UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of Policy Planning
Bureau of Economics
Bureau of Competition
Bureau of Consumer Protection

September 27, 2007

LouAnn Stanton, Esq.
Office of the General Counsel
Massachusetts Department of Public Health
250 Washington Street
Boston, MA 02108

Dear Ms. Stanton:

The staffs of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, Bureau of Consumer Protection, and Bureau of Competition[1] are pleased to respond to the Department of Public Health's invitation for testimony regarding the proposed regulation of limited service clinics in Massachusetts.[2] The Department of Public Health ("DPH") has undertaken an important initiative to facilitate the emergence of new models of health care delivery.[3] We agree with the DPH that a new category of limited service medical clinics has the potential to expand access to health care by making very basic medical care convenient and less costly.[4] In addition, such clinics

[1] This letter expresses the views of the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, Bureau of Consumer Protection, and Bureau of Competition. The letter does not necessarily represent the views of the Federal Trade Commission ("Commission") or any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

[2] Massachusetts Department of Public Health, MDPH Sets Public Hearings for Proposed Clinic Regulations [hereinafter MDPH Hearings], *available at* *http://www.mass.gov/?pageID=pressreleases&agId=Eeohhs2&prModName=dphpressrelease&prFile=070815_clinic_regs_hearings.xml*.

[3] The American Medical Association has noted the growth of what it terms store-based health clinics – generally located in pharmacies, shopping malls, and retail stores, and often staffed by nurse practitioners and/or physician assistants – and has stated that, "[i]n general, store-based health clinics are able to fulfill the immediate needs of patients with minor conditions with less waiting time, more flexible evening and weekend hours, and in some cases, lower out-of-pocket expenses." American Medical Association, Report 7 of the Council on Medical Service (A-06), Store-Based Health Clinics 1 [hereinafter Council on Medical Service Report] (June 2006).

[4] *See* Massachusetts Dept. Pub. Health, Commonwealth to Propose Regulations for Limited Service Clinics: Rules May Promote Convenience, Greater Access to Care (Jul. 17, 2007), *available at* http://www.mass.gov/?pageID=pressreleases&agId=Eeohhs2&prModName=dphpressrelease&prFile=070717_clinics.xml (Quoting the Commissioner of Public Health, "[i]f approved, these proposed regulations will not only help make very basic medical care convenient, they could also expand access to health care to very vulnerable populations.") It has been reported that consumers most commonly cite convenience factors such as clinic location, shorter wait times, and longer operating hours as advantages to store-based

might spur price or quality competition with more traditional clinics or physician practices.[5] To that end, the DPH's proposal to permit such clinics is commendable, and its proposal of regulatory flexibility – such that the Secretary of DPH may waive certain requirements as appropriate – might be especially helpful in an emerging market, as health care providers explore different ways to deliver basic care on a competitive basis.

At the same time, the FTC staff believes that the proposed pre-screening requirement for all limited service clinic ("LSC") advertising may be overly restrictive, and we recommend that it be struck. Requiring regulatory pre-approval of all advertising materials might represent an undue burden on LSCs and deprive consumers of useful information about basic health care services. In addition, requiring pre-approval for LSC advertising alone, and not that of other health care clinics, might put LSCs at a competitive disadvantage without offering countervailing consumer benefits.

Interest and Experience of the Federal Trade Commission

The FTC is charged generally under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.[6] In addition, Section 12 of the FTC Act specifically prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics.[7]

For several decades, the Commission and its staff have investigated the competitive effects of restrictions on the business practices of health care providers.[8] For example, in 2003, the FTC and the Department of Justice Antitrust Division held twenty-

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health clinics, but that a significant minority cites cost issues as well. *See* Council on Medical Service Report, *supra* note 3, at Executive Summary 1. Because of the limited services offered, and the reduced facilities required to offer such services, and because of typical staffing by, e.g., nurse practitioners, certain costs and prices may be lower. Some employers have reported better cost containment and store- and work-based clinics, as well. *See id.* at Executive Summary 1 and 1-3. It has also been reported that several major insurers cover RediClinic visits (store-based clinics in Wal-Mart, H-E-B, and some Walgreens stores in five states); and that Wal-Mart stores report that between 25% and 40% of the clinic visitors are uninsured. American Medical Association, Report of the Council on Medical Services, Update on Store-Based Health Clinics [hereinafter CMS Update] (2007), *available at http://www.ama-assn.org/ama1/pub/upload/mm/372/a07cms5.pdf*.

[5] Council on Medical Service Report, *supra* note 3 (noting that, "[a]s a result of the emergence of store-based health clinics, many physicians have begun to evaluate making changes to their practices in order to become more accessible to patients.") In addition, it has been reported that physicians have opened their own basic care clinics, employing both nurse practitioner and physician staffing. *See* CMS Update, *supra* note 4, at 3.

[6] Federal Trade Commission Act, 15 U.S.C. § 45; *cf.* MASS. ANN. LAWS ch. 93A (declaring unlawful under state law "unfair or deceptive acts or practices in the conduct of any trade or commerce" and declaring that the legislature intends the provision to be "guided by the interpretations given by the Federal Trade Commission and the Federal Courts to section 5(a)(1) of the Federal Trade Commission Act").

[7] *Id.* at § 52.

[8] *See* Federal Trade Commission, *FTC Antitrust Actions in Health Care Services and Products* (Aug. 2007), *available at* http://www.ftc.gov/bc/0608hcupdate.pdf.

seven days of hearings on health care and competition law and policy.[9] In 2004, the FTC and the Antitrust Division jointly released a report – based on those hearings, an FTC-sponsored workshop, and independent research – that covered diverse issues in health care competition and delivery.[10] Both the hearings and the report addressed, among other things, the impact of regulation on the dissemination of useful health care information to consumers and its impact on consumers' access to care.

The Commission and its staff have also undertaken research and advocacy directed specifically at health care advertising issues.[11] For example, the FTC staff has examined nutrition and health care issues in food product advertising[12] and the direct-to-consumer advertising (DTCA) of prescription drugs, dietary supplements, and medical devices, and has filed comments with the Food and Drug Administration ("FDA") regarding DTCA and DTCA regulation.[13]

The FTC's enforcement actions also have shown a special concern with the integrity of health care goods and services advertising. From April 2006 through February 2007 alone, the FTC initiated or resolved 13 law enforcement actions (involving 25 products) involving allegedly deceptive health claims.[14]

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[9] Federal Trade Commission and Department of Justice, Joint Hearings on Health Care and Competition Law and Policy (2003). Links to transcripts and other hearings materials are available at http://www.ftc.gov/bc/healthcare/research/healthcarehearing.htm.

[10] Federal Trade Commission and Department of Justice, IMPROVING HEALTH CARE: A DOSE OF COMPETITION Chapter 7 (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

[11] LSCs are, by definition, novel market entities and their putative advertising practices have not, to the best of our knowledge, been the subject of systematic study. The FTC has, however, conducted and analyzed research in other areas of health care goods and services advertising, including research regarding restrictions on advertising by health care professionals. *See, e.g.*, Federal Trade Commission, Bureau of Economics Report, The Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry [hereinafter Optometry Report] (1980).

[12] *See, e.g.*, P. Ippolito & J. Pappalardo, *Advertising Nutrition & Health: Evidence from Food Advertising 1977-1997* (2002) (FTC Bureau of Economics Staff Report), *available at* *http://www.ftc.gov/opa/2002/10/advertisingfinal.pdf*; P. Ippolito & A. Mathios, *Information & Advertising Policy: a Study of Fat and Cholesterol Consumption in the United States, 1977-1990* (1996) (FTC Bureau of Economics Staff Report), copies available upon written request, with executive summary available at http://www.ftc.gov/be/hilites/fatexsum.shtm; J. Calfee & J. Pappalardo, *How Should Health Claims for Food be Regulated? An Economic Perspective* (1989).

[13] Comments of the FTC Staff Before the FDA In the Matter of Request for Comments on Consumer-Directed Promotion [hereinafter 2003 DTCA Comments] (Dec. 1, 2003), *available at* http://www.ftc.gov/be/v040002text.pdf; Comments of the FTC Staff Before the FDA In the Matter of Request for Comments on Agency Draft Guidance Documents Regarding Consumer-Directed Promotion [hereinafter 2004 DTCA Comments] (May 10, 2004), *available at* http://www.ftc.gov/os/2004/05/040512dtcdrugscomment.pdf.

[14] *See, e.g., FTC v. Window Rock Enters., Inc.*, No. CV04-8190 (JTLx) (C.D. Calif. filed Jan. 4, 2007) (stipulated final orders) (Cortislim), *available at* http://www.ftc.gov/os/caselist/windowrock/windowrock.htm*; In the Matter of Goen Techs. Corp.*, FTC File No. 042 3127 (Jan. 4, 2007) (consent order) (TrimSpa), *available at* http://www.ftc.gov/os/caselist/goen/0423127agreement.pdf; *United States v. Bayer Corp.*, No. 07-01

At the same time, the Commission has long expressed concern with anticompetitive restrictions on advertising by health care professionals. Because consumers need access to information to be effective market participants and to play an active role in their own health care, it is important to avoid overly broad or otherwise excessive restrictions on consumer access to truthful and non-misleading information. Over several decades, the FTC has sought to limit the anticompetitive and anti-consumer effects of unnecessary restrictions on truthful and non-misleading advertising by, among others, physicians,[15] chiropractors,[16] and optometrists.[17]

Discussion

A. Overview: The DPH has proposed various amendments to its health clinic licensing regulations to permit the licensing of a new class of limited service clinics.[18] Most of the proposed amendments appear designed to apply general licensing requirements – including the procedural requirements of licensing, minimum standards for facilities, record keeping, and emergency transfer arrangements – to LSCs.[19] In some cases, certain modifications have been made to accommodate the more limited nature of

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(HAA) (D.N.J. filed Jan. 3, 2007) (consent decree) (One-A-Day), *available at* http://www.ftc.gov/os/caselist/bayercorp/070104consentdecree.pdf; *FTC v. Chinery*, No. 05-3460 (GEB) (D.N.J. filed Dec. 26 , 2006) (stipulated final order) (Xenadrine), *available at* http://www.ftc.gov/os/caselist/chinery/070104stipulatedfinalorder.pdf; *FTC v. QT, Inc.*, No. 03 C 3578 (N.D. Ill. Sept. 8, 2006) (memorandum opinion and order), *available at* http://www.ftc.gov/os/caselist/0323011/060908qt-qraymemoopinionandorder.pdf.

[14] *See Prepared Statement of the Federal Trade Commission, Before the S. Comm. on Commerce, Sci., & Trans.*, 110th Cong., 14 (Apr. 10, 2007), available at http://www.ftc.gov/os/testimony/P040101FY2008BudgetandOngoingConsumerProtectionandCompetitionProgramsTestimonySenate04102007.pdf.

[15] *See, e.g.*, In re American Medical Ass'n, 94 FTC 701 (1979) (final opinion & order) (regarding restrictions on truthful and non-misleading advertising by member physicians); Response from FTC Staff to Ms. Katherine M. Carroll, Executive Director of the Medical Practitioner Review Panel in New Jersey, concerning one of the advertising regulations of the New Jersey Board of Medical Examiners (Sept. 7, 1993), *available at* http://www.ftc.gov/be/healthcare/docs/AF%203.PDF.

[16] *See* Texas Bd. of Chiropractic Examiners, C-3379 (consent order issued Apr. 21, 1992), 57 Fed. Reg. 20279 (May 12, 1992).

[17] *See, e.g.*, Optometry Report, *supra* note 11.

[18] An announcement of the proposed amendments to 105 CMR 140.000, together with a link to the proposed amendments, is available at http://www.mass.gov/?pageID=pressreleases&agId=Eeohhs2&prModName=dphpressrelease&prFile=070808_limited_service_clinics.xml.

[19] *See, e.g.*, Proposed 140.020 (defining a new category of "limited services" such that the "requirements of 105 CMR 140.100 through 140.109 are applicable to all clinics" – including LSCs).

LSCs.[20] Several proposed regulations – such as the required pre-screening of all LSC advertising[21] – appear to impose novel requirements on LSCs.[22]

B. Advertising: Proposed section 140.1001 would require, among other things, that "[i]f a limited service clinic provides any form of advertising, the clinic must submit all advertising materials to the Department for prior approval. A limited service clinic may not use any advertising materials, including internet sites, that have not been reviewed and approved by the Department."[23] As written, the provision appears likely to raise the costs of operating LSCs and to delay or suppress their truthful and non-misleading advertising. To the extent that the proposed pre-screening requirement imposes significant burdens on LSCs, but on no other type of licensed health care clinic or physician practice, the requirement might raise competition issues for new health care service entities seeking to enter and compete in the market. Finally, because the proposed rule would require that "any" material be pre-screened (or else prohibited), and because "internet sites" are included among such materials, it is possible that the pre-screening requirement could act as an operational burden on small LSCs if, for example, minor changes of hours or staffing could not be announced without regulatory delay or other regulatory costs.

Truthful advertising performs an indispensable role in the allocation of resources in the market. As the FTC staff has observed in other health-related advertising research, "[t]he economics literature contains considerable evidence that the introduction of advertising into markets can have a positive effect on market performance, through lower prices, product improvements, or beneficial changes in consumer purchases, for instance."[24] That general finding about advertising goods and services has been found to apply equally to the advertising of professional health care services,[25] and to the

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[20] *See, e.g.*, Proposed 140.099 (providing that the "Commissioner [of Public Health] may waive the applicability to a particular clinic of one or more of the requirements," under certain conditions).

[21] Proposed 105 C.M.R. 140.1001(I)(2).

[22] We note that the scope of the proposed regulations might be clarified further. Proposed section 140.020 defines "Limited Services" as "[a] prescribed set of preidentified diagnostic and treatment services not otherwise defined as a Specific Service in 105 CMR 140.020 that do not require a complete physical examination and that may make use of CLIA-waived tests only." The list of specific services includes "Medical Service," defined as "service that provides diagnosis or treatment of illness or other medical services that are distinct from the services provided under other 'specific services' set forth herein." "Medical Service" thus appears to be a catch-all category, including health care clinic services not otherwise enumerated as specific services. If so, these various provisions of proposed section 140.020 could be read jointly to preclude any area of healthcare service for LSCs. Because that reading is inconsistent with the stated purpose of the proposed regulations, further clarification may be warranted.

[23] Proposed 105 C.M.R. 140.1001(I)(2).

[24] *Advertising Nutrition & Health*, supra note 16, at E-20.

[25] *See, e.g.*, Terry Calvani, James Langenfeld & Gordon Shuford, *Attorney Advertising and Competition at the Bar*, 41 Vand. L. Rev. 761, 779-781 (1988) (surveying empirical evidence regarding advertising in health care professions).

advertising of other professional services.[26] The free flow of truthful advertising can be equally critical to both providers and consumers, and might be especially important where emerging health care entities offer novel and more convenient access to care[27] or price advantages that might be critical to marginal health care consumers.[28] Such interests have, too, been at the core of the Supreme Court's commercial speech jurisprudence since *Virginia State Board of Pharmacy*.[29]

Hence, it is important that regulations aimed at protecting consumers from false or misleading information avoid unnecessarily impeding consumer access to truthful, non-misleading information about the range of available health care services.[30] The FTC has stated that targeted remedies addressing deceptive advertising generally are preferable to broad pre-market approval of health care claims.[31] As noted above, the FTC Act provides the FTC with enforcement authority in the event that false or misleading advertisements do arise, and the FTC has substantial interest and experience in the exercise of that authority in health care markets.[32] The Commonwealth, too, can enforce state law prohibitions against deceptive advertising.[33]

Because the DPH has not yet specified either the process whereby pre-screening is to take place, or the institutional resources to be devoted to such pre-screening, it is difficult to predict the extent to which the proposed regulation would burden truthful and non-misleading commercial speech. Nonetheless, we are not aware of any evidence supporting a special need for pre-screening for LSCs. In the absence of such evidence, general prohibitions against false or misleading advertising are preferable to overly broad restrictions that might prove costly for Massachusetts health care consumers, independent of the DPH's implementation costs.

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[26] *See id.* (comparing evidence regarding health professions advertising to evidence regarding attorney advertising); Timothy Muris & Fred McChesney, *The Effect of Advertising on the Quality of Legal Services*, 65 A.B.A. J. 1503, 1506 (1979).

[27] *See* MDPH Hearings, *supra* note 2; *see also* Council on Medical Service Report (A-06), *supra* note 3 at 1.

[28] Report 7 of the Council on Medical Service (A-06), Store-Based Health Clinics, *supra* note 4 at 1.

[29] Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976) (state's interest in integrity of profession does not justify unnecessary suppression of truthful advertising under First Amendment).

[30] *Cf.* 2003 DTCA Comments, *supra* note 13, at 37 (encouraging FDA to consider ways to facilitate the flow of truthful and non-misleading information in direct to consumer advertisements for prescription drugs).

[31] *See, e.g.*, Comments of the Federal Trade Commission Staff Before the Dept. of Health and Human Services Food and Drug Administration, In the Matter of Request for Comment on First Amendment Issues, 13 (Sept. 13, 2002), *available at* http://www.ftc.gov/os/2002/09/fdatextversion.pdf.

[32] *See, e.g.*, *supra* notes 6-7 and 14 (regarding FTC authority and enforcement actions, respectively). The threat of enforcement acts, in conjunction with market forces, as a deterrent to the dissemination of false or misleading advertising.

[33] *See, e.g.*, *supra* note 6 (regarding MASS. ANN. LAWS ch. 93A).

If there is evidence that certain claims are likely to mislead or confuse consumers, DPH may want to consider measures – such as agency guidance or mandatory disclosures – that are narrowly tailored to avoid serious harms, but preserve the flow of truthful and non-misleading information.[34]

Conclusions

The Commission staff agrees with the Department of Public Health that a new category of limited service medical clinics has the potential to expand access to health care. The DPH has undertaken an important initiative to facilitate the emergence of this new model of health care delivery within the bounds of responsible practice and professional licensing standards. At the same time, the staff has some concern that certain provisions of the proposed LSC regulations might be unclear or unduly restrictive of emerging clinic practices. In particular, the proposed requirement that all LSC advertising be pre-screened by the DPH is likely to prove an impediment to the dissemination of truthful and non-misleading information about health care alternatives for Massachusetts consumers. For that reason, the staff recommends that the pre-screening requirement be struck, especially as there appears to be no evidentiary basis for requirements above and beyond a prohibition of false or misleading advertising.

[34] *See id.* at 16-17 (regarding the Food Copy Test and FTC guidance on the qualification of certain health claims); *see also id.* at 21 (regarding certain mandatory disclosures).

Respectfully submitted,

Maureen K. Ohlhausen
Director
Office of Policy Planning

Michael R. Baye
Director
Bureau of Economics

Jeffrey Schmidt
Director
Bureau of Competition

Lydia B. Parnes
Director
Bureau of Consumer Protection