Massachusetts Council of Community Hospitals

Rationale for House No. 2063 AN ACT RELATIVE TO DETERMINATIONS OF NEED.

Rationale

The proposed amendment will promote (a) health care quality and patient safety, (b) more effective health care planning and allocation of health care resources and (c) more equitable sharing of the burdens of the uncompensated care pool and health care safety net trust fund liabilities by requiring that all providers of advanced surgical services be subject to the same rules for implementation and operation of those services.

A. Historical Basis for Current Law

Historically, major surgical services were provided only in hospitals or other institutional settings that were subject to the licensure, patient safety and healthcare planning and access requirements of state law. At that time, individual patients could take comfort that any facility in which they sought such services would be subject to some uniform and uniformly enforced standards of quality, and the public as a whole could be assured that such major healthcare facilities fit logically into an overall healthcare system providing comprehensive and readily accessible services.

At the same time, public oversight of physician practice was generally limited to licensing the individual practitioner, with no separate oversight of the facilities or equipment used by the practitioner in his or her practice. Two decades ago, this disparity in oversight of healthcare facilities and equipment may have been appropriate in light of the model of physician practice then generally prevalent.

However, with the subsequent rise of entrepreneurial medicine, physicians now commonly own and control facilities and equipment that the public would rightly expect to be subject to state oversight and regulation, and that cannot adequately be effectively regulated only through the individual physician's license to practice medicine.

B. Changes in the ASC Industry Requiring Change in the Law

More that half of outpatient surgeries nationally are now performed in free-standing centers and physician offices, according to the Medicare Payment Advisory Commission. Not only are the numbers of such procedures steadily rising, so are their complexities. Although originally providing only simple procedures like breast biopsies and cataract removals, ambulatory surgery centers ("ASCs") now offer complex orthopedic, gastroenterological and gynecological surgeries. Under the current law that is based upon a long outdated concept of the physician's office, those services can be provided without facility licensure, regulatory oversight or

healthcare planning consideration, provided that the facility is nominally an extension of a physician office (a few payors require licensure and Medicare program requires either licensure or third-party accreditation). Patient safety and the integrity of the healthcare delivery system are both threatened by the current shortcomings in the law.

C. Proposed Requirement of Annual State Survey and Licensure

The proposed amendment addresses these shortcomings in several ways. First, it requires state licensure/survey of all ASCs providing surgical services beyond a minimal level of invasiveness and risk. Rather than attempting to list all of the covered surgical procedures, the proposed amendment utilizes the associated level of required anesthesia as a line of demarcation. The anesthesia-based marker is described in the proposed amendment as "single or multiple specialty surgical services requiring general, spinal or major regional anesthesia". Deliberately excluded are procedures requiring only local anesthesia or conscious sedation. Although there are risks associated with all procedures requiring any form of anesthesia and with anesthesia itself, certain low risk, low complexity procedures may well be appropriate for true physician office settings. Therefore, nearly all dental and oral surgery procedures would be excluded from the separate licensure/survey and healthcare planning requirements of the proposed amendments, as would facilities only providing services requiring conscious sedation level of anesthesia (e.g., endoscopy centers). If, however, a procedure is sufficiently invasive or complex to require general, spinal or major regional anesthesia, the risk to patient safety from the procedure and the anesthesia is great enough to warrant regulatory oversight.

Annual inspection and licensure of any ASC will provide the public with an important level of assurance about the training and ability of facility personnel, the quality of the facility equipment and the validity of the ASC's policies and procedures relating to its scope and delivery of services. Forty-three other states currently require uniform state licensure of ambulatory surgery centers. Neither Medicare certification nor third party accreditation are adequate substitutes for state surveys and licensure. The Medicare certification standards for ASCs are significantly less comprehensive than are the standards for similar services provided in hospitals. Private accreditation agencies also have disparities in review standards and generally lack the kind of oversight capability that state surveys provide. In 2000 and again in 2004, the Massachusetts Board of Registration in Medicine recognized the need for some regulatory involvement in the ever-expanding activities of ASCs and endorsed the Massachusetts Medical Society's "Office Based Surgery Guidelines". As well intended as that effort may have been, the public would be right to expect more than just a state agency "endorsement" of industry "guidelines" as the extent of public safety protection in this increasingly complex area of activity.

The Department of Public Health carries out annual inspections of other essential health care providers (e.g., long term care facilities) in order to enforce uniformity of standards and provide public assurance of quality of care. With freestanding ASCs continuing to evolve as rapidly as they have and engage in increasingly complex procedures, similar annual inspections under the authority of the state licensing agency are necessary. Any incremental cost associated with such annual inspections can be self-funded through annual licensing fees.

The proposed amendment implements the annual inspection and licensure requirement effective for all freestanding ASCs operating in the Commonwealth immediately as of the effective date of the amendment. No freestanding ASCs would be "grandfathered" out of the inspection and licensing requirement regardless of how long they have been operating.

D. Proposed Requirement of Determination of Need for Freestanding ASCs

Just as freestanding ASCs that provide advanced levels of surgical services pose special public safety concerns, so too do they raise issues for healthcare planning. The proposed amendment requires that freestanding ASCs providing higher end surgical services (again defined by the level of required anesthesia) participate fully in the healthcare planning process.

The determination of need (DoN) process affords an opportunity for meaningful, statewide and regional planning of significant healthcare services to assure adequacy and fairness of patient access, minimize adverse impact on the healthcare delivery system as a whole and verify financial feasibility of a proposed healthcare project, including efficient deployment of healthcare resources. In addition, the community benefit assessment aspect of the DoN process also provides a source of funding for necessary healthcare projects in the Commonwealth that may otherwise not survive. Especially because they necessarily have the potential for significant impact on the healthcare delivery system in the Commonwealth, there is no reason that higher-end, freestanding ASCs not be required to participate fully in the DoN process.

Under current law, a freestanding ASC operator willing to forego a provider contract with the Commonwealth's Medical Assistance program can operate without a state license and, therefore, without any requirement to participate in the DoN healthcare planning process. The proposed amendment makes it clear that both a DoN and an annual license will be required for any freestanding ASC not in operation or under construction as of January 1, 2007 and that an annual license will be required for all freestanding ASC, as of the effective date of the amendment, regardless of when they went into operation.

E. Proposed Requirement for Parity in Surcharges and Assessments for Uncompensated Care Pool and Safety Net Trust Fund

A third area in which the proposed amendment seeks to equalize higher-end, freestanding ASCs and providers of similar services relates to participation in the uncompensated care pool and safety net trust fund.

To the extent that freestanding ASCs are providing services comparable to those provided by hospitals, they should carry a proportionate share of the uncompensated care pool and safety net trust fund burden. Under current law, freestanding ASCs are assessed surcharges only on the facility component of services and not on the physician services or other health services costs. The proposed amendment would require parity in calculation of surcharges and assessments between hospitals and freestanding ASCs.