REDEFINING FULL AND FAIR DISCLOSURE OF HMO BENEFITS AND LIMITATIONS

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I. Introduction

Since the earliest days of the consumer movement, federal and state governments have taken a keen interest in what information, by law, should be disclosed in consumer transactions. Not surprisingly, the most expensive transactions for consumers have been the tallest lightening rods for government action. Two prominent examples are consumer credit transactions[1] and the sale of securities.[2]

On the issue of consumer disclosure, government intervention often occurs on two plateaus. The first is anticipatory. As lawmakers shape the marketplace in which the product or service will be sold, they anticipate that if disclosure requirements are not enacted, the sellers will conceal facts that are material to the transaction, but which are unfavorable to them. The second plateau is reactionary. This level is reached only if the lawmakers find that their fears are well founded, but the original scope of disclosure is inadequate.

Health care is an enormously expensive commodity which only recently is beginning to become expensive for health care consumers. Until now, almost all HMO and insurance premiums have been borne by employers and government agencies. The trend is, however, to shift more of the cost to the consumer. As this shift occurs, the individual purchaser will become more involved in evaluating exactly what his money buys. As enrollees

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[1] 15 U.S.C.S. §§ 1601-1693r (Law. Co-op. 1982 & Supp. 1989); 12 C.F.R. §§ 226.1-226.30 (1989).

[2] 12 C.F.R. §§ 16.1-16.8 (1989).

pay a larger portion of the premium, disclosure of HMO benefits and limitations may be forced from the first plateau, where it is presently, up to the second plateau.

Federal and state laws require HMOs to provide prospective enrollees with a full and fair disclosure of each health plan. The issue of what constitutes a full and fair disclosure is ripe for re-examination. A developing school of thought considers that a full and fair disclosure permits consumers to evaluate not only the type and scope of benefits, but also how those benefits will be delivered. Such disclosures may include descriptions of financial incentives offered to physicians, or the use of cost containment techniques such as drug formularies[3] and therapeutic substitution.[4] The issue which must ultimately be decided is whether current disclosure requirements address the informational needs of consumers who have a growing economic stake in the cost of their managed health care.

II. Current Disclosure Requirements

A. *Federal Law*

The Federal HMO Act of 1973 (Act)[5] helped HMOs grow from merely an idea in California, into a nationwide industry serving over 33 million enrollees. The Act established the federal qualification process[6] that has become a seal of approval for over 500 plans.

The Act addresses the fiscal soundness of the HMO, requirements for quality assurance, and the range of health care benefits to be provided.[7] The Act does not contain a provision, however,

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[3] A drug formulary is a list of drug products approved for the treatment of patients within a health care organization. Formulary decisions are made by a committee of physicians, pharmacists, and business administrators within the organization. Formulary committees decide which FDA-approved drugs will be excluded from the formulary and whether any restrictions should be placed on the use of those drugs that are on the formulary.

[4] The term therapeutic substitution, as used here, refers to a formal organizational policy that allows a pharmacist to replace a prescribed drug with a different class or family of drug as long as the anticipated therapeutic effect of the two drugs would be the same. Therapeutic substitution is performed by reference to a predetermined list of drugs developed by a formulary committee.

[5] 42 U.S.C.S. § 300e (Law. Co-op. 1978 & Supp. 1989).

[6] *Id.*

[7] *Id.*

which describes the disclosures that HMOs must provide to prospective enrollees. Unfortunately, the legislative history of the Act offers no guidance in understanding how broadly or narrowly disclosure requirements should be interpreted.

The Health Care Financing Administration (HCFA) is responsible for regulating federally qualified HMOs. Under HCFA's regulations, HMOs must prepare a written description of the plan, including information about benefits and coverage.[8] Currently, there is no requirement of disclosure of the financial incentives to reduce utilization of various services. Furthermore, the regulations have not been interpreted by HCFA to require disclosure of cost containment mechanisms such as drug formularies or therapeutic substitution.

B. *State Law*

The HCFA regulations set minimum disclosure requirements for federally qualified HMOs.[9] Individual states, however, also govern the disclosures made by HMOs authorized to operate within their jurisdiction. California, Florida, and Pennsylvania are of particular interest as each has a large number of HMO enrollees[10] and regulatory agencies that are considered to be responsive to consumer interests. Of these three states, California represents the zenith in terms of disclosure protections. California law requires HMOs to provide prospective enrollees with a full and fair disclosure of the plan in readily understood language, and in an organized manner that will allow comparisons between plans.[11]

HMOs in California are regulated by the Department of Corporations. The Department has issued regulations which govern both the content and style of disclosure materials.[12] Due to the detail of the regulatory scheme, the California disclosure laws are more comprehensive than the federal regulations.

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8 42 C.F.R. 417.107(c)(1) (1988).

9 *Id.*

10 Based upon 1988 HMO enrollment statistics, California had 7,726,000 enrollees, Florida had 1,386,500, and Pennsylvania had 1,252,900. Collectively, the enrollment in these three states accounted for almost one third of the total HMO enrollment in the United States. MARION MANAGED CARE DIGEST, HMO Edition (1989).

11 *See* CAL. HEALTH & SAFETY CODE § 1363 (West Supp. 1990).

12 *See* CAL. ADMIN. CODE tit. 10, § 1300.63 (1983).

In Pennsylvania[13] and Florida,[14] disclosure requirements are far less detailed than those required under California law, but are similar in scope to those required by federal law. These regulations require little more than a description of the available benefits, how to obtain them, exclusions and limitations, and any copayments or deductibles that may apply. When compared to the sophisticated approach of the State of California, these laws are lacking. None of the three states, however, require any disclosure of physician financial incentive arrangements, drug formularies, or therapeutic substitution. In this regard, the laws which mandate disclosure in these three states are similar to the federal requirements.

III. Expanding Current Requirements

A. *Are Changes Needed?*

Disclosures required by existing laws tend to provide enrollees with a general understanding of the type and scope of benefits available, limitations and exclusions of benefits, how and where to access benefits, the enrollee's financial responsibilities, and grievance procedures. Is this enough? If consumers are faced with choices about health care plans, should they not be provided with information about how their plan may limit their utilization of services and treatments? The answer is probably yes. The real question is not whether consumers will obtain more information about HMO strategies, but whether legislators and regulators, the courts, or the HMOs themselves will lead the way.

Over the last few years, states have been more aggressive in regulating HMOs because of the growing concern about the industry's financial stability. The unanswered question is whether state HMO regulators will now direct the focus of their attention toward disclosure. Without consumer pressure, regulators are unlikely to expand their disclosure requirements. Consumers may have already begun to apply that pressure. Recently, an unsuccessful attempt to litigate the disclosure issue was made by

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[13] 31 PA. CODE § 301.61-301.65 (1987).

[14] FLA. ADMIN. CODE ANN. r.4-31.033 to 4-31.107 (1989).

former members of U.S. Healthcare, Inc.[15] In that case, the plaintiffs accused the HMO of failing to disclose financial arrangements that could lead doctors to make fewer referrals to specialists. The court dismissed the case after deciding that the plantiffs' allegations of injury under the federal Racketeer Influence and Corrupt Organizations Act (RICO) were insufficient. Despite the inability of the plaintiffs to present a viable case, similar litigation involving the issue of HMO nondiscosure is likely to follow. As courts begin to hear more cases involving allegations of HMO nondisclosure, legislators and regulators may find new inspiration to focus on the issue.

B. *What Should Be Disclosed?*

Physician financial incentives appear to be the first target for disclosure. The lawsuit against U.S. Healthcare underscores the demand for this information. Certainly there are physicians philosophically opposed to these incentives who will fan the fire on this issue.[16] As the public becomes more aware of these arrangements, there will be increased pressure upon the industry to make affirmative disclosures.

Limitations on access to specific medical care is another target for disclosure. The providers of those services and supplies not covered by the HMO will seek out public and governmental support. For example, a bill introduced last year in the California Assembly would require HMOs to inform prospective enrollees how health care services, methods of treatment, and access to licensed health practitioners may be limited or excluded.[17] Although chiropractors are the special interest behind this bill, the language used in the bill is not limited to chiropractors. Whether this bill will succeed in the California Legislature is of less importance than recognizing the demand for disclosure of this type of information.

Similarly, many HMOs providing prescription drug benefits are finding it necessary to limit enrollee access to new, and frequently more expensive, treatments through the use of drug for-

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[15] Teti v. U.S. Healthcare, Inc., No. 88-9808 (E.D. Pa. Nov. 21, 1989) (WESTLAW, DCTU database).

[16] *See* Levinson, *Toward Full Disclosure of Referral Restrictions and Financial Incentives by Prepaid Health Plans*, 317 NEW ENG. J. MED. 1729 (1987).

[17] A. 1803, Calif. Legis., 1989-90, Reg. Sess.

mularies and therapeutic substitution. Each of these cost containment strategies are effective tools in limiting a plan's financial exposure by slowing down the diffusion of new treatments. These strategies, however, can also represent a benefit limitation to consumers.

Most regulators only require HMOs to disclose the existence of drug benefits, how and where to get prescriptions filled, copayments or deductibles, and any generic substitution policies that may apply. There is presently no requirement to disclose the existence of drug formularies or therapeutic substitution. These strategies can limit enrollee access to new treatments, and accordingly, reduce the scope of a plan's drug benefits. As these policies are becoming more widespread and are being enforced more aggressively, HMO regulators should take an increased interest in evaluating how these policies affect the contours of a plan's drug benefits and consider whether the restrictions warrant disclosure.

IV. Conclusion

Existing HMO disclosure laws are not currently being interpreted to require that prospective HMO enrollees be informed of physician financial incentives to reduce enrollee utilization of services or cost containment policies, such as drug formularies and therapeutic substitution. Both federal and state governments must decide what financial incentives are acceptable. Once this occurs, regulations should be implemented to require a description of those incentives in HMO disclosure materials. Likewise, regulators should begin to scrutinize other cost containment mechanisms such as drug formularies and therapeutic substitution. If these mechanisms are found to limit enrollee access to specific prescribed drug treatments, they should be considered plan benefit limitations. As a benefit limitation, existing laws and regulations already demand that affirmative disclosures be made to prospective enrollees.

Current disclosure requirements set forth in the National Association of Insurance Commissioners (NAIC) Model HMO Act[18] and Model Regulation[19] covering HMO contracts and serv-

[18] Health Maintenance Organization Model Act, National Association of Insurance Commissioners (1989).

ices may also serve as a catalyst for expanding current disclosure requirements. Either the Model Act or the Model Regulation would provide an appropriate forum to develop a new disclosure requirement. For instance, section 6 of the Model Regulation defines what the evidence of coverage must disclose to consumers.[20] This provision could be amended to include specific language which identifies drug formularies and therapeutic substitution as examples of limitations that must be disclosed. The following draft of subparagraph (H) of section 6 provides a suggested change to the existing language. The italicized segment denotes the proposed revision.

> Section 6. Requirements for Contracts and Evidences of Coverage
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> H. Copayments, Limitations and Exclusions
> The contract and evidence of coverage shall contain a description of any copayments, limitations or exclusions on the services, kind of services, benefits, or kind of benefits to be provided, including any copayments, limitations or exclusions due to preexisting conditions, waiting periods or an enrollee's refusal of treatment, *or restrictions on patient access to medically accepted treatments or drugs and devices approved by the United States Food and Drug Administration, such as drug formularies or therapeutic substitution.*[21]

The inclusion of the suggested language would provide HMO regulators with a new perspective on what disclosures should be made in the evidence of coverage. Ultimately, the dissemination of this information will allow consumers to better evaluate the various health care plans which may be available.

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[19] Model Regulation to Implement Rules Regarding Contracts and Services of Health Maintenance Organizations, National Association of Insurance Commissioners (1987).

[20] *Id.* at 432-4.

[21] *Id.* at 432-7.