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ROBINSON
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Client Alert

Deadline for Licensing Outpatient Surgical Facilities

On July 18, 2006, the Department of Public Health (DPH) published a notice in the Connecticut Law Journal reminding outpatient surgical facilities that they must be licensed by March 30, 2007, as required by Connecticut General Statutes section 19a-493(b).

An outpatient surgical facility is defined as an entity, individual, firm, partnership, corporation, limited liability company or association, other than a hospital, engaged in providing surgical services or diagnostic procedures for human health conditions that include the use of moderate or deep sedation, moderate or deep analgesia or general anesthesia, as such levels of anesthesia are defined from time to time by the American Society of Anesthesiologists, or by such other professional or accrediting entity recognized by DPH. An outpatient surgical facility does not include a medical office owned and operated exclusively by a person or persons licensed to practice medicine and surgery, provided such medical office (i) does not have an operating room or designated surgical area; (ii) does not bill facility fees to third-party payers; (iii) does not administer deep sedation or general anesthesia; (iv) performs only minor surgical procedures incidental to the work performed in the medical office; and (v) uses only light or moderate sedation or analgesia in connection with such incidental minor surgical procedures.

DPH "strongly recommends" that outpatient surgical facilities begin the licensing process immediately because many facilities will not be able to comply with licensing requirements without first obtaining a waiver from DPH or making renovations to the facility. Unless facilities begin the process now, delays from renovations or the waiver process may cause outpatient surgical facilities to miss the March 30, 2007, deadline.

If you have any questions regarding the licensing process for outpatient surgical facilities, please contact a member of Robinson & Cole's Health Law Group.

Proposed Regulations for Outpatient Clinics and Homemaker Home Health

Aide Agencies

The Connecticut Department of Public Health (DPH) published a notice of intent to amend regulations regarding outpatient clinics and homemaker home health aide agencies (the "Proposed Regulations") in the Connecticut Law Journal on July 11, 2006. The Proposed Regulations create several new requirements for outpatient clinics and amend the current requirement related to nurse assessments for homemaker home health aide agencies.

Outpatient Clinic Regulations

The DPH is proposing a significant increase in the regulation of outpatient clinics. The Proposed Regulations include new patient rights, new clinical requirements aimed at improving quality of care, and staffing and governance requirements. The Proposed Regulations also expand the duties of the governing board and professional staff, impose additional building and equipment requirements, add specific procedures related to medical record confidentiality, and increase requirements for outpatient clinics with on-site pharmacies. Compliance with every provision of the Proposed Regulations would be required in order to obtain an operating license for the outpatient clinic, which is issued or renewed for a period not to exceed four years and is required for every freestanding clinic building.

Patient Rights and Quality of Care

The Proposed Regulations add specific rights of patients treated in outpatient clinics and require the outpatient clinic to inform patients of these rights, either orally or in writing. These rights, include but are not limited to, the right to file a grievance, the right to refuse to participate in experimental research, the right to be protected from abuse, neglect or exploitation, the right of the patient or the patient's legal representative to make health care decisions, and the right to initiate advanced directives or living wills. Under the Proposed Regulations outpatient clinics are also required to investigate all complaints regarding infringements of patients' rights and intervene whenever necessary to protect the patient.

The Proposed Regulations also create several new requirements regarding patient assessment, treatment, and quality of care. For example, the Proposed Regulations require that patients receive care and services under the direction of a physician or health care practitioner licensed in Connecticut, within the practitioner's statutory scope of practice, and in accordance with current standards of professional practice. The Proposed Regulations also require outpatient clinics to formulate an agreement with an acute care hospital for the transfer of any patient that has medical or emergent needs that cannot be met by the clinic.

Building Safety and Equipment

Existing regulations require outpatient clinics to simply maintain "adequate facilities." The Proposed Regulations impose additional staffing and physical plant requirements for certain specialized services, such as x-rays, pregnancy termination, infusion therapy, and urgent care. The Proposed Regulations also require outpatient clinics to develop programs for waste management, infection control, and emergency preparedness, including regular testing of emergency equipment. New requirements for air temperature (e.g., must be over 70 degrees), hot water (e.g., must be 105 to 120 degrees), and length of patient stays (e.g., maximum of 23 hours) are also included in the Proposed Regulations.

Governing Board and Professional Staff

The Proposed Regulations greatly expand the outpatient clinic governing board's duties. In addition to the duties currently required by law (e.g., appointing administrators and staff and adopting bylaws), the Proposed Regulations require the governing board to set policies and monitor the outpatient clinic's finances. The Proposed Regulations also require that the bylaws

include, without limitation, a delineation of powers, the qualifications for board membership, a mechanism for addressing non-compliance with policies and laws, a conflicts of interest policy, a process for adoption of an annual facility budget and approval of an organizational chart. The Proposed Regulations also expand the professional staff's duties by requiring the professional staff to develop professional staff bylaws, which govern quality assessment, staffing contingencies, and validation of credentials. Further, the Proposed Regulations require clinics to certify annually that every employee and consultant is properly licensed.

Recordkeeping and On-Site Pharmacies

The Proposed Regulations require clinics to report to DPH where medical records are stored and how such records can be retrieved. In addition, under the Proposed Regulations, outpatient clinics would be required to keep records for at least seven years, as opposed to the current five-year requirement.

Outpatient clinics with on-site pharmacies would be required under the Proposed Regulations to create procedures for pharmacy services, supervision, after-hours access to medication, and compliance with storage, control, and drug labeling laws. New requirements also apply to infusion therapy, direct patient pharmacies, and automated drug dispensers.

Homemaker Home Health Aide Agencies

The Proposed Regulations change the requirements for nurse assessments of homemaker home health aides. Under existing regulations, the homemaker home health aide agency's registered nurse supervisor must establish a plan for nurses to supervise homemaker home health aides in the patient's home. This plan must specify how often nurses will visit the patient's home and how they will monitor progress between visits.

The Proposed Regulations would require the registered nurse supervisor to visit and assess the patient in the patient's home as often as needed for the patient's condition, but at least every sixty days. Under the Proposed Regulations, all nurses' visits must be made while the homemaker home health aide is providing services in the patient's home.

Submitting Comments on the Outpatient Clinic and Homemaker Home Health Aide Agency Proposed Regulations

DPH must consider comments on the Proposed Regulations regarding outpatient clinics and homemaker home health aide agencies before issuing final regulations. Comments and requests for a public hearing on the Proposed Regulations are due to DPH by August 9, 2006. A complete copy of the Proposed Regulations related to outpatient clinics can be accessed by [clicking here](#).

If you would like assistance drafting comments related to the Proposed Regulations for outpatient clinics and/or homemaker home health aide agencies, please contact a member of Robinson & Cole's Health Law Group.

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