

Washington ASC

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Update

CMS Surveys: Preventing Deficiencies under the New Conditions for Coverage

By **BARBARA K. DERRY, BSN, FACMPE**
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Ambulatory surgery centers (“ASCs”) that wish to serve Medicare patients are required to be certified by the Centers for Medicare and Medicaid Services (“CMS”). Specifically, ASCs must meet the Medicare Conditions for Coverage (“CfCs”) adopted by the CMS and explained in the CMS’s Guidance for Surveyors (the “Surveyor Guidance”). Significant changes made to these CfCs in 2009 pose an ongoing compliance challenge for ASCs, especially those ASCs initially certified under the old CfCs.

Most Medicare-certified ASCs in Washington State were initially certified prior to May 18, 2009, the date the new CfCs became effective. The new Surveyor Guidance is more than three times the length of the old guidance and provides more sharply-defined standards. Regardless of when they were initially certified, ASCs must comply with new Surveyor Guidance in order to remain Medicare-certified.

For Washington’s ASCs, compliance with new CfCs and Surveyor Guidance is measured by a single yardstick: Washington State Department of Health (“DOH”) on-site surveys. These unannounced surveys occur

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Washington State Department of Health Investigates Compliance with Certificate of Need Law

By **EMILY R. STUDEBAKER, J.D.**,
Editor

The Washington State Department of Health’s certificate of need (“CON”) program recently confirmed that it is investigating compliance of ambulatory surgery centers with Washington’s certificate of need law (the “CON Law”). The scope of its investigation includes surgery centers licensed under Washington’s ambulatory surgical facility licensure law, chapter 70.230 RCW, and centers regulated by the Medical Quality Assurance Commission’s new office-based surgery rule, WAC 246-919-601.

Accordingly, it is important for owners and administrators of surgery centers to understand whether their centers’ operations implicate the CON Law and, if so, to determine whether their centers are in compliance with the law.

Background

Administered by the Washington State Department of Health (the “Department”), the CON program regulates the development and expansion of certain health care services and facilities, including ambulatory surgery facilities. The program was created in 1971 primarily as a response to rapid medical cost inflation. By regulating the supply of services and facilities, the program sought to restrain health

care costs, guide health service development to avoid undue duplication or fragmentation, promote quality of care and access, and provide adequate information about the health care system.

In general, the CON Law prohibits a person from engaging in any undertaking that is subject to CON review without first having received a CON from the Department. Among other things, in order for a CON to be granted, new facilities, or those seeking to expand, must demonstrate that current or projected need cannot be met by existing providers and that new services will not adversely affect access or charity care. Criteria for CON review are set out in legislation (chapter 70.38 RCW) and regulation (chapter 246-310 WAC).

Applicability of CON Law to Surgery Centers

The CON Law prohibits a person from constructing, developing or otherwise establishing an ambulatory surgical facility without first having received either a CON or an exception granted by the Department in accordance with the CON Law. For purposes of the CON Law, the term “ambulatory surgical facility” is defined as:

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Falling Bar for Medical Malpractice Plaintiffs

By **ROGER L. HILLMAN, J.D.**

Since 2009, it has become easier for medical malpractice plaintiffs in Washington to file and prevail in lawsuits against healthcare providers. Plaintiffs need no longer file a certificate of merit signed by a medical expert, or provide an expert witness at trial who practices the same specialty as the defendant. The door to malpractice litigation is therefore open wider - more cases will advance past the initial complaint - and it will be easier to cross the threshold separating plaintiffs from verdict winners.

In 2009, the Washington Supreme Court decided *Putman v. Wenatchee Valley Medical Center*. The court held unconstitutional Washington's requirement that a malpractice plaintiff file a certificate of merit from a medical expert. The requirement was enacted as part of compromise medical liability reform legislation to screen out frivolous malpractice claims in an effort to reduce the cost

of malpractice insurance. The *Putman* court held the Washington requirement unconstitutional on the grounds that it limited malpractice plaintiffs' access to courts, and that it was procedural and conflicted with two court rules, violating the separation of powers. Following *Putman*, plaintiffs no longer need to file a certificate, making commencement of a malpractice action easier, faster and cheaper.

Washington malpractice plaintiffs are also facing a lower bar once they enter the courtroom. To prevail at trial, a medical malpractice plaintiff must show that his or her injury resulted from a healthcare provider's failure to follow the applicable standard of care. Malpractice suits hinge on testimony about a violation of the standard of care (the yardstick against which the defendant's care is measured) and whether such violation caused plaintiff's injury. Standards of care differ across professions, schools of medi-

cine and, in some states, across medical specialties. Many states have enacted statutes setting high standards for medical experts, particularly specialists. Washington has no such legislative proscription on medical experts. Moreover, a 2011 appellate court opinion has further lowered the bar for expert testimony. The court in *Leaverton v. Cascade Surgical Partners* allowed otolaryngologists to testify regarding the standard of care required of a general surgeon. While the experts in *Leaverton* were surgeons, they had never actually performed the surgery at issue (a total thyroidectomy). The *Leaverton* court held that this was sufficient to qualify them as experts as to the standard of care required of the defendant. This decision is currently on appeal. ■

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Certificate of Need Law

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[A]ny free-standing entity, including an ambulatory surgery center that operates primarily for the purpose of performing surgical procedures to treat patients not requiring hospitalization.

However, the term does not include:

[A] facility in the offices of private physicians or dentists, whether for individual or group practice, if the privilege of using the facility is not extended to physicians or dentists outside the individual or group practice.

As indicated, a facility that is in a physician office does not constitute an “ambulatory surgical facility” – and is exempt from CON review – if the privilege of using the facility is not extended to physicians outside the group practice. To understand the scope of this exemption, it is necessary to understand, for purposes of the CON Law: (1) when a facility is *in* a physician office, (2) what constitutes a *group practice*, and (3) under what circumstances use of the facility is *extended to physicians outside the group practice*. Unfortunately, neither the CON Law nor its implementing regulations offer guidance regarding these issues.

In absence of such guidance, a review of past determinations of the CON program regarding the applicability of the CON Law to surgery centers is useful. These applicability determinations indicate that the CON program considers several factors when determining whether the exemption applies. These factors include:

- Whether a surgery center is organized as a separate legal entity from the practice;
- Whether the practice has the charac-

teristics of a “group practice” as that term is defined under the prohibition on physician self-referrals (commonly referred to as the “Stark Law”);

- Whether physicians who are not members of the group practice utilize the surgery center;
- Whether the surgery center is operated under a management agreement; and
- Whether an entity other than the surgery center holds the center’s Medicare-certification.

On-Site Surveys and Investigation of CON Compliance

Washington’s surgery centers are subject to two types of on-site surveys conducted by the Department – surveys conducted for purposes of Medicare certification and surveys conducted for purposes of state licensure. Specifically, in order to receive Medicare payment for surgical services furnished to program beneficiaries, surgery centers must meet certain requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subparts A through C. On behalf of the Centers for Medicare & Medicaid Services, the Department conducts on-site surveys of participating surgery centers to determine whether these centers are in compliance with the Conditions for Coverage. Similarly, the Department conducts on-site surveys of surgery centers subject to Washington’s ambulatory surgical facility licensure law to determine whether these centers meet requirements set forth in that law and its implementing regulations.

During these on-site surveys, certification of compliance with the Medicare Conditions for Coverage and state licensure requirements is accomplished through record reviews and surgery center staff interviews, among other things. According to recent reports, during on-site surveys the Department has also been investi-

gating compliance with the CON Law. As part of this investigation, surveyors gather information contained in patient records and information obtained during interviews of surgery center staff to assess compliance.

Upon inquiry, the CON program has confirmed that it is coordinating efforts with the Department’s survey team to ensure that surveyors are investigating CON compliance during these on-site surveys. Importantly, with respect to the CON Law, the Department has recently described itself as “enforcement-minded.”

Recommendations

Accordingly, surgery center owners and administrators seeking to rely on the CON Law exemption should determine whether their centers’ operations are consistent with the exemption as it is currently interpreted by the Department. For centers currently operating under a CONs, owners and administrators should determine whether their centers are complying with the terms and conditions, if any, of their CONs. ■

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CMS Surveys

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during normal ASC business hours and consist of three parts: (1) observations of care, (2) interviews with staff and patients, and (3) documentation and record reviews. The Surveyor Guidance provides additional detail on how the surveys are to be conducted and also provides useful information to ASCs regarding what to expect both during and after the surveys.

Preparing for DOH Surveys

A successful DOH survey requires that ASC leadership understand the Surveyor Guidance, devise and implement policies and procedures to

ensure compliance with the CfCs, and, most importantly, foster open communication about standards for patient care.

A successful leadership team will:

- Thoroughly understand the CfCs and Surveyor Guidance;
- Maintain an ongoing, constructive dialogue with the ASC staff;
- Conduct staff meetings that discuss the CfCs, including the quality improvement process, infection control, record-keeping, and emergency procedures; and
- Seek ongoing feedback from all members of the ASC team.

Based on recent survey results, DOH has recommended that Washington

ASCs focus their improvement efforts on the following three areas to comply with the CfCs: (1) infection control, (2) patient rights, and (3) quality assessment and performance improvement.

Infection Control

Beyond having solid infection control policies and procedures in place, an ASC must employ an infection control officer who is a licensed healthcare professional, such as a registered nurse, with recent and continuing infection control training. An effective infection control program will replicate guidelines from a nationally recognized infection control program, such as the Association for Professionals in Infection Control and

New Paid Time Off Proposed for Surgery Center Employees

By **JARED VAN KIRK, J.D.**

On June 27, 2011, Seattle City Councilmember Nick Licata proposed a city ordinance that would require all private employers, including ambulatory surgery centers, to provide paid time off to all employees who work at least 80 hours in Seattle per calendar year. Under the proposed ordinance, Council Bill Number 117216, surgery centers would need to ensure that their paid time off policies meet the minimum requirements of the ordinance.

Under the proposed ordinance, the accrual of paid time off would depend on a surgery center's size:

- Surgery centers with less than 49 full-time equivalent ("FTE") employees would be required to provide at least one hour of paid time off for every 50 hours worked.
- Surgery centers with between 50 and 249 FTE employees would be required to provide at least one hour of paid time off for every 35 hours worked.

- Surgery centers with more than 250 FTE employees would be required to provide at least one hour of paid time off for every 30 hours worked.

In addition, surgery center employees would be permitted to carry over limited amounts of unused paid time off from year to year.

Under the proposed ordinance, paid time off could be used when an employee is absent (1) due to his or her medical condition or need for preventative care, or (2) in order to provide care for a family member with a medical condition or with a need for preventative care. Paid time off could also be used by employees to seek legal assistance, treatment, or counseling, or to take safety measures relating to domestic violence, sexual assault, or stalking of themselves or their family members.

Surgery centers could ask for documentation of illness only after three

consecutive days of absence. However, centers that do not offer health insurance would have to pay some or all of an employee's out-of-pocket costs incurred in obtaining medical documentation.

Retaliation against employees would be presumed if they were discharged, suspended, disciplined, transferred, demoted, or denied a promotion within 90 days of filing a complaint alleging a violation of paid time off rights, cooperating in an investigation of an alleged violation of paid time off rights, or informing other employees of their rights to paid time.

The Seattle City Council has scheduled a public hearing to consider this proposal. ■

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Epidemiology, Inc. (“APIC”), regarding hand hygiene, injection practices, sterilization guidelines and monitoring of environmental and infection control practices. Additionally, every ASC should work to instill good sanitation habits through ongoing training. Training tools may include formal training sessions as well as prominently-displayed instructional posters in the ASC.

Patient Rights

The Washington Health Care Patient Bill of Rights (“PBOR”) protects patients and offers guidance to healthcare providers regarding their responsibilities with respect to patient care. Under the PBOR, a patient has rights to treatment with respect, privacy, and confidentiality. In addition, patients are entitled to formulate advance medical directives to be followed by their treating physicians.

Patients also have rights to certain information prior to treatment. A patient has the right to information sufficient to allow him or her to give informed consent to medical procedures. An ASC must provide its patients with information about patient rights. An

ASC must also disclose the treating physician’s financial interests in or ownership of the ASC, if any. All of the above information must be given in advance of the date of treatment, and the patient must confirm his or her receipt and understanding of the information via signature.

To ensure that patients understand their rights prior to surgery, ASCs are to then have patients sign a form listing both patient rights and responsibilities owed patients by the ASC staff. The same information given on the form should be available in a “Patient Rights” as a handout as well as a section of the ASC’s website. ASC staff should be sure to ask patients if they understand their rights, being prepared to answer any questions promptly.

Quality Assessment & Performance Improvement

Quality assessment and performance improvement (“QAPI”) programs require a significant investment of time and energy by all ASC staff. Successful QAPI programs require observation, documentation, and reporting of trends, findings and outcomes to an ASC’s governing body. ASCs should

conduct regular policy review meetings with all team members to report findings and concerns, as well as to train and, if necessary, re-train staff in proper procedure. Such meetings should analyze specific processes, working through the current process, noting issues and safety concerns, as well as how often they occur, and identifying how often staff actions are in compliance (or not) with the relevant ASC policy. ASCs should document the entire QAPI process, holding review meetings to assess the ASCs progress.

Washington ASCs must be proactive in the face of the new CfCs and Surveyor Guidance. ASCs should embrace the introspective assessment and subsequent corrective activities and training necessary to achieve a successful DOH survey and continued Medicare certification. ■

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An advertisement for Derry, Nolan & Associates, LLC. It features a logo with the letters "DN" in a teal square, followed by the company name "DERRY, NOLAN & ASSOCIATES, LLC" and "ASC Clinical & Operational Consultants". A teal banner asks "Is your ASC Compliant with CMS?". Below, it states "We can get you there!" and lists three services: Mock surveys, Quality Assessment & Performance Improvement Programs, and Infection Control Program Review & Revision. A teal box at the bottom right offers a "Free, one-hour consult for new clients!". The website and phone number are at the bottom.