I-111-84-49

COMMISSION APPROVED

FEDERAL TRADE COMMISSION
WASHINGTON, D. C. 20580

OFFICE OF THE SECRETARY

JUL 9 1984

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Dr. Carolyne K. Davis
Administrator of the Health Care
Financing Administration
U.S. Department of Health and
Human Services
P.O. Box 26676
Baltimore, Maryland 21207

Re: BERC - 247-P

Dear Dr. Davis:

The Federal Trade Commission submits the following comments on the proposed regulations implementing Section 114 of the Tax Equity and Fiscal Responsibility Act of 1982. 49 Fed. Reg. 22198 et seq. (May 25, 1984). The proposed regulations set forth requirements that Health Maintenance Organizations ("HMOs") and Competitive Medical Plans ("CMPs") must meet to enter into a Medicare contract with the Health Care Financing Administration ("HCFA") and to qualify for Medicare reimbursement. These comments relate solely to Section 417.428 of the proposed regulations, which specifies required and prohibited marketing activities by participating HMOs and CMPs. This section may affect competition among health care providers and the ability of Medicare beneficiaries to make informed decisions about competing health care providers.

The Federal Trade Commission and its operating units, the Bureau of Consumer Protection, the Bureau of Competition, and the Bureau of Economics, have accumulated considerable knowledge in recent years about competition and consumer protection issues in the health care field, and have developed expertise in assessing the reasonableness of regulations aimed at advertising by health care providers. In the course of its law enforcement activities, the Commission has investigated and prosecuted anticompetitive behavior and unfair and deceptive marketing and advertising practices on the part of individuals and organizations involved in various health care markets. In addition, the Commission seeks to work with groups in both the public and private sectors in an effort to promote the removal of obstacles that hinder competition among health care providers and institutions. In that regard, the Commission believes that the free flow of truthful, non-deceptive advertising increases competition in the delivery of health services to the benefit of consumers. The Commission believes that increased competition among health care providers enhances consumer choice and the availability of services, and that it can lower the overall cost of health care.

The Commission supports HCFA's efforts to afford Medicare beneficiaries the option of obtaining medical services from alternative health plans. We agree with HCFA that the participation of HMOs and CMPs in the Medicare program can benefit Medicare benificaries by increasing consumer choice and access to health care services, and by reducing the cost of health care.

At the same time, the Commission shares HCFA's concerns about the use of deceptive marketing activities by health care entities to persuade consumers to enroll in their plans. Such practices can be particularly egregious in the health care field because they not only can result in economic injury to consumers but also may endanger their health. The Commission staff continuously monitors health-related marketing activities in an effort to protect consumers from unfair or deceptive practices regarding health care.

Our comments on Section 417.428 of the proposed regulations are directed solely to its potential competitive impact. The Commission supports HCFA's efforts to deter deceptive marketing practices by participating HMOs and CMPs but is concerned that, as drafted, some provisions of Section 417.428 may be more restrictive than is necessary to prevent such practices. We offer the following comments for your consideration:

Section 417.428 (a)(2) - This section requires a participating HMO or CMP to submit all advertising and marketing material to HCFA for approval before issuance. HCFA then has sixty (60) days to act on the request. As a general matter, we believe that blanket pre-clearance requirements are more restrictive than is necessary to prevent deceptive marketing practices. We recognize that HCFA's role as a contractor of medical services may raise offsetting policies for permitting restrictions that, in more typical contexts, would be undesirable. In this specific instance, we request that HFCA carefully consider whether the proposed regulation may unnecessarily "chill" or burden bona fide and beneficial marketing activities of HMOs and CMPs participating in the Medicare program.

One example of our concern in this instance is the regulatory disadvantage that this section would impose on participating health care entities. During open enrollment, participating HMOs and CMPs would need approval under this section before they could respond to public criticisms of their plans by providers not subject to the pre-clearance restriction. Under these circumstances, effective and timely marketing of alternative health care plans may be hindered.

The Commission recognizes that this particular provision, as well as other prohibitions on marketing activities contained in the proposed regulations, restate, with minor changes, existing regulations that were first proposed in 1975 and that currently apply to certain aspects of HMO participation in the Medicare program. At that time, most marketing activities by health care providers were prohibited by ethical codes or state laws. Regardless of the merits of that earlier approach, we believe that the current regulatory and legal environment has significantly changed and should be carefully reviewed before imposing an additional broad pre-clearance requirement.

Since the Supreme Court's 1976 decision in Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (holding a state prohibition on advertising by pharmacists invalid on First Amendment grounds) and its 1977 decision in Bates v. State Bar of Arizona, 433 U.S. 350 (holding a state prohibition on advertising by lawyers invalid on First Amendment grounds) there has been an increasing interest on the part of the Commission, state regulatory bodies and private professional groups on how to formulate acceptable regulations prohibiting deceptive advertising by professionals, including health care providers. In today's regulatory climate, there is a developing consensus that such regulations should be narrowly drafted so as not to restrict or "chill" the dissemination of truthful, non-deceptive advertising.

We suggest that HCFA consider the adoption of less restrictive alternatives to a broad pre-clearance requirement. One approach would be for HCFA to rely solely on proscription of deceptive marketing activities with post-publication enforcement. If HCFA believes, however, that it cannot accomplish its contractual and regulatory objectives by this means, it should consider other alternatives such as pre-clearance of initial plan brochures only (which presumably represent the primary marketing tool of HMOs and CMPs) or a "sunset" provision that would eliminate any pre-clearance requirement after a reasonable trial period.[1] These less restrictive alternatives would establish HCFA's role in approving HMO and CMP marketing material and notify HMOs and CMPs that, after a track record is established,

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1 If HCFA retains a pre-clearance requirement, we suggest that it consider the use of a "false or deceptive" standard in reviewing promotional materials; we discuss this standard in our comments on Section 417.428(b)(2), infra.

they would not be subject to a pre-clearance requirement that would not ordinarily be imposed on other health care entities.[2]

Section 417.428 (b)(1) - One of the purposes of this section is to prohibit marketing activities that are "unethical." We are concerned that the proscription of "unethical" marketing activities may be unnecessarily vague, and might be used by competing organizations to try to persuade HCFA to restrict beneficial marketing activity by HMOs or as grounds for unwarranted disparagement of HMO activity.

This concern about the "unethical" standard stems from a history of its use to interfere with legitimate HMO activity. In the American Medical Association case, for example, the Commission challenged the AMA's so-called "contract practice" rules, which, among other things, said that it was "unethical" for a patient care physician to sign a salaried contract with an HMO, to agree to accept compensation that is inadequate based on usual fees in the community or to affiliate with a plan that advertises physician services to solicit enrollees.[3] The Commission's order eliminating these restrictions was upheld by the Court of Appeals for the Second Circuit and affirmed by an equally divided Supreme Court. These restrictions were essentially the same ones involved in the conspiracy that was the subject of a 1943 antitrust case against the AMA.[4] We recommend that HCFA consider deleting the word "unethical" and, instead, stating, to the extent possible, additional examples of other activities intended to be proscribed by the regulation.

Section 417.428 (b)(2) - This section prohibits advertising "that could mislead or confuse Medicare beneficiaries, or misrepresent the organization, its marketing representatives, or HCFA." We share HCFA's concern respecting the dangers to the public of false or deceptive advertising of health care plan information. We are acutely aware of the vulnerability of older

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[2] In a somewhat analogous situation, when the Office of Personnel Management contracts with health care insurers and providers (including HMOs) to offer health insurance to Federal Government employees and retirees, we find no similiar pre-clearance requirement. [See 5 C.F.R. § 890 et seq. (1984)].

[3] American Medical Association v. FTC, 94 FTC 701, 1012 (1979), aff'd sub nom. 638 F.2d 443 (2d Cir. 1980), aff'd mem. by an equally divided court, 455 U.S. 676 (1982).

[4] American Medical Association v. United States, 317 U.S. 519 (1943) (upholding a jury's conviction of the AMA and a local medical society for engaging in a criminal conspiracy to obstruct a prepaid health care plan).

Americans, and that their health care decisions involve potentially critical financial and physical risks. Together, these facts make the risk of deception particularly damaging to Medicare beneficiaries. The Commission has specifically recognized the need to protect vulnerable groups such as these from deceptive marketing practices. In the Commission's AMA case, cited above, in which it held AMA's blanket ethical restraint on physician advertising violative of Section 5 of the FTC Act, the Commission noted AMA's legitimate interest in protecting "patients who, because of their particular circumstance, are vulnerable to undue influence. See Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447 (1978)."[5]

In this instance, we urge HCFA to consider carefully whether the "could mislead or confuse" standard used in the regulation provides sufficient guidance as to what advertising is permitted and what advertising is prohibited. Taken literally, almost any advertising conceivably "could" confuse some Medicare beneficiaries. In the absence of clear standards as to what "could" confuse or mislead consumers, the regulation, if adopted, may be interpreted by health care providers to prohibit the dissemination of information that would not be considered false or deceptive by Medicare beneficiaries.[6] The Commission believes that a standard that allows all truthful, non-deceptive advertising, proscribing advertising that is "false or deceptive," protects consumers without unduly restricting competition and the free flow of information. We recommend that HCFA consider revising this section to substitute a standard prohibiting "false or deceptive" marketing activities in place of the phrase "could mislead or confuse".[7]

Section 417.428 (b)(3) - This section prohibits offers of gifts or payment as inducements to enrollment. We support HCFA's

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5 94 FTC at 1030.

6 The Commission order in the AMA case permits the AMA to adopt and enforce reasonable ethical guidelines concerning advertising that it has reason to believe is "false or deceptive" within the meaning of Section 5 of the FTC Act.

7 If HCFA believes the record of past abuses in this area makes it necessary to regulate abusive marketing activities that may not be included in a false or deceptive standard, it should consider whether to proscribe certain practices that may be considered "unfair," such as communications that would appeal to an individual's anxiety in an oppressive or unfair way. In order to provide guidance to HMOs wishing to market their services to Medicare beneficiaries, it would be particularly useful for any such regulation to spell out the criteria for determining what conduct is intended to be prohibited by application of that standard.

efforts to prohibit illegal activities, such as the deceptive use of gift offers as "lead-ins" that the consumer later finds out are available only if he or she enrolls in the plan. We request in this instance that HCFA consider whether this provision may proscribe initiation of particular forms of valuable competitive communications and activities that are otherwise truthful and beneficial.

The section as drafted could be viewed as a ban on particular forms of non-deceptive communications between health care entities and prospective enrollees and may hinder price competition among health care providers. For instance, the section could be read to prohibit legitimate offers of "free tests" at an HMO "open house" to encourage Medicare beneficiaries to come in and visit the facility. The proscription might also interfere with an HMO publicizing that it provides an annual "rebate" to beneficiaries, otherwise permitted by law, when the entity achieves sufficient savings under the Medicare program after payment of all incurred expenses. If HCFA nonetheless believes that such regulations are necessary to deter improper behavior,[8] we recommend that HCFA consider narrowing the text to specify those prohibited inducements of particular concern to HCFA.[9]

Section 417.428 (b)(4) - This section prohibits the use of oral or written communications "that conflict with, materially alter, or erroneously expand upon, the information [approved by HCFA under proposed Section 417.428 (a)(2)]". We support HCFA's efforts to prevent marketing activities that misrepresent health care services available to consumers. In this instance, we suggest that HCFA carefully consider whether this section may, in conjunction with the pre-clearance requirement, unintentionally inhibit an HMO or CMP from making timely non-deceptive communications regarding beneficial changes in its plan, such as additions to its physical plant or increased staff availability. If such communications are considered as "materially" altering prior information, members could not be informed about,

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8 See In re R.M.J., 455 U.S. 191, 203 (1982) where the Supreme Court spelled out the circumstances under which a state could permissibly proscribe specific forms of attorney advertising: "when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the state may impose appropriate restrictions."

9 The supplementary information provided in the Federal Register Notice on the proposed regulations described this section as prohibiting promises or offers of gifts "in return for enrollment." 49 Fed. Reg. 22,198, 22,204 (1984). It is not clear why such offers, which can amount to price reductions to consumers, are of concern to HCFA.

and thus could not take advantage of, improvements in the plan until additional approval of the new material were obtained from HCFA. We believe that such a result may unnecessarily restrict the legitimate activities of HMOs and CMPs, and recommend that HCFA consider revising this section to prohibit expressly only communications that misrepresent the cost, coverage or availability of services under the plan. If HCFA requires a broader proscription, it should consider limiting the regulation to descriptions of the HCFA contract. Such a regulation may, of course, be duplicative of the prohibition that would already be in effect under Section 417.428 (b)(2), and may be unnecessary if the pre-clearance requirement is eliminated from the regulation.

In summary, the Commission believes that the proposed regulations will benefit Medicare beneficiaries by enhancing their ability to enroll in innovative and competitive health care plans. As described above, we recognize and support HCFA's role in proscribing deceptive marketing activities by contracting health care entities, but request that HCFA consider whether certain provisions may unnecessarily restrict the ability of HMOs and CMPs to compete with traditional health care providers for Medicare patients.

By direction of the Commission.

Benjamin I. Sewell

~~Emily H. Rock~~

Acting Secretary