U.S. Department of Justice

Antitrust Division

City Center Building
1401 H Street, NW
Suite 4000
Washington, DC 20530

June 6, 2008

Senator Michael D. Bishop
Senate Majority Leader
P.O. Box 30036
Lansing, Michigan 48909-7536

RE: Proposed Certificate of Need Standards for Proton Beam Therapy Services

Dear Senator Bishop:

You have requested that the Antitrust Division comment on the proposed standards for proton beam therapy ("PBT") adopted by the Michigan Certificate of Need Commission and currently under review by the Michigan Legislature and Governor. Your request for comment describes PBT as a "highly sophisticated radiation therapy which can save the lives of many cancer patients."[1] Under Michigan law, either the Legislature or the Governor may disapprove the proposed standards if such action is taken by June 16, 2008. Specifically, you have asked whether the proposed PBT standards might lead to violations of the federal antitrust laws or raise other competition policy issues. In our view, the proposed standards are likely to harm competition and will potentially result in harm to cancer patients in Michigan. The proposed standards may also violate the Sherman Act. Accordingly, the Antitrust Division recommends that the Legislature or Governor reject the proposed PBT standards.

Under the proposed standards, an entity applying for a certificate of need ("CON") to construct a PBT unit and provide services must be a single legal entity authorized to do business in Michigan.[2] That entity must be a statewide collaborative, consisting of a majority of all Michigan hospitals offering megavoltage radiation therapy services with more than 30,000 equivalent treatment visits.[3] The standards further prohibit any hospital offering megavoltage

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[1] Letter from Senator Majority Leader Michael D. Bishop, Michigan Senate, to Joseph Miller, Assistant Chief, Litigation I Section, Antitrust Division, U.S. Department of Justice, May 23, 2008.

[2] Certificate of Need Review Standards for Megavoltage Radiation Therapy Services/Units, Michigan Department of Community Health, Section 10(1)(A).

[3] *Id.* at Section 10(1)(B).

radiation therapy from participating in more than one statewide collaborative to provide PBT.[4]

As you explain in your letter, these proposed changes would have several implications: First, the standards would likely permit only one PBT provider to operate in Michigan. Second, the entity granted the CON must include at least five of the nine largest radiation oncology hospitals in the state, which would allow a majority of the current competitors for radiation oncology services to block any PBT center from being built in Michigan, or in the alternative to form a joint venture to build the new PBT center themselves. Third, if the existing hospitals form a new joint venture to apply for the CON, that new entity would have significant commercial discretion to exclude other hospitals from joining the entity, to set the terms and conditions under which other hospitals and their physicians would be able to participate in the entity, and to set the rates and other terms and conditions of service. Further, the joint venture would operate without meaningful state supervision.

Based on the information provided in your letter, the Division believes that it is likely that the proposed changes to the certificate of need rules will harm consumers. The standards have the potential to delay or exclude a competing and perhaps superior technology from entering the marketplace, and therefore may have substantial negative health consequences for cancer patients in Michigan. By requiring a majority of the nine largest radiation oncology providers to agree to collaborate before a certificate of need for a PBT unit will be issued, the proposed standards create a significant economic incentive for the current providers of radiation oncology services to protect their revenues by delaying or defeating entry of a competing product.

Proponents of the proposed changes to the CON standards assert that the incumbent radiation oncology providers ("the consortium") should be the only ones permitted to build a PBT unit and offer associated oncology services,[5] and indeed the proposed rules appear designed to advance that goal. The consortium projects a need for only one PBT unit, and suggests that anything more would result in unnecessary spending. The consortium also claims that it would benefit the public by using the new PBT unit to perform research, that it would spread the revenues among consortium providers, and that forming a consortium would allow the participating hospitals to ensure appropriate utilization and case management. Even assuming the consortium's members will not use the proposed standards to completely block entry of a new PBT unit in Michigan, their arguments do not address why changing the CON rules would bring the new technology to market faster than would otherwise be the case. Moreover, the consortium's arguments appear to be based on the premise that competition is wasteful and should be limited by legal rules. We disagree with that proposition, and have offered testimony about the benefits of competition in healthcare to the legislatures of Georgia, Alaska, and Florida as those states have debated whether to abolish their own CON regimes.[6] We have stated that market forces improve the quality and lower the costs of health care services. They drive

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[4] *Id.* at Section 10(1)(I).

[5] *See* www.protontherapyformichigan.org.

[6] *See, e.g.,* http://www.usdoj.gov/atr/public/comments/233821.pdf.

innovation and ultimately lead to the delivery of better health care, and arguments to the contrary lack support in the law, as well as the economics literature.[7]

The proposed PBT standards (or their exercise) may also violate the Sherman Act, which prohibits agreements in restraint of trade. Certificate of need regimes, by their nature, limit competitive entry and impede the proper functioning of the market process. They can create market power where it may not otherwise exist, limit patient choice, and create opportunities for existing competitors to thwart or delay new competition.[8] If CON activity were purely private action instead of the actions of a state government, it would likely violate the Sherman Act. In most circumstances, however, CON authorities are exercising the powers of the state government, and qualify for "state action" immunity from the federal antitrust laws even if the effects of the regulations are anticompetitive. For a regulation to qualify for state action immunity it must satisfy two requirements: (1) there must be a clearly articulated and affirmatively expressed state policy to displace competition; and (2) the underlying conduct enabled by the regulation must be actively supervised by the state.[9] The "active supervision" requirement assures that potentially anticompetitive conduct is carried out in a way that the state considers to be in the public interest, rather than merely the private interests of the parties involved.[10]

Although we have not undertaken the fact-based investigation needed to allege a violation of the Sherman Act, we believe that it is possible that the proposed PBT standards would not qualify for state action immunity. The PBT standards could fail to satisfy the active supervision requirement for state action immunity because they may allow hospitals to enter into what would otherwise be unlawful agreements without review or supervision by the State in any meaningful way.[11]

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[7] *Id.*

[8] The practice of competitors using CON laws to restrict competition is illustrated by two recent antitrust enforcement actions. *See U.S. v. Charleston Area Medical Center, Inc.*, Civil Action 2:06-0091 (S.D.W.Va. 2006) (available at: http://www.usdoj.gov/atr/cases/f214400/214477.htm) (hospital used the threat of objection during CON process, and the potential ensuing delay and cost, to induce a rival hospital to select an alternate, inferior location for a new facility); *U.S. v. Bluefield Regional Medical Center, Inc.*, 2005-2 Trade Cases ¶ 74,916 (S.D.W.Va. 2005) (with the encouragement of state CON officials, two competing hospitals allocated health care services between themselves, one applying for an open heart program and the other for cancer services).

[9] *See California Retail Liquor Dealers Assn. v. Midcal Aluminum, Inc.*, 445 U.S. 97, 105 (1980).

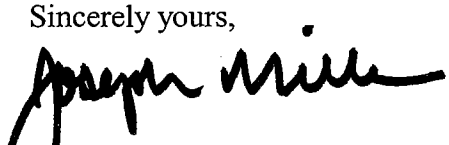
[10] *See FTC v. Ticor Title Ins. Co.*, 504 U.S. 622, 634-35 (1992).

[11] *See generally Midcal*, 445 U.S. at 106 (prohibiting states from thwarting a national policy in favor of competition by casting "a gauzy cloak of state involvement over what is

As we have explained in prior settings, the Antitrust Division does not have a preference for any particular model for the financing and delivery of health care. Rather, our goal is to protect competition so that consumers will have the benefit of high quality, cost-effective health care and a wide range of choices.[12] Thus, while it is our general understanding that PBT is an improvement over standard photon (X-ray) technology for some patients, we express no preference for one technology over another. Our purpose in writing this letter is to allow the competitive process to deliver lower costs and higher quality without being thwarted by anticompetitive and potentially illegal certificate of need rules.

Thank you for providing the Antitrust Division the opportunity to comment on the proposed standards. In conclusion, the Antitrust Division believes that (1) the proposed PBT standards are likely to impose substantial costs on consumers and the market for radiation therapy; and (2) the standards, as currently written, may violate the Sherman Act. In light of these concerns, the Antitrust Division recommends that Michigan reject the proposed standards.

Sincerely yours,



Joseph Miller
Assistant Chief, Litigation I Section
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essentially a private price-fixing arrangement").

[12] Statements of Antitrust Enforcement Policy in Health Care, August 1996, Introduction, pg. 3 (available at: http://www.usdoj.gov/atr/public/guidelines/1791.htm).