

The Bulletin

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Governor Enacts Amendments To "Codey Act" – Single Operating-Room Facilities Must Be Registered And Certified: Will Overlapping Requirements Cause Problems For Physicians

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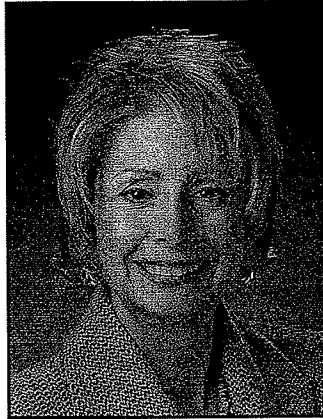
In the wake of a court decision that called into question the ability of physicians to refer patients to a health care facility that he or she owned, the Legislature under the leadership of Senate President Richard Codey, passed several new requirements governing single operating-room facilities as well as ambulatory care facilities (SCS-787). On March 21, 2009, Governor Jon Corzine signed into law, legislation, which establishes standardized requirements for health care facilities in New Jersey that provide ambulatory surgery and related procedures, to enhance the quality of care and patient safety, to address the economic disadvantage that hospitals face with the proliferation of free-standing ambulatory surgical facilities throughout the State, and to ensure that patients receiving care at such facilities are adequately informed as to whether they will be responsible for out-of-network cost sharing.

One provision in the new law, which has garnered little attention, requires that a single operating-room surgical facility, which is generally in a physician's office, must now register with the Department of Health and Senior Services ("DHSS") and report certain information to DHSS, such as the number of physicians, physician assistants, and advanced practice nurses providing professional services at the surgical practice. Currently DHSS' regulations governing the operation of ambulatory care facilities contain a provision exempting single operating-room facilities from complying with the licensure requirements.

There was no apparent consideration of the confusion that may result when a physician tries to determine whether his or her facility is regulated by DHSS or by the Board of Medical Examiners ("BME") which is part of the Division of Consumer Affairs in the Department of Law and Public Safety and headed by the Attorney General. These two departments each have their own legal authority to regulate the same group of health care professionals – namely physicians operating single operating-room facilities. The BME has adopted in office anesthesia regulations governing the performance of surgery or procedures in a physician's office, whereas, DHSS regulates ambulatory care facilities as discussed above.

Under the new law a single operating-room facility known as a "surgical practice" in the bill, is defined as a structure or suite of rooms that:

- Has no more than one room dedicated for use as an operating room, which is specifically equipped to perform surgery, and is designed and constructed to accommodate invasive diagnostic and surgical procedures;



- Has one or more post-anesthesia care units or a dedicated recovery area where the patient may be closely monitored and observed until discharged; and

- Is established by a physician, physician professional association surgical practice, or other professional practice form specified by the State Board of Medical Examiners solely for the physician's, association's, or other professional entity's private medical practice.

A single operating-room facility operating on the effective date of the law must register annually with DHSS. The initial registration

must be within one year of the date of enactment of the law. A new single operating-room facility must file its plans with the municipality in which it will operate within 180 days of the law's enactment date and register with DHSS prior to providing services.

In addition, as a condition of registration with DHSS, the single operating-room facility must obtain certification by the Centers for Medicare and Medicaid Services ("CMS"), under the ambulatory surgical center provisions or accreditation from an accrediting body recognized by CMS.

Currently, there are four CMS approved national accreditation organizations for ambulatory care facilities: the Joint Commission – <http://www.jointcommission.org>, the American Association for Accreditation of Ambulatory Surgery Facilities – <http://www.aaaasf.org>, the Accreditation Association for Ambulatory Healthcare – <http://www.aaahc.org>, and the Healthcare Facilities Accreditation Program of the American Osteopathic Association – <http://www.hfap.org>.

The law specifies the information that must be submitted to DHSS by an applicant for registration. The new law also provides that its provisions shall not be construed to limit the BME from establishing standards of care with respect to the practice of medicine.

The issue of regulating single operating-room facilities was discussed in the Commission on Rationalizing Health Care Resources' ("Commission") report, which stated that in 2006, there were "181 Medicare-certified ASCs in New Jersey," yet just 95 state licensed [by DHSS] facilities (as an ambulatory care facility).

The Commission notes that "these uneven licensing standards are largely without basis and should be evenly applied across all facilities providing similar services." The report goes on to state that "the lack of uniform regulations and reporting of quality and performance data is a major impediment to understanding their actual impact on the health care system or the quality of care."

Any rational policymaking needs to include more robust data reporting requirements on the part of these facilities with respect to quality and cost and apply uniform regulations based on the services provided rather than the specific venue as is the case with the current exemption for single operating room surgical practices."

Therefore, the Commission recommended that the State "eliminate the licensure exemption for single operating room surgical practices. . . All surgical facilities in New Jersey should meet nationally recognized accreditation standards."

The New Jersey Hospital Association ("NJHA") supported the Commission's recommendation calling for licensing standards that would apply to all ambulatory care facilities and requiring reporting on quality outcomes, among other reporting requirements. According to the NJHA these requirements would level the playing field between hospital-based ambulatory surgical centers and non-hospital based centers and provide consumers with

valuable and essential information allowing them to make educated choices regarding where they will receive healthcare services.

Whether the increased oversight of single operating-room facilities will result in better healthcare services remains to be seen. A better solution might have been to address the continuing overlap between the BME's regulations governing physicians who practice in office surgery and the DHSS requirements for single operating-room facilities. These overlaps may lead to more confusion about which standards really govern how a physician should operate his or her office.

Alma L. Saravia is a shareholder in the Cherry Hill office of Flaster/Greenberg, P.C. She practices in the area of health law and was a member of the New Jersey State Board of Medical Examiners from 1992 - 1994.

In Memoriam

Frank A. Iula, MD
1926-2009

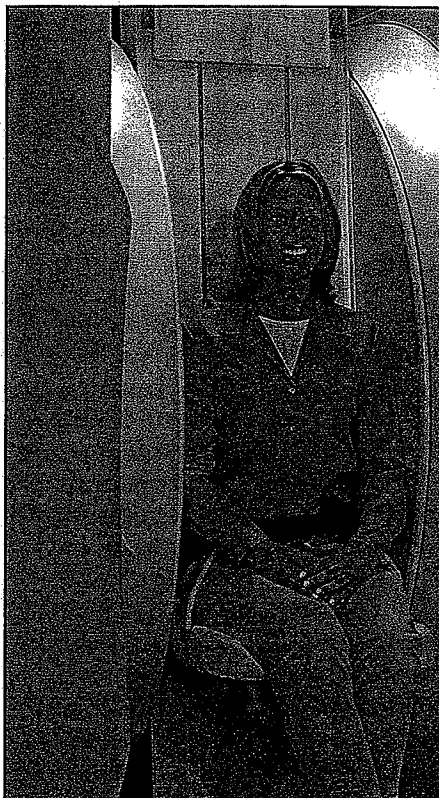
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