SECTION 2 CHAPTER 4 OUTPATIENT SURGERY

4.0 OUTPATIENT SURGERY

4.1 RELATIONSHIP TO CERTIFICATE OF NEED

Connecticut General Statutes Section 19a-638(a)(1) specifies a Certificate of Need is required for the establishment of a new health care facility and subsection (a)(5) specifically lists the establishment of an outpatient surgical facility, as defined in section 19a-493b, or as established by a short-term acute care general hospital. Facilities seeking authorization to establish a new outpatient surgical center are required to demonstrate that they meet clear public need as well as other criteria set forth in Connecticut General Statutes Section 19a-639.

4.2 OVERVIEW

Forty years ago, virtually all surgery was performed in a hospital. Since the early 1980s, however, there have been many changes in how surgical care is provided, due largely to advances in medical technology and changes in payment arrangements. The medical advances include new anesthesia that allow a patient to awaken more quickly after surgery, and better analgesics for pain control. In addition, minimally invasive and noninvasive procedures such as laser surgery, laparoscopy and endoscopy have been developed.[65] These advances allow many procedures formerly done in inpatient settings to be performed in outpatient surgical facilities.

Concerns about rising health care costs also have contributed to the growth of ambulatory surgery. The federal government expanded Medicare coverage to include services provided in outpatient surgical facilities (OSFs). The prospective payment system based on diagnosis-related groups (DRGs) that was adopted for hospital inpatient care created financial incentives for hospitals to shift less complex surgeries to an outpatient setting. Under impending health care reform, how lucrative payments to OSFs are, hospital-owned and privately, remains to be determined.[66]

Ambulatory surgical care is defined in the Connecticut Public Health Code as "surgical care not requiring overnight stay but requiring a medical environment exceeding that normally found in a physician's office".[67] This care may be delivered in a licensed outpatient surgical facility or at an acute care hospital's designated outpatient surgical center. Along with the elimination of an inpatient hospital admission, surgery in an outpatient setting makes better use of resources, especially the surgeon's time. Currently, approximately 70% of the surgeries in Connecticut are performed as ambulatory procedures.[68]

4.3 AMBULATORY SURGICAL PROCEDURES

The U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) reviews surgical procedures to determine those that are appropriate for the outpatient setting. The CMS also determines which procedures are eligible for reimbursement of services under Medicare or Medicaid. A major consideration for the inclusion or exclusion of a procedure is patient safety in an OSF environment.[69]

CMS follows an established set of eligibility standards. The general standards for covered surgical procedures are those surgical and other medical procedures that:

- Are commonly performed on an inpatient basis in hospitals, but may be safely performed in an OSF;
- Are not of a type that are commonly performed, or that may be safely performed, in physicians' offices;
- Are limited to those requiring a dedicated operating room and generally requiring a post-operative recovery room (not overnight);[70] and

[65]Cullen, K.A, Hall, M.J. & Golosinky, A. (2009). Ambulatory surgery in the United States, 2006. National health statistics reports, 11. Revised. National Center for Health Statistics. Retrieved from http:www.cdc.gov/nchs/

[66]Cullen, et al.

[67]State of Connecticut, Public Health Code, 19-13-D56 (a) (2).

[68]OHCA Hospital Reporting System. 2012. 12 month filing, Report 450 - Hospital Inpatient & Outpatient Other Services Utilization & FTE Employees, as of April 11, 2012.

[69]Federal Register. Friday, March 28, 2003. Rules and regulations 68(60), 15271.

[70]Public Health, Ambulatory surgical services. 42 C.F.R § 416. (2012).

- Are not cosmetic surgery and related services, except as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.[71]

Eligible surgical procedures are limited to the following specific standards:

- Those procedures that do not generally exceed a total of 90 minutes operating time and a total of four hours recovery time;
- Anesthesia must be local or regional or general anesthesia of 90 minutes or less;
- Those procedures that do not generally result in extensive blood loss or required major or prolonged invasion of body cavities or directly involved major blood vessels; or
- Those procedures that are not generally emergency or life-threatening in nature.[72]

4.4 OUTPATIENT SURGICAL FACILITIES (OSFs)

The acronym OSF is the term used in Connecticut law and regulation to refer to a particular type of licensed facility. The term ambulatory surgery center (ASC) is a specific term used in federal law and regulation that refers to a specific type of facility that must comply with CMS rules and accreditation standards. Connecticut has many ASCs that are licensed as OSFs, but not all OSFs are ASCs.

4.4.1 LICENSURE AND CERTIFICATION

4.4.1.1 DPH Licensure

OSF is a distinct DPH licensure category. New OSFs require Certificate of Need authorization prior to applying for a license to operate. All facilities, regardless of the type and procedures performed and/or reimbursed[73], are subject to regular State and federal inspections.

4.4.1.2 CMS Certification

To receive reimbursement through Medicare, the CMS requires OSFs to have Medicare certification. The majority of CMS' conditions for Medicare certification are concerned with patient safety. The CMS Ambulatory Surgery Center Quality Reporting Program requires each OSF to submit information to track whether patients are transferred or admitted directly to a hospital, including a hospital emergency department, upon discharge from the facility. This information can indicate a potentially preventable complication, serious medical error, or other unplanned negative outcome. A high rate of transfers or inpatient admission may be an indication of suboptimal care or provision of care to patients that should not have been treated in an ambulatory surgical setting.[74]

4.4.2 OSF TYPES AND OWNERSHIP

OSF ownership structures include hospital only; physicians only; hospital and physician joint venture; and corporate-hospital. OSFs based at acute care hospitals operate under the hospital's license and management and provide the same types of services as other outpatient surgical facilities. These facilities may be part of the main hospital, in a separate building on the hospital campus or in a building off the hospital campus. Those facilities located off the hospital campus are listed on the general hospital licenses as satellites.

Physician-owned OSFs provide physicians with more direct control over their surgical practices. They may schedule procedures at their convenience, assemble their surgical teams, ensure the equipment and supplies being used are best suited to their technique and design the OSF to suit their specialties. Physicians also benefit from the professional autonomy over their work environment and the quality of their care. These facilities are often referred to as "free-standing" as they are not hospital owned or hospital operated.

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[71]Public Health, Exclusions from Medicare and limitations on Medicare payment. 42 C.F.R § 411. (2012).
[72]Public Health, Ambulatory surgical services. 42 C.F.R § 416. (2012).
[73]For example, cosmetic surgery is licensed and regulated by the State of Connecticut, although CMS does not reimburse for many cosmetic procedures.
[74]Medicare Payment Advisory Committee. (2012). Report to the Congress: Medicare payment policy. Ambulatory surgical center services. 5(131-132).

Joint venture facilities owned by both hospitals and physicians became popular to help hospitals increase market share and stay profitable, and physicians to grow their surgical practices. In addition to the financial benefits, joint ventures enabled hospitals and physicians to provide patients with services in an efficient and convenient facility.[75] Health care reform may dictate which ownership structures remain and how profitable they will be.

4.4.3 FACILITIES AND OPERATING ROOMS

As of October 1, 2011, Connecticut had:

- 30 general or children's general hospital-based[76] multi-specialty OSFs;
- 16 multi-specialty hospital satellite OSFs;
- 2 single-specialty hospital satellite OSFs;
- 17 free-standing multi-specialty OSFs; and
- 44 free-standing single-specialty OSFs.

The locations and categories of the licensed OSFs are indicated in the maps in Appendices J, K and L. The categories are hospital-based, single-specialty and multi-specialty (Appendix J); hospital satellite, single-specialty and multi-specialty (Appendix K); and free-standing, single-specialty and multi-specialty (Appendix L). Each Connecticut acute care general hospital performs outpatient surgical procedures either within the main hospital or at a separate building on the hospital's main campus. Fifteen of the 30 hospitals have satellite outpatient surgical office locations, including the children's general hospital, Connecticut Children's Medical Center. Middlesex Hospital, in addition to the OSF on its main campus, has a second facility at its outpatient center 2 miles away. Hartford Hospital has two satellite OSFs, a multi-specialty OSF in West Hartford and a single-specialty OSF in Newington.

The 44 free-standing single-specialty OSFs in Connecticut have a total of 70 operating rooms. Almost half are dedicated to endoscopic procedures, and approximately 36% to cosmetic surgery and eye surgery. Twenty-two OSFs have a single operating room and are located in a physician's office. These facilities are not generally used daily as the surgeries are scheduled to meet the needs of patients and the physicians themselves. The most common practitioners with office-based operating rooms are plastic surgeons, ophthalmologists, orthopedic surgeons, pain management physicians and gynecologists. Reimbursement from a third-party payer may be provided depending on the patient's insurer, except in the case of cosmetic surgery. As most cosmetic procedures are elective, patients are generally self-pay, and pay for their procedures in advance.

The 17 multi-specialty free-standing OSFs have a total of 37 operating rooms, with a range of one to five operating rooms per facility. These facilities have many physicians that utilize block operating room times suitable to their surgical specialty. These facilities mostly operate on a regular five-day a week schedule with varying hours for the convenience of the physicians, staff and patients. It is common to combine two or more specialties with surgeries for each performed on the same day.

There are 15 hospital satellite OSFs with a total of 67 operating rooms, with a range of one to five operating rooms per facility. One of the facilities is a two-operating-rooms endoscopy center and one is a four-operating-rooms eye surgery center; the remaining facilities are multi-specialty with the number of operating rooms ranging from one to 12. It is difficult to determine the number of operating rooms dedicated to outpatient surgery when a hospital does not have a designated OSF within its main facility or on its main campus.

[75]Pizzo, J. & Redd, L. (2006). Hospital-Physician Joint Ventures: Maximizing the Potential. Health Care Financial Management Association.
[76]Connecticut acute care hospitals have an estimated 413 operating rooms available for surgery/surgical procedures.

4.5 SURGERIES PERFORMED IN THE OUTPATIENT SETTING

Multi-specialty OSFs may be free-standing, hospital joint-venture, or wholly-owned hospital facilities. A vast array of surgical procedures is performed at these facilities. Common procedures performed in multi-specialty OSFs include:

- Colonoscopy and biopsy;
- Upper gastrointestinal endoscopy and biopsy;
- Gastrointestinal procedures, such as cholecystectomy, common duct exploration, tonsillectomy and adenoidectomy;
- Urinary procedures, such as ureteral catheterization and removal of ureteral stones;
- Musculoskeletal procedures, such as arthroscopic procedures on the knee, carpal tunnel release, reconstruction of cruciate ligaments in the knee;
- Cataract surgery and other eye procedures;
- Ear, nose or throat procedures, such as ear tube surgery;
- Inguinal and femoral hernia repair; and
- Gynecological procedures, such as breast biopsy and diagnostic dilatation and curettage.[77]

Endoscopy procedures are one of the common types of procedures performed in a single-specialty OSF. Endoscopic procedures are mainly non-operative procedures performed through a scope to observe the interior of organs in the body, such as the bronchi, esophagus, and colon.

4.6 STANDARDS/GUIDELINES

DEFINITIONS

1. Section 19a-493b, (CGS) defines an OSF as "any 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 the Department of Public Health. An outpatient surgical facility shall not include a medical office owned and operated exclusively by a person or persons licensed pursuant to section 20-13, provided such medical office: (1) Has no operating room or designated surgical area; (2) bills no facility fees to third party payers; (3) administers no deep sedation or general anesthesia; (4) performs only minor surgical procedures incidental to the work performed in said medical office of the physician or physicians that own and operate such medical office; and (5) uses only light or moderate sedation or analgesia in connection with such incidental minor surgical procedures."
2. Nothing in this subsection shall be construed to affect any obligation to comply with the provisions of Section 19a-691, CGS, concerning anesthesia accreditation or Section 19-13-D56 of the Public Health Code concerning licensing of outpatient surgical facilities operated by corporations.
3. "Primary Service area" for an OSF is the area where approximately 75% of the facility's patients reside. Service area may be towns, zip codes, or other U.S. Census geographical type.
4. "Maximum Capacity" is the number of surgical cases that may be performed in a year based on Monday through Friday, eight hours per day, and 250 days per year. It is the responsibility of the Applicant to provide sufficient documentation to establish the length of time the average case requires and the time required for cleanup.
5. "Optimum utilization" is the percent of the maximum capacity that a facility can achieve under a regular work environment, considering the variation in procedures performed, the number of physicians utilizing the facility, and other factors.

[77] Agency for Healthcare Research and Quality. (2010). Hospital-Based Ambulatory Surgery, 2007. *Healthcare Cost and Utilization Project (HCUP) Statistical Brief #86*. Retrieved from http://www.hcup-us.ahrq.gov/reports/statbriefs/sb86.jsp

The following guidelines and/or standards for the establishment of an OSF will be considered by OHCA when considering a Certificate of Need request:

1. When an Applicant proposes to establish a new multi-specialty OSF, the case volume of single-specialty OSFs dedicated solely and exclusively for endoscopy may be excluded from the existing; volumes when establishing need for the multi-specialty OSF as required by Sec. 19a-639 (3), CGS.
2. Unless otherwise established by the Applicant and supported with documentation:
    - The capacity of the proposed facility will be based on eight (8) hours per day, five (5) days per week fifty (50) weeks per year for a total of 2,000 hours per year;
    - The optimal utilization for an operating room in an OSF is 80%;
    - The average time for an outpatient case will be sixty (60) minutes; and
    - Thirty (30) minutes will be allocated to cleanup between cases;
3. Unstaffed operating rooms are considered as available and shall be included in any calculations for capacity and utilization;
4. Delivery rooms for Caesarean sections and operating rooms specifically reserved for cardiac cases shall be excluded from calculations for capacity and utilization;
5. Proposed new OSFs must have written policies concerning access to care by persons who are underinsured or uninsured;
6. The Applicant must demonstrate the financial feasibility of the OSF within the first three (3) years of operations or within a reasonable time based on factors reported and supported by the Applicant;
7. The proposed new OSF will have in place at start of operations a transfer agreement with an acute care general hospital;
8. The Applicant must have in place at the start of operations a quality Assessment and Performance Improvement Program and be certified by Medicare or a national accrediting body for which CMS grants status to accredit ambulatory surgery centers;
9. The applicant must have in place at the start of operations a contract with a patient safety organization as defined at CGS § 19a-127o.

OTHER FACTORS FOR CONSIDERATION

Supplemental to the current guidelines and principles, as listed in Section 19a-639, CGS, OHCA may consider the following factors when reviewing a Certificate of Need request:

1. Changes in technology and changes in medical treatment specialties;
2. Proposed service areas that include patients from those states that border Connecticut, i.e., Massachusetts, New York and Rhode Island;
3. Physician referral patterns;
4. Underserved populations;
5. Unique populations, specific clinical needs or performance of procedures more lengthy in nature;
6. Limited specialty programs where access to surgical services is limited; and
7. Atypical barriers to care based on cost, quality, financial access or geographic access.

4.7 CURRENT ISSUES PERTAINING TO OSFs

OSFs, as other healthcare facilities and providers, are operating under the strain of current economic conditions, including physician shortages and regulatory mandates. They will also be affected by the changes resulting from health care reform. Commercial insurers often base their procedure reimbursements on the rates paid under Medicare and Medicaid. Historically, Medicare and Medicaid have paid providers at lower rates than other third-party payers. In addition, mandated electronic reporting will likely increase operating expenses for OSFs.

With the aging of the population in Connecticut, most OSFs will require Medicare certification to obtain reimbursement for the services they provide to older patients. To receive Medicare certification, the OSFs will be required to meet Medicare's conditions of coverage, which specify standards for administration of anesthesia, quality evaluation, operating and recovery rooms, medical staff, nursing services and other areas.[78] Under the CMS' new quality reporting programs, those that fail to report the required information will face a reduction in their Medicare payments. As of October 1, 2012, OSFs are required to report data on patient burns, patient falls, wrong side of patient, procedure, implants, hospital admissions and transfers, and prophylactic IV antibiotic timing. In 2013 they will be required to report two additional measures: safe surgery checklist use in 2012 and 2012 volume of certain procedures. While these two measures will not be reported until 2013, OSFs must ensure they are using a safe surgery checklist and have a system in place by January 1, 2012 to capture surgical volume data.

[78]Federal Register. Wednesday, November 30, 2011. Rules and Regulations. 78(230), 74126-74127.