

## **Justification and Senate 576 as filed.**

### **Justification for SB 576**

#### ***An Act Relative to the Determination of Need for Independently Licensed/Commercial Laboratories***

The proposed legislation would ensure that an additional key component of the outpatient health care delivery system is subject to determination of need (DoN) to promote the rational allocation of health care services. Clinical laboratories provide some of the same components of outpatient services typically provided by hospitals, and they are included within the statutory and regulatory definitions of those health care facilities that are subject to DoN. Historically, however, the department had not enforced DoN requirements in the clinical laboratory context most likely because of the exemption for outpatient services.

Recently, however, the legislature and the department determined that the broad outpatient services exemption from DoN must be restricted. Ambulatory surgery centers (ASCs) and major hospital outpatient expenditures are now subject to DoN.

Independent/commercial clinical laboratories contract independently with HMOs and together they are encouraging more and more patients to obtain their laboratory testing outside of the hospital setting – even if their doctor’s offices are located on the hospital site. Hospitals are obligated to operate laboratories for their inpatients and depend on additional testing for their outpatients to provide a minimum number of procedures to ensure high quality, efficient and cost effective care.

Commercial labs duplicate many of the outpatient services provided by hospitals, and are able to do so at lower expenses because they are not subject to the same regulatory requirements. Such legislation also would have the effect of leveling the playing field by reducing inequities among like health care providers. If commercial laboratories are attempting to serve more and more hospital outpatients, they, like ASCs, should be subject to similar regulatory requirements. Currently, commercial labs can open or expand their facilities at any time in any community with only licensing review of their laboratory services. The proposed legislation would ensure that such facilities are subject to the same disclosure and planning requirements to which other outpatient projects are subject.

**SENATE . . . . . No. 576**

**The Commonwealth of Massachusetts**

PRESENTED BY:

**Robert A. O'Leary**

*To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:*

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

**An Act Relative to the Determination of Need for Independently Licensed/Commercial Laboratories .**

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Robert A. O'Leary	Cape and Islands

**The Commonwealth of Massachusetts**

**In the Year Two Thousand and Nine**

**AN ACT RELATIVE TO THE DETERMINATION OF NEED FOR INDEPENDENTLY LICENSED/COMMERCIAL LABORATORIES .**

*Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:*

SECTION 1. Chapter 111 of the general laws is hereby amended by inserting after section 53G, as added by section 11 of chapter 305 of the acts of 2008, the following new section: -

“Section 53H. Notwithstanding any general or special law or regulation to the contrary, no original license shall be issued to establish a clinical laboratory unless there is a determination by the department that there is a need for such facility. The department shall promulgate regulations to implement this section, including with respect to grandfathering of existing facilities.”

SECTION 2. Section 25B of said chapter 111 is hereby further amended by inserting within the definition of "Expenditure minimum with respect to substantial capital expenditures", after the clause "other than ambulatory surgery," the following:-

"or other than expenditures with respect to an independently licensed clinical laboratory".