b) Use scientifically grounded evidence to inform professional decisions when available.

29
30 (c) Help patients articulate their health care goals and help patients and their families form
31 realistic expectations about whether a particular intervention is likely to achieve those
32 goals.

33
34 (d) Endorse recommendations that offer reasonable likelihood of achieving the patient's health
35 care goals.

36
37 (e) Use technologies that have been demonstrated to meaningfully improve clinical outcomes
38 to Choose the course of action that requires fewer resources when alternative courses of
39 action offer similar likelihood and degree of anticipated benefit compared to anticipated
40 harm for the individual patient but require different levels of resources.

41
42 (f) Be transparent about alternatives, including disclosing when resource constraints play a
43 role in decision making.

44
45 (g) Participate in efforts to resolve persistent disagreement about whether a costly intervention
46 is worthwhile, which may include consulting other physicians, an ethics committee, or
47 other appropriate resource.

Physicians are in a unique position to affect health care spending. But individual physicians alone cannot and should not be expected to address the systemic challenges of wisely managing health care resources. Medicine as a profession must create conditions for practice that make it feasible for individual physicians to be prudent stewards by:

- (h) Encouraging health care administrators and organizations to make cost data transparent (including cost accounting methodologies) so that physicians can exercise well-informed stewardship.
- (i) Advocating that health care organizations make available well-validated technologies to enhance diagnosis, treatment planning, and prognosis and support equitable, prudent use of health care resources.
- (j) Ensuring that physicians have the training they need to be informed about health care costs and how their decisions affect resource utilization and overall health care spending.
- (k) Advocating for policy changes, such as medical liability reform, that promote professional judgment and address systemic barriers that impede responsible stewardship.

4. Opinion 1.1.6, Quality

As professionals dedicated to promoting the well-being of patients, physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable.

While responsibility for quality of care does not rest solely with physicians, their role is essential. Individually and collectively, physicians should actively engage in efforts to improve the quality of health care by:

- (a) Keeping current with best care practices and maintaining professional competence.
- (b) Holding themselves accountable to patients, families, and fellow health care professionals for communicating effectively and coordinating care appropriately.
- (c) Using new technologies and innovations that have been demonstrated to improve patient outcomes and experience of care, in keeping with ethics guidance on innovation in clinical practice and stewardship of health care resources.
- (d) Monitoring the quality of care they deliver as individual practitioners—e.g., through personal case review and critical self-reflection, peer review, and use of other quality improvement tools.

(Modify HOD/CEJA policy)

Fiscal Note: Less than \$500

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REPORT 5 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (I-13)
Professionalism in Health Care Systems
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

As payment and delivery models in health care have evolved over the last two decades the Council on Ethical and Judicial Affairs (CEJA) has analyzed emerging ethical challenges and offered guidance for physicians. Thus the *Code of Medical Ethics* now contains multiple opinions on closely related topics involving managed care and the use of various incentives and tools to help contain health care costs and promote safety and quality. CEJA recently reviewed these opinions and determined that they are informed by a common analysis and the same enduring ethical values:

- the overriding importance of preserving trust in patient-physician relationships,
- the imperative to minimize the effects of financial conflicts of interest and competing responsibilities, and
- the need to sustain physicians' commitment to use their best professional judgment in the service of their patients and to preserve opportunities for physicians to advocate meaningfully on behalf of their patients.

CEJA also found that the guidance in these opinions is often quite narrow, relevant only to very specific mechanisms, structures for care delivery, or payment models and thus is difficult to interpret and apply as health care continues to evolve rapidly. To ensure that guidance remains timely and readily accessible, CEJA has developed updated guidance to address these issues of professionalism in the context of health care systems. Physician leaders have a responsibility to ensure that practices for financing and delivering health care are transparent; reflect input from both physicians and patients; recognize that over-reliance on financial incentives may undermine physician professionalism; make use of well-designed, ethically acceptable, thoughtfully implemented incentives; support physicians to respond to the unique needs of individual patients and meaningfully advocate on behalf of their patients; and monitor practices for both unintended adverse consequences and positive outcomes. All physicians have a responsibility to hold physician-leaders accountable for meeting conditions of professionalism in health care systems and to advocate for changes in payment and delivery models to promote access to high quality care for all patients.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 5-I-13

Subject: Professionalism in Health Care Systems

Presented by: Susan Dorr Goold, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Larry E. Reaves, MD, Chair)

1 The past 20 years and more have seen significant change in health care in the United States. Over
2 this period, new organizations for delivering health care (such as health maintenance organizations
3 [HMOs], preferred provider organizations [PPOs], and more recently, accountable care
4 organizations [ACOs]) have combined with new payment systems (notably capitation) and third-
5 party payers' adoption of new roles to influence treatment recommendations and decisions, to
6 change the landscape of health care for both patients and physicians. At the same time, the goal of
7 controlling the cost of health care has been joined by enhanced emphasis on improving patient
8 safety and quality of care and new visions for "learning health care organizations" that create a
9 dynamic, rapidly changing environment.

10
11 Over this period, the Council on Ethical and Judicial Affairs (CEJA) analyzed ethical challenges
12 that emerged with the changes in health care, including challenges to physician professionalism
13 posed by "gag clauses" in contracts with managed care organizations and the use of formularies,
14 financial incentives, and other tools to help contain costs and promote safety and quality. As a
15 result, the *Code of Medical Ethics* now contains several opinions that address various aspects of
16 professionalism in physicians' relationships with health care organizations and payers:

- 17
- 18 • E-8.051 Conflicts of Interest under Capitation (1997, updated 2002)
- 19 • E-8.054 Financial Incentives and the Practice of Medicine (1998, updated 2002)
- 20 • E-8.056 Physician Pay-for-Performance Programs (2006)
- 21 • E-8.13 Managed Care (1996, updated 2002)
- 22 • E-8.135 Cost Containment Involving Prescription Drugs in Health Care Plans (1996,
23 updated 2002)
- 24

25 CEJA recently reviewed these opinions and found that each is informed by a common core analysis
26 and the same enduring ethical values:

- 27
- 28 • the overriding importance of preserving trust in patient-physician relationships,
- 29 • the imperative to minimize the effects of financial conflicts of interest and competing
30 responsibilities, and

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- the need to sustain physicians' commitment to use their best professional judgment in the service of their patients and to preserve opportunities for physicians to advocate meaningfully on behalf of their patients.

However, CEJA also found that the ethical guidance these opinions offer is often closely tied to details of specific cost-containment mechanisms, structures for delivery of health care, or payment models. Such narrowly focused guidance can be difficult to apply, and thus of limited value, in a health care system that continues to evolve rapidly.

CEJA concluded that it could best ensure that guidance in this area remains timely and readily accessible by combining and updating guidance from these earlier opinions into a new opinion addressing core ethical considerations for physician professionalism in the context of efforts to contain costs and improve quality in health care systems. To develop updated guidance, CEJA has based its analysis on its review of current opinions and on a review of ethics literature published in the years since existing opinions were issued. The following report summarizes the Council's deliberations and updates ethical guidance.

PHYSICIAN ACCOUNTABILITY: FROM COST CONTAINMENT TO QUALITY & VALUE

Existing opinions in the *Code* addressing professionalism in health care systems were formulated largely in response to mechanisms introduced by managed care in the 1990s that sought to control health care costs, especially by holding physicians accountable in new ways.[1–3] While many of these mechanisms, in the right environments, offered the possibility of controlling overall costs, supporting cost-effective care, and improving quality of care, they could also pose ethical conflicts for physicians.[4–6]

Models for delivery and payment of health care focus increasingly on questions of value in health care, defined by a leading proponent as “the health outcomes achieved per dollar spent,”[7,8] and toward models that share accountability among health care professionals differently than managed care.[7,9] Emerging models, such as accountable care organizations (ACOs) and medical homes, take advantage of lessons learned, a stronger evidence base, ongoing refinement of quality measures, a more collaborative approach to care, and greater physician control in health care organizations than did their managed care predecessors.[9]

ETHICAL CHALLENGES TO PROFESSIONALISM IN HEALTH CARE SYSTEMS

Models for financing and organizing the delivery of health care, whether fee for service, managed care, or ACOs and other emerging models can create financial conflicts of interest, set competing responsibilities for physicians, undermine trust and the integrity of patient-physician relationships, and have unintended consequences in relation to patients' access to care and physicians' professional satisfaction.[10–15]

Conflicts of Interest & Competing Responsibilities

As CEJA noted in its report on ethical issues in managed care, “financial conflicts are inherent in the practice of medicine, regardless of the system of delivery” or method of payment.[1] The intensity and immediacy of incentives, as well as how broadly or narrowly incentives are targeted shape how deeply particular incentives raise conflicts of interest.[1,6,16–17] Physician-leaders in health care organizations have a responsibility to minimize the intensity and immediacy of incentives and to use incentives targeted to specific interventions only when there is evidence of

overuse of the intervention and there are scientifically sound guidelines for appropriate use.
[1,6,17]

Efforts to contain costs can also create conflicting loyalties and competing responsibilities for physicians in asking them to serve both the interests of individual patients and the interests of populations of patients or of health care organizations.[1,11,18] At the same time, physicians are uniquely positioned to recognize the effects of uneven or unfair distribution of health care resources, and they do have a responsibility to be wise stewards of health care resources. To fulfill that responsibility, physicians must be able to rely on health care organizations to minimize the possible effects of competing responsibilities and to support appeals and meaningful advocacy on behalf of individual patients.[1,19]

Trust

A defining obligation of physicians as members of the medical profession is to put patients' interests ahead of physicians' personal financial interests.[1,4,16,17,19–21] Conflicts of interest and competing responsibilities created by models for financing and organizing the delivery of health care have the potential to undermine trust.[4,22] Yet trust is a complex phenomenon and multiple factors can influence how strongly payment mechanisms or incentives affect patient trust in their individual physicians and the medical profession.[22–26] Payment models and incentives should minimize conflicts of interest and care delivery systems should support robust patient-physician communication, enable physicians to advocate effectively for individual patients, and make available resources physicians need to provide high value, cost-conscious health care.[1,17]

UNINTENDED CONSEQUENCES

Mechanisms intended to influence what care is available to patients and how or by whom care is provided can have unintended consequences for patients, physicians, and health care systems. For example, formulary restrictions may help contain medication costs for a majority of a health care organization's patient population, but provide lesser benefit or poorer outcomes for a subset of the population, possibly offsetting cost savings.[4] Inadequate capitation rates may result in pitting the needs of one patient against the needs of others in a physician's practice, undermining trust.[4] Among the issues of greatest concern are the possible adverse effects of payment and delivery models on health care disparities and physician professionalism.

Exacerbating Health Care Disparities

Incentives also carry the potential to exacerbate inequities in health care. For example, pay-for-performance programs can adversely affect care for vulnerable populations of patients if they incentivize physicians to avoid patients for whom performance targets would be difficult to achieve.[10,12–14,27] To minimize the risk that pay-for-performance or other incentives will "accentuate inequity in health care," incentives must be appropriately adjusted for case mix, practice structure, availability of resources, etc.[1] Adjustment methods must be carefully considered, however. Hong and colleagues note that "to the extent that health systems reward physicians for higher measured quality of care, lack of adjustment for patient panel characteristics may penalize physicians for taking care of more vulnerable patients, incentivize physicians to select patients to improve their quality scores, and result in the misallocation of resources away from physicians taking care of more vulnerable populations. Conversely, adjustment for patient panel characteristics may remove the incentive to improve care or may inappropriately reward lower-quality physicians caring for more vulnerable patients." [13]

1 *Physician Professionalism & Satisfaction*

2
3 Experience with managed care has also led to questions about other ways in which payment
4 models, delivery structures, and incentives built into health care can have unintended consequences
5 for physicians as well, especially for physician professionalism. Pressures to contain costs “may
6 encourage some physicians to try to manage cases longer than they should,” especially under a
7 capitated system of payment.[1] Incentives may perversely encourage physicians to “treat to the
8 measure, rather than the patient’s presenting complaint,”[28] or to “game” the system in various
9 ways to improve performance ratings.[27] Similarly, incentives in one practice area may shift
10 physicians’ attention away from other, unmeasured areas,[27] including “communication,
11 compassion, and trust.”[11] Research has also indicated that incentives can undermine physician
12 satisfaction—for example, studies showing reduced satisfaction among physicians in pay-for-
13 performance programs.[14]

14 15 FLAWED ASSUMPTIONS & UNCERTAIN UTILITY

16
17 The use of incentives rests on the assumption that a given incentive will motivate a specific desired
18 behavior—in health care, that incentives will motivate physicians to act in specific ways so as to
19 help lower health care costs and improve quality of care. But whether the use of incentives in
20 health care is an effective way to influence the behavior of professionals is open to question.
21 Moreover, there is growing evidence that incentives, particularly financial incentives, are not
22 effective in controlling costs or improving quality.

23 24 *Incentives as Motivators*

25
26 Financial incentives presume that money is an important motivator for physicians. As Glasziou and
27 colleagues note, financial incentives “assume that paying more for a service will lead to better
28 quality.”[27] However, financial rewards are only one among several extrinsic motivators, which
29 can include lifestyle considerations, recognition, and patient appreciation.[27,29] For physicians,
30 intrinsic motivators, including “feelings of accomplishment associated with completing difficult
31 tasks; satisfaction in delivering positive clinical outcomes; and experiencing autonomy, respect and
32 collegial relationships” may play a stronger role than financial rewards (or penalties) in shaping
33 behavior.[29] Further, incentives to reach specific performance targets fail to reward skills that are
34 central for physicians, such as managing complexity or solving problems,[29] or creating rapport
35 with patients.

36
37 Perversely, incentives may have the opposite of their intended effect, undermining motivation
38 instead of enhancing performance.[29,30] Rewards can “worsen performance on complex
39 cognitive tasks, especially when motivation is high to begin with” and “undermine the intrinsic
40 motivation crucial to maintaining quality when nobody is looking.”[30]

41
42 Biller-Andorno and Lee argue that the most appropriate incentives for physicians are those that are
43 based in a sense of shared purpose and protect and promote physicians’ sense of moral
44 responsibility and enable physicians to “take ownership” of the incentive.[15] With shared purpose
45 incentives “instead of being passively graded or rewarded, physicians engage in the development,
46 ongoing evaluation, and critical review” of an incentive scheme. Physicians should also have
47 opportunity to report “any negative effects on quality, efficiency, and equity of patient care” that
48 result from an incentive scheme.

Weaknesses in Design & Implementation; Uncertain Utility

Criticism has also been voiced about the design of incentives. In its report on ethical issues in managed care, CEJA noted that flawed incentives based on too large or too small a sample of patients (or physicians), or on too long or short a time interval of measurement can have the effect of penalizing physicians whose panel includes patients with difficult to treat medical conditions [1; cf. 17]. If not carefully designed, performance measures can hold physicians accountable for aspects of quality over which they have no control, including limitations in the delivery system itself or social factors external to health care that affect patient outcomes.[11]

Measures may also be based on a problematic understanding of quality that “equates quality with the achievement of non-individualized, pre-determined health goals for broad populations.” [11] Measures also have tended to focus on processes rather than clinical outcomes or other endpoints of value to patient.[7,14]

Evidence to date also suggests that incentives are not necessarily effective in controlling health care costs or improving health care quality. Glasziou and colleagues note that “evidence on the effectiveness of financial incentives is modest and inconsistent.”[27] The absence of robust evidence for the effectiveness of pay-for-performance programs led the Society for General Internal Medicine to criticize pay-for-performance from an ethical perspective “because of significant potential for unintended consequences but scant data regarding its impact.”[28] The Society further noted that pay-for-performance programs “generally lack key safeguards as well as monitoring” and may be unable to identify adverse events to which they give rise.[28]

PRESERVING PROFESSIONALISM

Models for financing and organizing the delivery of health care undoubtedly will, and should, continue to evolve. However, efforts to refine payment mechanisms or to reorganize where and by whom care is provided in the interests of promoting high value, cost conscious care and better outcomes for patients must be sensitive to the ethical risks such efforts can pose. They must be designed and implemented with an eye toward preserving the core values of medicine and sustaining physicians’ professionalism and patients trust.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that Opinions E-8.051, Conflicts of Interest under Capitation; E-8.054, Financial Incentives and the Practice of Medicine; E-8.056, Physician Pay-for-Performance Programs; E-8.13, Managed Care; and E-8.135, Cost Containment Involving Prescription Drugs in Health Care Plans, be amended by substitution as follows and the remainder of this report be filed:

Containing costs, promoting high quality care for all patients, and sustaining physician professionalism are important goals. Models for financing and organizing the delivery of health care services often aim to promote patient safety and to improve quality and efficiency. However, they can also pose ethical challenges for physicians that could undermine the trust essential to patient-physician relationships.

Payment models and financial incentives can create conflicts of interest among patients, health care organizations, and physicians. They can encourage under treatment and over treatment, as well as dictate goals that are not individualized for the particular patient.

Structures that influence where and by whom care is delivered—such as accountable care organizations, group practices, health maintenance organizations, and other entities that may emerge in the future—can affect patients’ choices, the patient-physician relationship, and physicians’ relationships with fellow health care professionals.

Formularies, clinical practice guidelines, and other tools intended to influence decision making, may impinge on physicians’ exercise of professional judgment and ability to advocate effectively for their patients, depending on how they are designed and implemented.

Physicians in leadership positions within health care organizations have an ethical responsibility to ensure that practices for financing and organizing the delivery of care:

- a) Are transparent.
- b) Reflect input from key stakeholders, including physicians and patients.
- c) Recognize that over reliance on financial incentives may undermine physician professionalism.
- d) Ensure ethically acceptable incentives that:
 - i) Are designed in keeping with sound principles and solid scientific evidence. Financial incentives should be based on appropriate comparison groups and cost data, and adjusted to reflect complexity, case mix, and other factors that affect physician practice profiles. Practice guidelines, formularies, and other tools should be based on best available evidence and developed in keeping with ethical guidelines.
 - ii) Are implemented fairly and do not disadvantage identifiable populations of patients or physicians or exacerbate health care disparities.
 - iii) Are implemented in conjunction with the infrastructure and resources needed to support high value care and physician professionalism.
 - iv) Mitigate possible conflicts between physicians’ financial interests and patient interests by minimizing the financial impact of patient care decisions and the overall financial risk for individual physicians.
- e) Encourage, rather than discourage, physicians (and others) to:
 - i) Provide care for patients with difficult to manage medical conditions;
 - ii) Practice at their full capacity, but not beyond.
- f) Recognize physicians’ primary obligation to their patients by enabling physicians to respond to the unique needs of individual patients and providing avenues for meaningful appeal and advocacy on behalf of patients.
- g) Are routinely monitored to

1 i) identify and address adverse consequences;

2
3 ii) identify and encourage dissemination of positive outcomes.

4
5 All physicians have an ethical responsibility to:

6
7 h) Hold physician-leaders accountable to meeting conditions for professionalism in health
8 care systems.

9
10 i) Advocate for changes in health care payment and delivery models to promote access to
11 high quality care for all patients.

12
13 (New HOD/CEJA Policy)

Fiscal Note: Less than \$500 to implement.

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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.

3. When obtaining the informed consent of individuals to participate in genomic research, standard informed consent requirements apply (see Opinion 2.07, "Clinical Investigation"). In addition:
 - (a) Special emphasis should be placed on disclosing the specific standards of privacy contained in the study: whether the material will be coded (i.e., encrypted so that only the investigator can trace materials back to specific individuals) or be completely de-identified (i.e., stripped of identifiers).
 - (b) If data are to be coded, subjects should be told whether they can expect to be contacted in the future to share in findings or to consider participating in additional research, which may relate to the current protocol or extend to other research purposes.
 - (c) Individuals should always be free to refuse the use of their biological materials in research, without penalty.
 - (d) Disclosure should include information about whether investigators or subjects stand to gain financially from research findings (see Opinion 2.08, "Commercial Use of Human Tissue"). Such disclosure should refer to the possible conflicts of interest of the investigators (see Opinion 8.0315, "Managing Conflicts of Interest in the Conduct of Clinical Trials").
 - (e) Subjects should be informed of when, if ever, and how archived information and samples will be discarded.
4. To strengthen the protection of confidentiality, genomic research should not be conducted using information and samples that identify the individuals from whom they were obtained (i.e., by name or social security number). Furthermore, to protect subsets of the population from such harms as stigmatization and discrimination, demographic information not required for the study's purposes should be coded. (I, IV, V, VII)

3. COST CONTAINMENT INVOLVING PRESCRIPTION DRUGS IN HEALTH CARE PLANS, *AMENDMENT*

HOUSE ACTION: FILED

Resolution 3 (A-01), "Restrictive Drug Policies in Public Programs such as Medicaid," which was introduced by the New England Delegation, asked that the American Medical Association Council on Ethical and Judicial Affairs study the ethical implications of restrictive drug formularies in public tax-supported medical assistance programs. This charge primarily was to consider prior authorization requirements and physicians' responsibilities regarding such formularies, which potentially place patient's interest secondary to cost containment. Finally, the resolution requested that related current ethical Opinions be re-examined in accordance with these considerations. CEJA found that restrictive drug formularies raise the same access questions for enrollees in public tax-supported medical assistance programs ("public programs," from here on, such as Medicaid) as they do for enrollees of private programs, only with different levels of intensity and implications. In particular, the option of paying out-of-pocket may not be available to those in public programs, whose eligibility for the program often is an indicator of poverty. In addition, public programs generally have more restrictive formularies and require longer waiting periods for adding new drugs—even ones that are more therapeutically effective—which may limit physicians' choice of covered drugs. Moreover, many of these programs legally prohibit the prescribing of off-formulary drugs at a higher charge to the patient.

CEJA believes it can address Resolution 3 (A-01) by amending Opinion 8.135, "Managed Care Cost Containment Involving Prescription Drugs," which already covers these concerns.

In addition to extending the scope of the Opinion to private *and* public health care plans and to reinforcing physicians' commitment to address the needs of their patient with high quality and cost conscious care, CEJA offers minor edits to clarify that its recommendations are directed to physicians only.

Accordingly, CEJA proposes that current Opinion 8.135, "Managed Care Cost Containment Involving Prescription Drugs," be amended as follows:

8.135 ~~Managed Care~~ Cost Containment Involving Prescription Drugs in Health Care Plans

~~Managed care organizations~~ When health care plans, whether publicly or privately financed, establish drug formulary systems, physicians are obligated to advocate for formularies that meet the medical needs of their patients so that physicians will supplement medical judgment with cost considerations in drug selection. To ensure optimal patient care, various ethical requirements must be established for formulary application.

1. ~~Physicians who participate in managed care plans~~ should maintain awareness of plan decisions about drug selection by staying informed, where appropriate, about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influences on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.
2. ~~Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians~~ When scientifically based evidence is available, physicians are ethically required to advocate for additions-changes to the formulary when they think patients-that would benefit the patient. materially and Physicians also should advocate for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy. Quality improvement rather than cost containment should be the primary determinant for formulary exclusions. In order to be cost efficient, however, physicians should select the lowest cost medication of equal efficacy for their patients.
3. ~~Limits-Physicians~~ should advocate that limits be placed on the extent to which ~~managed-health~~ care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians should not be made to feel that they jeopardize their compensation or participation in a ~~managed-health~~ care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, ~~incentives which~~ should be calculated according to the practices of a sizeable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Prescriptions should not be changed without the physician's knowledge and authorization. This affords the physician the opportunity having-a-chance to discuss the change with the patient.
4. ~~Managed-Physicians should encourage health care plans should to develop mechanisms to educate and assist physicians in and implement educational programs on cost-effective prescribing practices, including the availability of clinical pharmacists. Such initiatives are preferable to financial incentives or pressures by health care plans maintenance organizations or hospitals, which can be ethically problematic.~~
5. ~~Patients must be informed of the-Physicians should advocate that methods used by their managed care plans to limit prescription drug costs- within health care plans in which they participate be disclosed to patients. In particular, they should encourage health care plans to inform patients upon enrollment concerning:~~
 - (a) ~~During enrollment, the plan should disclose the existence of formularies;~~
 - (b) ~~the provisions for cases in which the physician prescribes a drug that is not included in the formulary;~~
 - (c) ~~and the incentives or other mechanisms used to encourage formulary compliance by physicians;~~
 - and

- (d) ~~to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary.~~

If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, ~~more costly~~ drug to the patient, so that the patient can ~~decide~~ consider whether to ~~pay out of pocket~~ obtain the medication out-of-plan. Under circumstances in which the health care program will not subsidize the drug, physicians should help patients by identifying alternative forms of financial assistance, such as those available through pharmaceutical companies' assistance programs. (III)

Issued June 1996 based on the report "Managed Care Cost Containment Involving Prescription Drugs," adopted June 1995; updated June 2002.

4. CONFLICTS OF INTEREST UNDER CAPITATION, *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 8.051, "Conflicts of Interest Under Capitation." The revised Opinion will appear in the next edition of the *Code of Medical Ethics*.

8.051 Conflicts of Interest Under Capitation

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. ~~Managed care organizations and the p~~Physicians who contract with health care plans ~~them~~ should attempt to minimize these conflicts and to ensure that capitation is applied in a manner consistent with ~~the patients'~~ the patients' interests.

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~~Physicians should advocate that capitation payments ~~should be~~ calculated primarily on the basis of 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 that is the physician's obligations to deliver~~ 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~~the cost of care. ~~Capitation~~Therefore, physicians should advocate for 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.~~

6. FINANCIAL INCENTIVES AND THE PRACTICE OF MEDICINE, *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 8.054, "Financial Incentives and the Practice of Medicine." The revised Opinion will appear in the next edition of the *Code of Medical Ethics*.

8.054 Financial Incentives and the Practice of Medicine

In order to achieve the necessary goals of patient care and to protect the role of physicians as advocates for individual patients, the following statement is offered for the guidance of physicians:

1. Although physicians have an obligation to consider the needs of broader patient populations within the context of the patient-physician relationship, their first duty must be to the individual patient. This obligation must override considerations of the reimbursement mechanism or specific financial incentives applied to a physician's clinical practice.
2. Physicians, individually or through their representatives, should evaluate the financial incentives associated with participation in a health plan before contracting with that plan. The purpose of the evaluation is to ensure that the quality of patient care is not compromised by unrealistic expectations for utilization or by placing that physician's payments for care at excessive risk. In the process of making judgments about the ethical propriety of such reimbursement systems, physicians should refer to the following general guidelines:
 - (a) Monetary incentives may be judged in part on the basis of their size. Large incentives may create conflicts of interest that can in turn compromise clinical objectivity. While an obligation has been established to resolve financial conflicts of interest to the benefit of patients, it is important to recognize that sufficiently large incentives can create an untenable position for physicians;
 - (b) The proximity of large financial incentives to individual treatment decisions should be limited in order to prevent physicians' personal financial concerns from creating a conflict with their role as individual patient advocates. When the proximity of incentives cannot be mitigated, as in the case of fee-for-service payments, physicians must behave in accordance with prior Council recommendations limiting the potential for abuse. This includes the Council's prohibitions on fee-splitting arrangements, the provision of unnecessary services, unreasonable fees, and self-referral. For incentives that can be distanced from clinical decisions, physicians should consider the following factors ~~should be considered~~ in order to evaluate the correlation between individual act and monetary reward or penalty:
 - (i) In general, physicians should favor incentives ~~should be that are~~ applied across broad physician groups. This dilutes the effect any one physician can have on his or her financial situation through clinical recommendations, thus allowing physicians to provide those services they feel are necessary in each case. Simultaneously, however, physicians are encouraged by the incentive to practice efficiently.
 - (ii) The size of the patient pool considered in calculations of incentive payments will affect the proximity of financial motivations to individual treatment decisions. The laws of probability dictate that in large populations of patients, the overall level of utilization remains relatively stable and predictable. Physicians practicing in plans with large numbers of patients in a risk pool therefore have greater freedom to provide the care they feel is necessary based on the likelihood that the needs of other plan patients will balance out decisions to provide extensive care.

- (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:

- (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.~~
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7. MANAGED CARE, AMENDMENT

HOUSE ACTION: FILED

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8.13 Managed Care

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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 organizationshealth 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.

REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports; 1-13, were presented by Robert M. Tenery, Jr., MD, Chair

1. FINANCIAL INCENTIVES AND THE PRACTICE OF MEDICINE**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
AND REMAINDER OF REPORT FILED****INTRODUCTION**

Several past Council reports and opinions have addressed, whether directly or indirectly, the ethical implications of practicing medicine in an environment that provides financial rewards and penalties to physicians. The House of Delegates has also examined the issues surrounding financial incentives, and has produced a number of policy statements relating generally to the application of monetary inducements to the practice of medicine. Despite the wide variety of issues these past statements address, they are all based on a fundamental appreciation of the patient-physician relationship and the role of the profession in advocating for the medical needs of each patient. Maintaining a focus on this ethical foundation is increasingly important as the nation's health care system continues to evolve and the methods of physician reimbursement continue to change. Although it is impossible to provide a discrete ethical analysis of each model of physician reimbursement, the Council presents this report in an effort to highlight the fundamental ethical concerns of any health care payment regime.

BACKGROUND

There are numerous types of financial incentives including bonuses attached to specific patterns of practice or utilization goals, payments made out of a pool of withheld funds used to cover the cost of referral services, and fee-for-service payments. The many forms and combinations of incentive payments are often divided into two categories according to the "direction" they encourage physicians to move along the spectrum of utilization. This simple system distinguishes between incentives to provide care and incentives to limit resource use. For example, paying physicians on a fee-for-service basis provides an inducement to provide more services. On the other hand, paying physicians a portion of whatever balance remains in a pool of funds used first to cover referral services strongly encourages physicians to reduce utilization.

Although the system of categorization described above can be a useful model for discussion, it has important shortcomings. The choice of "direction" as the defining characteristic of a particular incentive is often not value-neutral. It is often assumed that providing more care is preferable to providing less, and that incentives to limit care are necessarily worse than those that encourage resource utilization. This assumption persists despite the lack of conclusive data linking different incentives to reductions in quality of care. Identifying the "direction" of an incentive also does little to reflect the underlying goal or goals of a particular payment regime, focusing instead exclusively on levels of utilization. Finally, such a system of labeling incentives has no category for those incentives which are not directly related to providing or limiting services, such as incentives which target improvements in quality and patient satisfaction. This report resists separating incentive plans into these two categories. It attempts instead to find the elements common to all, and to provide general guidance on the ethical implications of introducing the financial interest of the physician into the treatment relationship. Having established the ethical parameters governing the universe of incentives, it will be possible to provide more specific guidelines to ensure that the goals of the profession are protected and in fact actualized.

One element common to different financial incentive plans is that they encourage specific behaviors by penalizing or rewarding physicians on the basis of their patterns of clinical practice. Although fee-for-service medicine was not introduced as an explicit incentive, several studies have shown that providing a financial return for each service rendered can have an impact on the decision-making process of some physicians. Noting the

effectiveness of incentives at modifying clinical behavior, managed care organizations have developed a wide variety of payment mechanisms that target either specific practices or general patterns of care in an effort to reduce the cost of providing care to plan patients.

Financial incentive plans share the same general hazards. Regardless of the specific behavior targeted for a monetary inducement, the potential exists to create a conflict of interest involving the needs of the patient and the personal financial interests of the treating physician. For instance, a sufficiently large bonus tied to reducing the length of hospital stays could force a physician to choose between a substantial portion of his or her income and potentially beneficial care for a patient. Although the ethic of the profession demands that physicians provide their patients with all necessary care regardless of the personal reward or penalty involved, the conflict becomes particularly acute in cases of marginal need or when the benefits of treatment are uncertain. Fee-for-service medicine creates a similar conflict, except that the physician may be inclined by his or her financial interests to provide care that is only marginally indicated.

Although medicine has a long tradition requiring physicians to resolve these conflicts to the benefit of the patient, avoiding or minimizing these conflicts is important both to the patient's perception of clinical objectivity and to the physician's ability to practice medicine as an advocate for the patient. It is appropriate and important, therefore, for the profession to establish the goals upon which incentive plans should be based and to provide basic parameters that will protect the system of fundamental values governing physician behavior.

Goals for the Application of Incentives

The most fundamental goal of the medical profession is to provide for the health of patients. Applied broadly, this objective encompasses a commitment to safeguard the public health through the provision of quality, cost-effective care and to extend access to adequate health care to every individual. Applied in the context of clinical care, this requires physicians to place the health interests of their individual patients before all other concerns and to facilitate access to all necessary treatments. Financial incentives should be designed around this principle and ultimately judged according to their success or failure at fostering improvements in patient care.

Incentives should also be judged according to the extent to which they foster the treatment relationship between patient and physician by allowing physicians to assume their role as advocates for the health of individual patients. Physicians should never be discouraged by incentives from fulfilling their obligations to disclose all treatment options, to appeal any denials of coverage for necessary care, to make referrals on the basis of individual patient needs, and to provide to each patient those treatments which they believe will be of material benefit. Individual patients do not behave according to statistics and physicians must have the freedom to recognize and to accommodate the specific medical, financial, and psychosocial needs of the individuals in their practices.

Potential Benefits of Employing Financial Incentives

One of the strongest potential benefits financial incentives can provide is a reduction of waste in the application of medical resources, thereby effectively increasing the pool of resources for care. Fee-for-service medicine provides no incentive for physicians to economize use, and abuses of that system are manifest in cases of overutilization. Incentives can be applied to eliminate inefficiencies and defensive practices that may lead to artificial inflation of health care costs. Such incentives can be tailored to encourage the conservative but appropriate provision of medical care, thus maximizing the benefit gained from limited resources. For example, assuming appropriate utilization could be established by objective means, bonuses could be paid to physicians on the basis of their success at applying resources in an effective and efficient manner.

Applying incentives to specific patterns of care allows health plans to encourage a shift in practice towards preventive medicine and ambulatory care. Not only can such a shift produce cost savings, it can encourage physicians to become more involved in the health-related lifestyle choices of their patients. Ultimately, it can also improve the long-term health of patients. Additionally, incentives can be used to reward the integration and coordination of services, benefiting patients by providing more convenient access to care at a variety of levels.

A final advantage afforded by many incentive programs is the increased attention paid on a system level to patient satisfaction. Many managed care entities tie bonuses or reimbursement to patient surveys critiquing the performance of physicians and the managed care organization itself. Such plans encourage physicians to provide quality care and give patients the opportunity to voice any concerns they have regarding the level or type of care available through their plan.

Potential Risks Associated with Financial Incentives

Financial incentives operate by involving the personal interests of the physician in the therapeutic relationship. Physicians have a long-established obligation to put the interests of patients before all others, and in the majority of treatment circumstances, the appropriate manifestation of this obligation is clear. No physician can justify denying a patient absolutely necessary care or providing clearly unnecessary care, regardless of the incentive involved. However, there are certainly cases in which multiple treatment options exist, and in which the best among them is not abundantly clear. The physician must then exercise his or her judgment and weigh the probabilities of benefit against potential harms, taking into consideration factors including efficacy and cost in an effort to identify the treatment (or lack of treatment) most likely to benefit the patient.

The effect of financial incentives is felt most acutely in situations such as this, when the clinical imperfections of medicine become apparent and the physician is called upon to render an objective analysis of several complex considerations. It is exceedingly difficult to maintain true objectivity when a monetary reward or penalty is associated with a specific course of action. While this inducement will have little if any effect when the best treatment course is clear, its influence will grow as the gap separating different clinical options shrinks and the effects of each become similar. It is not reasonable to expect that all physicians can resist completely the influence of a financial incentive on true borderline cases. It is therefore critical to place limits on financial incentives to ensure that clinical objectivity is protected.

The potential to affect the objectivity of physicians is not the only cause for concern associated with financial incentives. Inducements that are based on the use of resources across physicians' practices compound the conflict between the interests of the physician and those of the patient by introducing conflicts between patients. When physicians are provided with incentives to meet specific levels of utilization, they are encouraged to consider the needs of the individual patient relative to the needs of other patients. For instance, bonuses attached to patterns of reduced use encourage physicians to consider which patients need certain services most rather than simply which patients need certain services. Such an incentive would not, in all likelihood, have any noticeable impact on the cases of clear patient need. Again, however, these incentives would have a greater impact on the care offered in cases of potential but unclear benefit.

Incentives that encourage physicians to consider the needs of patients in relation to one another could impact the ability of physicians to carry out their fundamental obligation of individual patient advocacy. Whether or not physicians are ever forced by incentives into a form of circumstantial or "bedside" rationing, patients may feel as though they must compete for scarce resources in a forum lacking significant oversight or consistent structure. The essential premise that physicians act wholly in the interests of each individual, constrained only by publicly determined limits on resources, allows patients to trust their physicians. Any incentive plan that challenges or appears to challenge this fundamental notion could have a far-reaching impact on the patient-physician relationship.

Even the appearance of rationing hints at perhaps the most troubling side-effect of incentive programs, namely their potential to disrupt the trust that exists between patients and physicians. No consequence of applying financial incentives would be more destructive to patient care than a widespread degradation of the public trust in the medical profession. While perceived competition between patients for resources could cast doubt on the ability of the treating physician to act as an individual advocate, the simple fact that a physician could stand to reap significant financial gain by providing (or not providing) a specific form of care may raise fundamental questions about the therapeutic relationship. This challenge to the patient's conception of medical practice could arise regardless of the actual effect any given incentive has, or does not have, on the clinical decision-making process.

Disclosure of Financial Incentives

Since the existence of financial incentives alone could impact the patient-physician relationship, developing an appropriate strategy to disclose those incentives is not a straightforward task. Patients have a right to be informed of all factors that could affect their care, including the payment system under which their physician practices. Disclosure is also necessary because the sense of betrayal and suspicion that would result from the independent discovery of a system capable of affecting clinical judgment would far outweigh the impact of full disclosure.

A much more difficult question to answer than whether or not to disclose incentives is where the responsibility for providing such information lies. A compelling argument can be made for disclosure prior to enrollment in a health plan, as the structure of financial inducements could influence the patient's decision to purchase a specific form of coverage. However, if disclosure of the nature of financial arrangements between payer and physician does not occur at the level of the payer, some obligation exists on the part of the physician to provide that information.

Effects of Financial Incentives on the Profession

The biggest concern associated with financial incentives is the conflict of interest they generate and the possible impact of that conflict on clinical objectivity and patient care. However, the ramifications of monetary inducements are by no means limited to the health of patients; they extend to physicians' perceptions of the profession and their role in caring for patients. The reaction of many physicians to the increasingly prevalent tension between personal economic interests and the therapeutic relationship has been one of discontent. In many ways, the application of financial incentives to reduce or limit utilization has changed the manner in which physicians are being asked to treat patients. The bottom line requires constant attention, breeding resentment towards those patients who require the most care and resources. Physicians are implicitly or even explicitly encouraged to shorten office visits and to reduce the use of certain services. Many recognize the inherent conflict of interest created through the use of financial incentives, but feel they have few options available to alleviate that conflict. The effect of this discontent on the patient-physician relationship and ultimately on the practice of medicine is not yet clear, but is cause for some concern.

Another sentiment common among physicians is that many financial incentives are transforming their station in the health care system. Physicians have defined themselves as a profession by their dedication to the principles of ethical practice, their dedication to the individual patient, and their ability to weigh these and other factors in determining the appropriate course of treatment for the sick. In many ways, the increased use and specificity of financial incentives is challenging this definition. The practice of medicine is not an exact science and relies heavily upon the ability of physicians to interpret a number of conditions other than physiological symptoms when recommending treatment. However, some financial incentive plans tied directly to average utilization rates encourage physicians to treat in exactly the same way all patients presenting the same or similar symptoms. In this way, many plans attempt to define rigidly what has for years been the purview of professional judgment and expert interpretation of non-quantifiable factors. The end result may be that physicians question their status as professionals in the face of increased micromanagement through utilization review and bonus schedules.

Limiting the Influence of Incentives to Preserve the Goals of the Profession

The Council has long recognized the primacy of patient interests, stating in part, "If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit." This broad statement applies equally to all financial conflicts engendered by incentives. There is also an obligation on the part of the medical profession to protect medical resources against waste and thereby to minimize the costs borne by patients. The intersection of these obligations provides a standard with which to judge the ethical propriety of various incentive plans. Well-designed plans encourage the appropriate use of medical resources without creating conflicts of interest that could affect individual, clinical care. Poorly designed plans are either ineffective at encouraging efficiency, or intrusive on the independent judgment of patient and physician. In light of this standard, the task before the profession is to provide a

framework identifying the factors that influence the degree to which different incentive plans allow physicians to uphold their ethical commitments.

The size of the financial reward or penalty associated with certain practices can help distinguish appropriate from inappropriate incentives. All other factors being equal, a direct correlation exists between the size of a financial inducement and the degree of influence it exercises. Large bonuses are more likely to affect objectivity than smaller ones, and placing a large portion of a physician's income at risk for treatment decisions creates a more substantial conflict of interest than placing a small percentage of potential earnings at risk.

Although the size of the incentive is important, it is not the sole determinant of ethical propriety and often works in conjunction with other factors. For instance, the proximity of an incentive to an individual act is crucial in predicting its eventual influence on services rendered. Proximity is a function of the degree to which physicians can reap personal benefit from individual treatment decisions rather than broader patterns of practice. The closer the proximity of an incentive to individual clinical encounters, the more likely it is to be given undue consideration.

Perhaps the most direct incentive is provided by a system of fee-for-service in which a direct correlation is established between individual service and payment. Unethical conduct under such circumstances can come in a variety of forms, including the provision of unnecessary services, self-referral, and fee-splitting. It is difficult to create systemic limitations which can eliminate these abuses; however, the individual acts themselves are readily identified and proscribed. In addition to prohibiting these specific abuses, the Council has issued guidelines governing the establishment of appropriate fees in an effort to ensure that physicians charge rates commensurate with their skill and training.

The influence on clinical practice of most other forms of financial incentives can be limited by altering the proximity of the incentive to specific clinical encounters. Spreading the risks can dilute incentives and benefits accrued through individual treatment decisions across panels of physicians. Because the savings generated by one individual physician will benefit a group, the amount the individual stands to gain from any single act is dramatically reduced. Likewise, in those situations where personal income is placed at risk, physicians who share that risk stand to lose substantially less potential income as a result of any single clinical decision. In either case, an incentive to practice in accordance with standards of efficiency exists; however, the immediacy of that incentive to individual treatment options is dramatically reduced.

Similar to applying incentives across broad physician groups, the proximity of incentives to single decisions can also be reduced by tying inducements to experience related to a large patient pool. As the laws of probability dictate, larger patient populations are more likely to have stable and predictable health care needs. When considering the care offered to a large number of patients, it becomes clear that expensive or extensive treatments for one patient will be balanced by the relatively minor or non-existent needs of others. Because the physician whose incentive plan applies to a large group can rely upon other cases to balance the needs of even exceptional patients, the freedom to exercise clinical judgment is preserved.

Following the same laws of probability, it becomes clear that incentives attached to utilization can also be limited by calculating patterns of use over longer rather than shorter periods of time. Despite potentially wide variations in individual care, the mean rates of resource consumption more closely approximate a consistent average as the time period over which they are calculated expands. Therefore, lengthening the time frame over which incentive payments are calculated reduces the risk that any one treatment decision will have a significant impact on the physician's financial reward or penalty.

It is important to note that some incentive plans that appear on their face to incentivize treatment patterns rather than individual decisions may in fact create circumstances in which enormous and unintended inducements result. Incentives that are awarded when a discrete point of utilization is achieved may satisfy the requirement to consider the use of resources across broad patterns of care. In some situations, though, they may create untenable conflicts. For instance, a bonus attached to an increased number of patient-visits may be awarded in its entirety when the physician reaches a specific number of clinical encounters. As the end of the fiscal period approaches, if the physician is within striking distance of that goal, an enormous incentive is created to see enough patients to realize what might be a substantial bonus.

Consider the case of a physician who stands to be awarded a \$15,000 bonus if he can conduct 8,000 patient visits in a year. If, on the other hand, he conducts 7,999 visits, he receives nothing. In the last week of the year, \$15,000 may ride on his ability to see 200 patients and a coercive incentive is established. In general, it is necessary to guard against the possibility that an incentive intended for annual or broadly calculated patterns could effectively ride on a much smaller number of individual cases. Consequently, incentives that are established on a continuum of utilization rather than a system of bracketed cutoff points will be more likely to prevent potentially severe conflicts of interest.

Even with safeguards in place, catastrophic care for a single patient can in many instances have a significant impact on the incentive payment that a physician receives. It is important, therefore, to provide some further protection from the potentially significant impact any treatment for a single patient could have on the income of a physician. The best means to achieve this protection is through the provision of a stop-loss plan. When the costs of treatment for a single patient climb above a fixed level, an insurance policy or an overflow pool of funds pays the majority of the balance. This allows physicians to recommend and provide treatment that would otherwise deplete a pool of withheld money or skew the appearance of their utilization rate.

A final means through which the potentially negative effects of financial incentives can be avoided is to include among other specific mechanism rewards and penalties tied to quality measures. This will reinforce the importance of establishing efficient but effective practice patterns. It also provides a simple check against any movement to view reductions in utilization rather than the provision of optimal care as the primary goal.

CONCLUSION

The purpose of incentive plans is to motivate physicians to eliminate waste and to provide optimal levels of care. The specific mechanisms used to achieve this goal should therefore be tailored in accordance with predictions of utilization dictated by medical necessity rather than by market economics and a plan's competitive standing. Physicians should not be offered monetary incentives that are designed to reduce costs below levels compatible with the provision of all necessary care. Such inducements introduce conflicts of interest that encroach upon the therapeutic relationship and threaten individual as well as public trust in the profession. To protect against such eventualities, the health needs of each patient and the ability of physicians to act as individual advocates must remain the principal considerations of any reimbursement plan.

RECOMMENDATIONS

To achieve the necessary goals of patient care and to protect the role of physicians as advocates for individual patient needs, the Council recommends the following:

1. Although physicians have an obligation to consider the needs of broader patient populations within the context of the physician-patient relationship, their first duty must be to the individual patient. This obligation must override considerations of the reimbursement mechanism or specific financial incentives applied to a physician's clinical practice.
2. Physicians, individually or through their representatives, should evaluate the financial incentives associated with participation in a health plan before contracting with that plan. The purpose of the evaluation is to ensure that quality of patient care is not compromised by unrealistic expectations for utilization or by placing that physician's payments for care at excessive risk. In the process of making judgments about the ethical propriety of such reimbursement systems, physicians should refer to the following general guidelines:
 - a. Monetary incentives may be judged in part on the basis of their size. Large incentives may create conflicts of interest that can in turn compromise clinical objectivity. While an obligation has been established to resolve financial conflicts of interest to the benefit of patients, it is important to recognize that sufficiently large incentives can create an untenable position for physicians.

2. PATENTING THE HUMAN GENOME

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

INTRODUCTION

The Human Genome Project (HGP) is a joint endeavor overseen by the National Institutes of Health (NIH) and the Department of Energy (DOE). International research efforts are coordinated through HUGO (Human Genome Organization). The 15-year HGP began in 1990 and proposes to find the location of 100,000 (or more) human genes, as well as to read the entire genetic script (approximately 3 billion base pairs) by the year 2005. Initial investments focused primarily on developing computerized tools for mapping, sequencing, storing, and handling genes. Despite this, the development of physical and genetic maps has moved forward faster than originally expected. Recently, with the development of new technologies that enable research to proceed more rapidly and efficiently, larger-scale sequencing efforts have begun.

With genetic research moving ahead at light-speed, patenting has become an important issue. Much of the concern in this area has focused on DNA sequences. These sequences may be fragments of a gene (i.e., they code for certain amino acids), or a full gene (i.e., they code for a full protein). Patenting of the former is more controversial, both legally and ethically, than the latter. In this report the Council provides a brief explanation of patent law and its potential application to genomic sequences. After examining some of the ethical concerns regarding patenting human genomic material, it concludes that caution is warranted in this area.

UNITED STATES PATENT LAW

Patent law is controlled by federal legislation, federal court decisions, and decisions of the Patent and Trademark Office (PTO). The Constitution notes that Congress has the power to "promote the progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive right to their Writings and Discoveries."

Patent holders do not own an invention—they own merely the patent. A patent then grants the holder the right, for a limited amount of time, to prevent others from commercializing their inventions. In this sense a patent does not confer ownership rights, it confers property rights. This is an important distinction. For example, an easement (another type of property right) granting X access over Y's property to the ocean front does not mean that X owns the property, merely that X has certain rights with respect to the property.

The obverse of patent law is trade secret law. It may be more lucrative to maintain an invention as a trade secret than to disclose it under patenting requirements. For example, Coca Cola originally sought patent protection for Coke, but dropped the application in light of the disclosure requirements. The formula for Coke turned out to be much more valuable as a trade secret than if patented (since the company would have had to disclose how to make it).

Patent law is designed to allow inventors to profit from their inventions, safeguarding intellectual property. At the same time, the patent system is designed to foster information sharing since full disclosure of the invention enabling another trained in the art to replicate it is necessary to obtain a patent. One author described a patent as "a contract between its owner and the U.S. government, whereby the owner is given security in exchange for sharing knowledge with the public." The "contract," as such, lasts 20 years from the date of filing.

There are two aspects to consider when a patent application is filed: the first is determining whether the thing is an invention, which is potentially patentable, or a discovery, which is not. In some sense, all inventions can be reduced to naturally occurring substances that are merely discoverable. Another way to think about the difference between a discovery and an invention is to consider the distinction between basic and applied research. This distinction, however, is not always clear-cut in the realm of biotechnology. As a result, whether or not to classify a finding as a discovery or an invention often reduces to the requirement of "utility" discussed

- 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.)

2. MANAGED CARE COST CONTAINMENT INVOLVING PRESCRIPTION DRUGS

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

INTRODUCTION

In an earlier report, the Council on Ethical and Judicial Affairs discussed the ethical tensions placed on physicians by the cost containment techniques of managed care. As managed care plans strive to meet the needs of society to restrain the growth of health care costs and to allocate health care fairly among different patients, the physician's duty of loyalty to patients may be unduly compromised. Excessive pressure may be imposed on physicians to preserve resources for other patients and to withhold too much care from individual patients they are treating. Financial incentives to limit care may pressure physicians to sacrifice patient welfare to protect their own financial security. The Council concluded that allocation decisions should be made at a policy-making level, at which physicians provide their expertise, so that allocation decisions need not be made at the bedside. The Council also recommended that limitations be placed on the kinds of financial incentives that are used by managed care plans.

In this report, the Council addresses efforts to limit the cost of prescription drugs. It is important that these efforts be designed in ways that do not compromise patient welfare or the integrity of the patient-physician relationship.

Formularies, limited lists of approved pharmaceuticals, are the most prevalent means of containing drug costs and are utilized by most managed care plans. In a formulary system, if a physician prescribes a drug that is not on the formulary list, the plan ordinarily will not cover the cost of the drug. The needs of specific patients may be ignored in this framework, as approved drugs are selected on the basis of average patient outcome, not individual effectiveness. Patients may not be duly informed of formulary implications, either in advance of enrolling in the plan or on a prescription-to-prescription basis. There is also the potential for doctors to sacrifice optimal therapeutic treatment for the benefits of cost-containment.

Other managed care strategies threaten patient welfare as well. Prior authorization procedures can be cumbersome for physicians, prescription caps can be unduly restrictive for patients with chronic conditions, and excessive copayments can block access to optimal treatment. As large pharmaceutical manufacturers purchase pharmaceutical benefit management companies, the manufacturers may use their control to ensure that their products are given priority when decisions are made about including or excluding drugs from the formularies. In addition, personal financial incentives have been used to encourage physicians to switch patients to different drugs, pitting the interests of patients against the economic interests of their health care providers. Managed care plans have also used techniques to encourage switches to a different drug without ensuring adequate disclosure of the benefits and risks of the different drug to the patient.

PHARMACEUTICAL INDUSTRY RELATIONSHIPS

As managed care plans increasingly limit prescription drug costs through formularies, volume discounts, and other techniques, pharmaceutical manufacturers have countered with measures to preserve or enhance their bargaining power. Since managed care plans often use generic versions of pharmaceuticals to keep costs down, manufacturers of brand-name drugs have expanded their activities into the production of generic drugs. There have also been some efforts by drug companies to exercise greater control over prescribing by managing health maintenance organizations (HMOs). Perhaps the most troublesome trend has been the purchase of drug-benefit management companies by pharmaceutical companies.

Pharmaceutical benefit management companies (PBMs) contract with managed care organizations, insurance companies and employer health plans to oversee prescription plans. They offer cost-effective management of

formularies and accumulate data on prescribing practices, price controls and therapeutic effectiveness to determine where cost savings can be realized. Pharmaceutical benefit managers coordinate drug coverage for 44 percent of the American population. This figure is expected to grow.

PBMs became the focus of public attention in 1993 when Merck bought one of the leading PBMs, Medco Containment Services. Other multi-billion dollar agreements followed, including SmithKline Beecham's acquisition of Diversified Pharmaceutical Services and Eli Lilly's purchase of PCS Health Systems. These three pharmaceutical-benefit managers oversee prescriptions for more than 100 million Americans. There appeared to be a clear conflict of interest in such consolidation, since presumably drug companies would want the PBMs they purchase to give preference to their products in promotion and marketing. The Federal Trade Commission (FTC), concerned about possible antitrust violations, undertook review of these transactions. The Food and Drug Administration (FDA) also expressed concern over the influence of pharmaceutical manufacturers on the managed care drug-distributors they had acquired. The FDA contacted Eli Lilly, Merck, and SmithKline Beecham, admonishing them to neither pressure doctors to prescribe drugs that are not medically indicated nor withhold sufficient disclosures to patients regarding the risks of adverse side effects.

Fears that formularies would be compromised may be exaggerated; in a competitive market, a PBM could not make concessions for the parent company unless the concessions were in fact the most cost-effective measures available. Nevertheless, PBMs' access to valuable industry data would be advantageous for any pharmaceutical company, particularly when trying to prove its drugs more cost-effective than those of their competitors.

FTC monitors gave the Eli Lilly deal the closest scrutiny and finally gave conditional approval. Under the agreement, the FTC required that PCS Health Systems remain open to competitors' products and that Lilly build a "fire wall" to keep it from obtaining other companies' pricing information, particularly when bids for formulary inclusion are being considered. These requirements may prevent undue influence by drug manufacturers in the formulary decisions of their subsidiary PBMs and may also discourage other manufacturers from purchasing PBMs. However, it remains unclear how the FTC intends to monitor and enforce compliance with these provisions.

The FTC is reconsidering prior deals and may impose similar requirements on the companies involved. Of particular interest is Merck, which announced a 15 percent increase in fourth-quarter earnings, crediting a rise in Merck drugs on Medco formularies. Merck's share of Medco's recommended drugs rose from less than 10 percent to 12 percent.

In sum, consolidation in the pharmaceutical industry may provide an unfair competitive advantage to pharmaceutical manufacturers that own pharmaceutical benefit management companies. FTC requirements may provide a sufficient safeguard against abuse. If not, then it may be necessary to prohibit manufacturers from purchasing PBMs entirely.

USE OF FORMULARIES AND OTHER COST CONTAINMENT MECHANISMS

1. The Typical Design of Formularies

The evolution of formularies has had an impact on care in a variety of clinical settings and largely preceded the boom of managed care. Formulary systems were first adopted in hospitals to limit the variety of drugs a hospital pharmacy needed to keep in stock. Since the 1993 Omnibus Budget Reconciliation Act, formularies have also been applied to state Medicaid programs. Most recently, they were proposed as part of the Clinton health plan's Medicare prescription drug benefit. However, they have had the greatest effect on HMOs, preferred provider organizations (PPOs), and other managed care constructs.

Formularies derive from formulary systems, a method whereby the medical staff of an institution evaluates, appraises and selects drugs considered to be most useful in patient care. In most all managed care formulary systems,

a pharmacy and therapeutics (P&T) committee is appointed to review candidates for the formulary, generally considering a variety of drugs from the same class and selecting the most cost-effective for inclusion. Physicians participating in the plan are bound to prescribe drugs from that formulary. If patients choose to go outside a formulary, they may be subject to a higher copayment or may even be held responsible for the full cost of the prescribed drug. Physicians can request additions to formularies and accommodations can be made in exceptional cases for provision of non-formulary drugs. While the percentage of HMOs that allow for physician overrides of formularies is increasing, there is little or no data on the percentage of requests for additions or exceptions that are actually approved.

Managed care plans benefit from adherence in formulary systems because they can ensure that their patient care funds are not spent on unnecessarily expensive drugs. In addition, by ordering fewer drugs at a higher volume per drug, they can negotiate more favorable terms with the pharmaceutical companies. Indeed, discounts can be as much as 10 percent of a drug's cost. Plans encourage physicians and plan-affiliated pharmacists to adhere to formularies by linking their compensation or status in the plan to their prescribing practices or simply by making it more costly for patients if physicians deviate from the formulary.

Physicians, pharmacists, plan executives and benefit managers are the most regular participants on P&T committees which determine formularies. Ideally, committee representatives are independent from plan influence and are elected by the plan's medical executive committee, much like the medical staff organization. In some cases, the position may be too time-consuming for volunteers. When it is necessary to hire committee members the administrative structure may be bypassed and recommendations may go directly to the Board. The P&T committee usually assesses drugs to determine therapeutic equivalence. Once satisfied that the considered drugs do not vary significantly in therapeutic benefit, P&T committees will often put the drug slot out for bid, choosing the drug (or drugs) for which the best terms are offered by the pharmaceutical company. In making their choice, P&T committees consider presentations from drug company representatives offering clinical trials and outcome analyses that indicate cost-effectiveness.

There are a variety of established mechanisms for reducing the costs of prescription drugs. The first is therapeutic interchange, where a related but less expensive drug will be substituted for its costly counterpart. This practice recognizes the proliferation of so-called "me too" drugs that replicate the action of already established drugs. Another is generic substitution, where the brand-name drug will be replaced by its generic form. According to recent published data, some 40 percent of all HMO prescriptions are generics, compared with 20 percent outside HMOs. Current use of generic drugs is likely higher. Also, 64 percent of HMO plans use therapeutic equivalent strategies and 96 percent use generic substitution to varying degrees.

To monitor all of these efforts, virtually all institutions create review mechanisms to ensure that the formulary is up to date and is affording appropriate patient care. Reviews are generally conducted on at least a quarterly basis. The drug use evaluation (DUE) or drug utilization review (DUR) committees play instrumental roles in the proper application of formulary policy. These entities oversee establishment and use of drug therapy management protocols, organize periodic review of drug use statistics by the P&T committee, monitor pharmacist intervention, and evaluate drug-dispensing habits of individual medical staffs. In addition, there should be a mechanism for ongoing peer review of formulary policy.

The vast majority of HMOs utilize formularies to contain drug costs. However, there are a variety of formulary system configurations being employed in the managed care industry. Some HMOs still adhere to "open" formularies, where less expensive and therapeutically similar drugs are recommended to participating providers, but the option to prescribe outside the formulary still exists. Usually these plans offer coverage for drugs off the formulary, possibly charging a higher copayment. However, the current trend is towards "closed" formularies, where only the drugs on the list can be prescribed unless patients are willing to pay for a non-formulary drug themselves. Other cost-containment efforts include maximum allowable costs (MACs), which specify upper limits for payment of prescription ingredient costs, and prior authorization, where coverage depends on prior approval for prescribing or dispensing.

Previous American Medical Association policy has addressed the practicalities of formulary structures. These policies have advocated the establishment of formularies in inpatient hospital and selected outpatient settings where there is an established P&T committee and concurrence of organized medical staff. Therapeutic interchange, the authorized exchange of therapeutic alternates in accordance with previously approved guidelines, was also recognized. Finally, AMA policy requires provision of protocols for timely procurement of non-formulary drug products prescribed by a physician for the individualized care of a specific patient. The AMA's policies are intended to encourage physicians to supplement medical considerations with cost considerations when selecting the drug of choice for an individual patient and to become well-informed about the quality of prescription drug products available from multiple sources.

2. Ethical Concerns with Cost Containment Mechanisms

Proponents have argued that streamlining of prescription options has succeeded in containing the growing cost of pharmaceuticals and has resulted in the most appropriate utilization of available drug therapy. But the basic question of whether formularies are truly cost-effective is much debated in managed care analyses. Some commentators believe that prescription of generics or marginally less therapeutic drugs in managed care organizations compromises patient care to the point where any savings are offset by increases in costly office consultations and hospitalizations. The empirical data are inconclusive; while some studies support assertions of cost-effective patient care, other investigations of uncertain validity raise cause for concern. An unpublished Duke University study of hospital formularies found that limiting a physician's choice of drugs for ulcers, asthma and heart conditions saved a marginal amount of money, but hospitalization utilization rose, offsetting any savings. Prior authorization, which requires physicians to secure permission from a specialist or other designated person before using high-cost drugs, can unduly discourage optimal drug therapy. Prior authorization requirements also may increase administrative costs. Managed care organizations sometimes restrain drug costs by imposing prescription caps with provisions for waivers of the caps when justified by a patient's particular circumstances. With a prescription cap, patients are ordinarily limited to a certain number of prescriptions in any month or other fixed time period unless their physician receives permission to exceed the cap. Studies have shown that prescription caps without waivers threaten patient welfare. Patients on maintenance drug therapy for chronic conditions are especially endangered when access to pharmaceuticals is limited by a prescription cap. In one study of schizophrenic patients on Medicaid, hospitalizations rose significantly with the introduction of prescription caps.

Formularies, specifically, may compromise patient care in several ways. Necessary pharmaceuticals may be omitted in the process of formulary compilation, either because consolidation results in pharmaceutical manufacturers favoring their own drugs over the drugs of competitors or because formulary decisions may fail to account sufficiently for variations among individual patients. Some drugs may not provide additional benefit than their counterparts on average, but may make a substantial difference to a minority of patients. Eliminating the option of what may be better for some inevitably compromises the care of a small population of patients. In addition, these compromises may not even be offset by cost savings. The additional expenses for a patient who was inadequately treated initially may far outweigh the savings on the drugs with which the patient was treated.

3. Preventing Ethical Abuses

Physicians should be informed of formulary constraints while negotiating provider contracts. Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about P&T committee actions and by ongoing personal review of formulary composition. In addition, physicians should recognize that there are risks to patient care from pharmaceutical industry consolidation involving the managed care plans or pharmacy benefit plans with which they deal. Any perceived inappropriate influence on formulary development should be reported to regulatory authorities.

Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients

would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Efficient mechanisms to appeal formulary exclusions should be established.

Other cost-containment mechanisms, including prescription caps and prior authorization, should be designed in ways that do not unduly burden physicians or patients in having access to optimal drug therapy. For example, prescription caps should be liberal and there should be flexible waiver provisions to allow for appropriate exceptions to the caps, so that the threat to patient welfare can be neutralized.

PRESSURES OR INCENTIVES TO LIMIT PRESCRIPTION DRUG COSTS

In addition to excluding certain drugs from the plan's formulary, managed care plans control prescription drug costs by encouraging or pressuring physicians to prescribe lower-cost drugs within the formulary or to not prescribe a drug at all. Many of these efforts are an important part of the plan's efforts to contain their health care costs. Physicians who developed their prescribing practices in a fee-for-service environment may not have had sufficient incentive to consider costs when prescribing drugs. Consequently, managed care plans may need to ensure that physicians incorporate cost considerations in their decisions about drug prescribing.

However, some techniques may create undue incentives or pressures. In some cases, physicians are given financial incentives by their managed care plan or the plan's pharmaceutical benefit manager to keep prescribing costs down. For example, physicians' end-of-the-year bonuses may rise if they minimize the prescription drug costs of their patients or if they comply with requests by the plan to switch their patients to lower-cost drugs. Managed care plans may also have plan administrators or pharmacists call physicians about changing prescriptions, and sometimes the frequency and intensity of the calls can rise to the level of harassment. Both incentives and pressures are particularly troublesome if the plan sends the message to physicians that failure to comply with requests for prescription changes will jeopardize the physician's participation in the plan. Physicians should guard against acquiescing to switch requests too readily. In some plans, the pharmacist or the plan secures a switch from the doctor and directly notifies the patients that they are to pick up the new drugs at the pharmacy as soon as possible. This approach eliminates the possibility of an informed consent dialogue between the physician and the patient; patients lose the opportunity to receive an explanation or instructions from their physician or to express their preference for the original drug. Of particular concern are plans in which switches are automatic and neither the physician nor the patient is made aware of the change.

While it is not always possible to discern the line between appropriate persuasion and inappropriate harassment, limits need to be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation if they prescribe drugs that are necessary for their patients but that may also be costly. In accordance with the Council on Ethical and Judicial Affairs' report, *Ethical Issues in Managed Care*, there should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizeable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Other than generic substitutions, prescriptions should not be changed without physicians having a chance to discuss the change with the patient. All fiscal incentives should be disclosed fully to the patient. The American Pharmaceutical Association (APhA) has also supported pharmacist disclosure of incentives to physicians and patients when they propose a switch. This is in keeping with their APhA Code of Ethics which states, "A pharmacist should strive to provide information to patients regarding professional services truthfully, accurately, and fully and should avoid misleading patients regarding the nature, cost or value of these professional services."

Educational efforts can be an important adjunct to financial incentives. Publication of price lists, at the very least, goes a long way to boosting physicians' awareness of cost. Many plans encourage cost-effective prescribing practices by informing physicians of the existence of drugs that provide comparable benefits at lower cost than drugs

currently being used. Pharmaceutical benefit managers offer computer technology to access medical information networks which detail the cost and effectiveness of formulary options. In addition, almost two-thirds of HMOs reported automated systems for tracking drug interactions.

DISCLOSURE TO PATIENTS

Patients should fully understand the methods used by their managed care plans to limit prescription drug costs. In the course of enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary, and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. Plans should also disclose any relationships with PBMs or pharmaceutical companies that could influence the composition of the formulary. This information should be included in HMO literature and patient orientations. Any inquiries patients have about inclusion of particular drugs on formularies should be answered prior to enrollment. When physicians do not prescribe a drug that would offer significant advantage to the patient because it is not on the formulary, and they are unable to secure a formulary exception, the physician must disclose that information to the patient.

While some would consider it cruel to disclose treatment options that a patient clearly cannot afford, physicians should never presume that they are acting in their patient's best interest by prescribing the less expensive, less effective drug. It is possible that a patient would be willing to sacrifice some other expense to pay out-of-pocket for a drug that may give a better, sustained quality of life. As Morreim notes, "the patient's right to self-determination encompasses the right to decide one's budget as well as one's body." A doctor should not assume that the patient cannot afford an opportunity for better outcome. As with any managed care restriction, if patients do not like a particular recommended course of treatment, they have the option to disenroll from the plan or pay out-of-pocket for an alternative. Physicians must become more comfortable weighing these cost-benefit issues with their patients.

Involving patients in specific prescription decisions can be very helpful. Studies have shown that, when patients have been thoroughly educated about the expenses involved and the therapeutic comparability of two drugs, they are generally receptive to accepting the more cost-effective drug. Such preliminary studies should encourage physicians to include their patients in prescribing choices.

CONCLUSION

In the case of prescription drugs, the AMA in the past has encouraged physicians to supplement medical judgment with cost considerations in drug selection. Managed care organizations establish drug formulary systems for this purpose. To ensure optimal patient care, various ethical requirements must be established for formulary application. The Council offers the following recommendations.

RECOMMENDATIONS

For the reasons discussed in this report, the Council recommends that the following be adopted:

1. Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influence on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.
2. Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions

based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

3. Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizeable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Prescriptions should not be changed without physicians having a chance to discuss the change with the patient.
4. Managed care plans should develop and implement educational programs on cost-effective prescribing practices. Such initiatives are preferable to financial incentives or pressures by HMOs or hospitals, which can be ethically problematic.
5. Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician prescribes a drug that is not included in the formulary and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient, so that the patient can decide whether to pay out-of-pocket.
6. Research should be conducted to assess the impact of formulary constraints and other approaches to containing prescription drug costs on patient welfare.

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

3. ASSERTION OF THE PROFESSIONAL HIPPOCRATIC FIDUCIARY ETHIC IN THE FACE OF HEALTH CARE REFORM PROPOSALS (RESOLUTION 214, A-94)

HOUSE ACTION: RECOMMENDATION ADOPTED IN LIEU OF RESOLUTION 214 (A-94) AND REMAINDER OF REPORT FILED

Resolution 214 was introduced at the 1994 Annual Meeting by the Hospital Medical Staff Section and requested the American Medical Association to "review state health care reform proposals and federal health care reform legislation to assure that no provisions are included in such plans that grant physicians immunity from the professional code of ethics." Resolution 214 was referred to the Board of Trustees. Association policy on health care reform seeks to maintain the physician's primary role as patient advocate. The Association's legislative office vigorously asserts this policy when health care reform legislation is proposed at the federal or state level.

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 Locomotion 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 may be 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.)