

October 7, 2016

Monica Bharel, MD  
Commissioner  
Massachusetts Department of Public Health  
250 Washington Street, 2nd Floor  
Boston, MA 02108

Re: Proposed Revision of 105 CMR 100.000: Determination of Need

Dear Commissioner Bharel:

On behalf of the American Medical Association (AMA) and its physician and medical student members, I appreciate the opportunity to provide comment on the Department of Public Health's (the Department) proposed revision to the Determination of Need (DON) regulations (sometimes called certificate of need or CON laws) in 105 CMR 100.000. We appreciate the Department's efforts to simplify the DON regulations and better align them with the public policy goals of improved access, quality and cost control. However, we are concerned about the proposed changes that would permit DON applications only from ambulatory surgery centers (ASCs) that are affiliated, co-located or in a joint venture with an acute care hospital.

The proposed limitation on ASCs applications would effectively prohibit independent and freestanding entities from establishing an ASC. Underlying this proposal is the faulty assumption that hospital-affiliated facilities provide better, less expensive care. To the contrary, research has shown that ASCs are a cost-effective alternative to hospital-based surgery and outpatient services. ASCs are able to increase patient choice by providing greater specialization for select procedures, convenient locations and more appointment flexibility than hospitals. Further, both public and private health care payers reap significant savings when patients seek care in ASCs because the facility fees are significantly lower than those billed by hospitals.

Requiring only ASCs to be affiliated with an acute care hospital draws an arbitrary line between ASCs and other health care entities. We see no worthy reason to discriminate against a segment of DON applicants in this way. We are, however, extremely concerned about the anticompetitive effects the proposed regulation will have. Ample research has demonstrated that impeding market entry stifles competition to the detriment of innovation, patient access and costs. By drawing an unsubstantiated distinction between independent ASCs and those connected to an acute care hospital, the Department will provide a competitive advantage to market incumbents, rather than fulfilling the stated goal of encouraging competition and ensuring patient access to facilities which provide high quality, innovative and cost-effective surgical care.

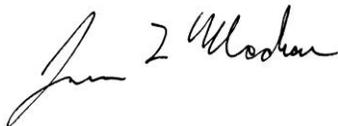
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While we appreciate the Department's emphasis on protecting community hospitals, we believe a more narrowly-tailored policy approach would better address the financial solvency of community hospitals. Research has shown that safety-net hospitals are no better off in states with DON laws than in those without DON laws.<sup>1</sup> Further, the protectionist rationale is at odds with the cost-control rationale for DON reform. As the Federal Trade Commission and US Department of Justice have pointed out, "the notion that CON-protected incumbents will use their market power and profits to cross-subsidize charity care supposes that those providers will charge supracompetitive prices for non-charity care. Such supra-competitive pricing might harm many ... health care consumers, including low-income or under-insured patients ...."<sup>2</sup> It is also important to note that striking the hospital affiliation requirement would not lead to a surge in the number of new ASCs, as they would still be required to meet the DON criteria specified in the regulations, just as other DON applicants would.

For these reasons, we respectfully request that the Department remove the requirements in 105 CMR 100.730 and 100.740 that prohibit DON applications from ASCs if they are not affiliated, co-located or joint ventured with an acute care hospital. We fear that by burdening ASCs with this unnecessary restriction, the Department risks jeopardizing their valuable contribution to the health care system. We urge the Department to implement DON regulations that promote a fair and evenhanded DON assessment of all entrants to the health care market.

The AMA thanks you for your consideration of this important issue. If you have any questions, please contact Annalia Michelman, Senior Legislative Attorney, Advocacy Resource Center, at [annalia.michelman@ama-assn.org](mailto:annalia.michelman@ama-assn.org) or (312) 464-4788.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD

cc: Massachusetts Medical Society  
Ambulatory Surgery Center Association

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<sup>1</sup> The Lewin Group, An Evaluation Of Illinois' Certificate Of Need Program: Prepared For The State Of Illinois Commission On Government Forecasting And Accountability (2007)

<sup>2</sup> Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250, (January 11, 2016)