October 7, 2016

Monica Bharel
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street
Boston, MA 02108

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

Dear Commissioner Bharel,

On behalf of the Ambulatory Surgery Center Association (ASCA), American Academy of Ophthalmology (AAO), the American College of Gastroenterology (ACG), the American Society of Cataract and Refractive Surgery (ASCRS), the American Society for Gastrointestinal Endoscopy (ASGE), the Outpatient Ophthalmic Surgery Society (OOSS), and the Society for Excellence in Eyecare (SEE), representing the interests of over 5,400 Medicare-certified ambulatory surgical centers and the physicians that provide services in those facilities, we appreciate the opportunity to comment on the draft regulations relative to 105 CMR 100.000 on Determination of Need (DoN). Our organizations support the proposed elimination of the oppressive moratorium on ASCs that has been in place since 1994. However, we do not support the restrictive requirement contained in the proposed regulations that would require a freestanding ASC applying for a Determination of Need for any proposed project to be affiliated with or in a joint venture with an acute care hospital.[1]

Ambulatory Surgery Centers (ASCs) are innovative, high-quality surgical facilities located in every state and offers patients a convenient and cost efficient care. In a 2013 study, researchers at the University of California-Berkeley found that ASCs saved the Medicare program and its beneficiaries $7.5 billion during the four-year period from 2008 to 2011.[2] It is projected that ASCs could reduce Medicare costs by an additional $57.6 billion over the next decade if the use of these innovative healthcare facilities is promoted within the Medicare system. Further, a recent analysis of private health insurance claims nationwide found that ASCs reduce the cost of outpatient surgery by more than $38 billion dollars per year by providing a lower cost site of care[3]. The study also showed that if a mere 5% of the ASC eligible procedures migrated to ASCs each year, it would generate $114 billion in savings over 10 years, including $17 billion in lower co-pays for patients. The research concluded that ASC prices are significantly lower than HOPD prices for the same procedures throughout the country, regardless of payer.

[1] 105 CMR 100.740

[2] *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, September 2013.

[3] *Commercial Insurance Cost Savings in Ambulatory Surgery Centers*, Healthcare BlueBook and Health Smart, June 2016.

We are pleased to find that the Massachusetts Health Policy Commission (HPC) agrees. The HPC is an independent state agency whose goal is better health and better care at a lower cost across the Commonwealth. In a recent report, which was the sole study referenced in a memorandum[4] from the Department of Public Health on the proposed regulations, the HPC highlighted the stellar quality of ASCs, the cost reductions and the convenience for patients. The 78-page report, entitled *Community Hospitals at a Crossroad* was compiled to examine the current state of community hospitals in Massachusetts amid concerns that hospitals closing and service reductions can result in patients losing "access to necessary services and communities scrambling to fill the gaps."[5] Our organizations agree that when hospitals, urgent care centers or ASCs close, patients lose access to the care they need.

We are unclear as to why this report was the sole reference in a memorandum from the department on the proposed regulations, particularly because ASCs are mentioned only eight times in the report focused on community hospitals, but we agree with its findings on ASCs. The report ascertains that ASCs provide "low-cost, time saving alternatives" and attract patients due to convenient locations.[6] Another report found that the state's private and public health care system total costs rose by 3.9 percent in 2015 and per capita health care costs per resident rose to $8,424, up from $8,010 in 2014.[7] In fact, the HPC report cites outdated 2013 CMS data that ASCs are paid 22% less on average for the same procedure performed in a hospital outpatient department. The most recent data, from 2016, shows that ASCs are only paid 53% of what HOPDs are paid for the exact same services.

We strongly support the DPH's decision to lift the oppressive moratorium on ASCs. We thank DPH for considering the needs of Massachusetts communities and recognizing that the moratorium hindered access to high quality, low cost care for patients all over the commonwealth. However, this positive step towards better access to the same high-quality care is once again being hindered, by a newfound burden. Despite all the accurate information from the HPC on ASCs, ASCs are being restricted in the proposed regulations. No other state has such a burdensome and anti-competitive restriction on ASCs. We are not opposed to determination of need regulations. We appreciate and understand the role it plays in regulating the healthcare market to best serve the needs of the citizens of Massachusetts. However, the proposed policy does not allow for the state to make these decisions, but rather for acute-care hospitals to make the decision on ASC viability.

As the regulator, the DPH should maintain its decision-making power and seriously reconsider the proposed regulation which gives acute-care hospitals sole control over ASCs. In the past year, the Federal Trade Commission has expressed great concern with the certificate of

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[4] *Informational Briefing on Proposed Revision of 105 CMR 100.000: Determination of Need*, Department of Public Health, the Commonwealth of Massachusetts (Aug. 23, 2016)
http://www.mass.gov/eohhs/docs/dph/legal/don/phcmemo-100final.doc

[5] *Community Hospitals at a Crossroads*, Health Policy Commission (Feb. 2016) pg. 4
http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/community-hospitals-at-a-crossroads.pdf

[6] *Ibid* at pg. 61.

[7] *Report: Health care costs top benchmark in Massachusetts*, Portland Press Herald (Sept. 7, 2016)
http://www.pressherald.com/2016/09/07/report-health-care-costs-top-benchmark-in-massachusetts/

need laws in Virginia, Georgia and North Carolina. Specifically, in North Carolina, the FTC took issue with the requirement that ambulatory surgical centers must obtain written transfer agreements from hospitals. The FTC believed that this provision "could be improperly used by incumbent hospitals to block a potential competitor's license."[8] With the proposed regulations in Massachusetts, it is very likely that hospitals could also abuse its newfound power and improperly block their potential competitors, the ASCs. Just as the FTC was concerned with giving executive power to the hospitals, we hope the DPH will be as well.

The HPC report does recommend that policies be put in place to require financial and clinical partnerships to assure community hospital sustainability. Community hospitals, teaching hospitals, urgent care centers and ASCs each play important roles in community healthcare. Each provide unique care for the needs of patients throughout the commonwealth. As the DPH explains in its press release, its goal with the proposed regulations is to "incentivize competition" on a provider's ability to innovate, increase competition on the basis of price and successfully incorporate population health management.[9] However, forcing private entities to partner with potential competitors in the marketplace does nothing to increase competition, and in fact forces ASCs to negotiate with hospitals with significantly greater market power in the negotiation. This regulation has the potential to effectively eliminate ASCs as a lower cost, high-quality alternative to HOPDs and significantly increase costs to Massachusetts patients.

The report does state that the trend towards non-hospital care is "good for patients and more cost-effective for consumers" but threatens the financial stability of hospitals.[10] Competition in the healthcare market, like any other market, threatens providers who are inefficient and fail to adapt to changing market conditions. Moreover, unlike ASCs, other entities such as retail clinics and urgent care facilities have grown rapidly in the past eight years, as patients have sought alternative sites of care. Urgent care centers grew from 10 to 85 centers and retail clinics grew from 3 to 56.[11] The number of ASCs actually has decreased, from 63 in 2008 to 56 today, and will inevitably continue to decline under the proposed regulation. This short-sighted proposal will have a severe impact on the viability of ASCs, the proven cost-savings they provide to patients, and patient access to high-quality healthcare.

We commend the department's desire to promote a free-market and "incentivize competition" to help drive costs down and quality up.[12] We agree that promoting competition in the healthcare market will benefit all. However, we are baffled as to how giving sole control to acute-care hospitals, ASCs' competitors, will foster competition. By requiring ASCs to be affiliated with their competitor, the regulation effectively will produce monopolies. By granting the decision-making power for ASCs to make any changes in their operations to their competitor,

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[8] Federal Trade Commission, *Comment on North Carolina Certificate of Need Regulations*, July 10, 2015. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-concurring-comment-commissioner-wright-regarding-north-carolina-house-bill-200/150113ncconadv.pdf

[9] Proposed Revision of the Determination of Need Regulation 105 CMR 100.000 Presentation, Massachusetts Department of Public Health, Aug. 23, 2016, pg. 22. http://blog.mass.gov/publichealth/wp-content/uploads/sites/11/2016/08/Determination-of-Need.pdf

[10] *Community Hospitals at a Crossroads* at pg. 59.

[11] *Ibid* at pg. 60.

[12] DoN Regulation Presentation, pg. 22.

this proposal will effectively eliminate competition, thereby causing costs to rise. At the very least, DoN should be a level playing field for all entities, including ASCs. ASCs have already been disadvantaged since the moratorium was enacted, but ASCs should be treated similarly to all others entities. The unfair restriction on standalone ASCs is unduly burdensome, without merit, and creates a legitimate anti-trust concern.

We are confident that the Department will ensure that it maintains high-quality healthcare options for its citizens at a lower cost to insurers and their patients. As established by the state's own research group, the high quality and cost reductions provided by ASCs are unquestionable and we hope that competition will be enabled by amending the proposed regulation. We applaud the removal of the moratorium and seek the removal of the anti-competitive requirement that ASCs must be partnered with acute-care hospitals. If you have any questions, please contact Nawa Arsala at narsala@ascassociation.org or 571-429-8108.

Sincerely,

Ambulatory Surgery Center Association
American Academy of Opthalmology
American College of Gastroenterology
American Society of Cataract and Refractive Surgery
American Society for Gastrointestinal Endoscopy
Outpatient Opthalmic Surgery Society
Society for Excellence in Eyecare