PETITION FOR CHANGE IN BASIC POLICIES AND METHODOLOGIES STATE MEDICAL FACILITIES PLAN

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Petitioner

1. Petitioner

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2. Requested Change

Historically the exceptions to certificate of need ("CON") and state licensure law have not been and currently are not being applied equally to all medical/surgical specialties that operate ambulatory surgical facilities in North Carolina. In 2005, gastroenterology as a medical/surgical specialty was provided with an exception to CON law under H.B. 1060 and resulting changes to G. S. 131E. This legislation allowed single specialty gastrointestinal endoscopy centers to gain state licensure as ambulatory surgical facilities without the requirement of a CON. No other medical/surgical specialty was provided with a similar and equal exception. At this time more than one hundred and fifteen (115) plastic surgery, oral maxillofacial surgery, and otolaryngology (ENT) ambulatory surgical facilities in North Carolina operate with anesthesia services and are not subject to CON and state licensure requirements as referenced in Appendices A and B. It is requested that CON and licensure exceptions be applied equally to all ambulatory surgical facilities, regardless of medical/surgical specialty. The request is that orthopedic surgery, ophthalmology, urology, OB/GYN, general surgery, and other medical/surgical specialties be allowed to develop and operate single specialty ambulatory surgical facilities, not subject to the requirements of CON and state licensure, equally as plastic surgery, oral maxillofacial surgery, and otolaryngology (ENT) do presently. Legal challenge or legislation may have to be initiated to gain equal protection as was provided to the medical/surgical specialty of gastroenterology under H.B. 1060.

3. Reasons for Proposed Change

Certain medical/surgical specialties (e.g. plastic surgery, oral maxillofacial surgery, and otolaryngology (ENT)) have been permitted to develop outpatient medical/surgical programs without the requirement of a CON and are not subject to state licensure as a

result. Please review Appendices A and B for research support. Appendix A lists the unlicensed but operational ambulatory surgery centers by medical/surgical specialty. Appendix B demonstrates the public signage select outpatient surgery centers without the requirement of a CON or licensure.

Under NCGS 131E-176, an ambulatory surgical facility is defined as a surgical program requiring "local, regional, or general anesthesia" among other requirements:

> **§ 131E-176. Definitions.**
> As used in this Article, unless the context clearly requires otherwise, the following terms have the meanings specified:
>
> (1b) "Ambulatory surgical facility" means a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least one designated operating room or gastrointestinal endoscopy room, as defined in Article 5 Part 1 and Article 6, Part 4 of this Chapter, and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program as defined in subdivision (1c) of this section and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.

All of the unlicensed ambulatory surgery centers listed in Appendix A use anesthesia services incidental to their surgery. Lists of licensed ambulatory surgical facilities for gastrointestinal endoscopy and multi-specialty surgery that also use anesthesia services are provided in Appendices C and D respectively.

NCAC regulations regarding CON applications are outlined below and list specific medical/surgical specialties, including plastic surgery, otolaryngology (ENT), and oral (maxillofacial) surgery that are supported by CON requirements:

> 10A NCAC 14C .2102 INFORMATION REQUIRED OF APPLICANT
> (a) An applicant proposing to establish a new ambulatory surgical facility, to establish a new campus of an existing facility, to establish a new hospital, to convert a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or to add a specialty to a specialty ambulatory surgical program shall identify each of the following specialty areas that will be provided in the facility:
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> (1) gynecology;
> (2) otolaryngology;
> (3) plastic surgery;
> (4) general surgery;
> (5) ophthalmology;

(6) orthopedic;
(7) oral surgery; and
(8) other specialty area identified by the applicant.

The State of North Carolina has not enforced CON legislation equally across all medical/surgical specialties, given the exceptions to CON and state licensure provided to the medical/surgical specialties of gastroenterology, plastic surgery, oral maxillofacial, and otolaryngology (ENT) surgery in the past and currently.

4. Evidence of Unnecessary Duplication of Health Resources

The demand for ambulatory surgery is increasing due to advances in technology and anesthesia, and single-specialty ambulatory surgery operating rooms are recognized as a highly effective means of expanding access while achieving cost savings, regardless of the availability and potential underutilization of hospital-based operating rooms.

5. Evidence Consistent With Three Basic Principles

Single specialty ambulatory surgical facilities may be safer than multi-specialty hospital-based surgical operating rooms due to lower infection rates as documented in medical literature.

Hospital outpatient surgery costs to patients do not represent fair or equitable value. Patients and other purchasers have been forced to purchase outpatient medical/surgical services at paid fees that are excessive and far in excess of underlying cost incurred by hospitals, even taking into account certain less profitable or money losing service lines (e.g. emergency departments). Patients who are under- and uninsured are often forced to pay for necessary outpatient services at billed charges due to their lack of insurance coverage, which is the greatest social travesty of all.

Excessive hospital charges and costs have been well documented in recent years, most recently in the March 4, 2013 **TIME** magazine article, *Bitter Pill – Why Medical Bills Are Killing Us*, by Steven Brill. The lack of cost control effectiveness by CON legislation has been longstanding from a research perspective. The State of California in 2006 conducted a review of the demise of its own CON program in *Hospital Planning: What Happened to California's Certificate of Need Program?* The research was conducted by Charlene Wear Simmons, Ph.D. Assistant Director of the California Research Bureau, a state agency. The Executive Summary references North Carolina's CON legislation:

> **Other states, notably North Carolina and Michigan, apparently have effective, well-staffed CON programs. Their impact on reducing health care costs has not been demonstrated, however.**

Hospitals in North Carolina, given the protection of CON legislation, have increased inpatient and outpatient charges and reimbursement without sufficient competition over the past forty (40) years.

In 2010-2011, the State of North Carolina through The Medical Care Commission ("MCC") engaged Greg Vistnes, Ph.D., a consultant with Charles River Associates and a former research staff leader with the Federal Trade Commission, to review the Certificate of Public Advantage ("COPA") extended to the merger of St. Joseph's Hospital and Memorial Mission Medical Center (now Mission Health System). In May 2011, Cory Capps, Ph.D. of Bates White Economic Consulting then reviewed Dr. Vistnes' research in a report, *Revisiting the Certificate of Public Advantage Agreement Between The State of North Carolina and Mission Health System*. Clearly, the COPA has reduced competition and not resulted in lower costs for consumers. Indeed, Dr. Capps recommended "price caps" for services provided by Mission Health System under the COPA.

Equally as troubling is the fact that North Carolina's largest, non-for-profit health systems, Novant Health ("Novant") and Carolinas Healthcare System ("CHS"), possess billions of dollars of cash and investment dollars in non-building and real estate Net Assets on their balance sheets.[1] Yet, both Novant and CHS have chosen to use some of these Net Assets earned from non-payment of North Carolina taxes to invest in hospitals and health systems in other states, including Virginia and South Carolina, as opposed to reducing North Carolina patient charges and fees, especially to the under- and uninsured.

[1] Audited financial reports for many health systems and hospitals in North Carolina are available from the Medical care Commission under FOIA requests.