BACKGROUND:
The Healthcare Regulation and Quality Improvement program ensures that a safe and healthy environment is provided by over 500 health related facilities and agencies. Current oversight is inadequate due to gaps in the law and inadequate resources and as a result, SB 158 was passed by the 2009 Oregon Legislature.

Permanent administrative rules have been filed to address the provisions of SB 158. These rules address new fees for hospital and ambulatory surgical center (ASC) licensing, classification of ASCs, inspections, complaint investigations, disclosure and consent provisions, care of patients, and quality assessment and performance improvement standards.

SUMMARY OF CHANGES:

Effective January 1, 2011 new fees are in effect for licensing of ASCs.

ASC Fees
- $1,750.00 for Certified ASCs with three or more procedures rooms;
- $1,250.00 for Certified ASCs with two or fewer procedure rooms;
- $1,750.00 for High Complexity, Non-certified ASCs with three or more procedure rooms;
- $1,250.00 for High Complexity, Non-certified ASCs with two or fewer procedure rooms; and
- $1,000.00 for Moderate Complexity, Non-certified ASCs regardless of the number of procedure rooms.

Procedure rooms are defined as rooms where surgery or invasive procedures are performed. Refer to OAR 333-076-0101 for further definitions.

ASCs will now be defined and classified in the following manner:

Definition:
ASC means a facility or portion of a facility that operates exclusively for the purpose of providing surgical services to patients who do not require hospitalization and for whom the expected duration of services does not exceed 24 hours following admission.

An ASC does not mean individual or group practice offices of private physicians or dentists that do not contain a distinct area used for outpatient surgical treatment on a regular and organized basis, or that only provide surgery routinely provided in a physician’s or dentist’s
office using local anesthesia or conscious sedation; or a portion of a licensed hospital
designated for outpatient surgical treatment.

Classifications:

Certified
A facility that is licensed by the Division and is deemed as meeting the Medicare
Conditions of Participation for ambulatory surgical services, 42 CFR 416, Subpart C.

High-complexity, non-certified
A facility that is licensed by the Division, is not deemed as meeting the Medicare
Conditions of Participation for ambulatory surgical services, 42 CFR 416, Subpart C,
and performs surgical procedures involving deep sedation or general anesthesia.

Moderate-complexity, non-certified
A facility licensed by the Division, is not deemed as meeting the Medicare Conditions
of Participation for ambulatory surgical services, 42 CFR 416, Subpart C, and
performs procedures requiring not more than conscious sedation.

Refer to OAR 333-076-0101 for further definitions.

Onsite Inspections
The Division will conduct an initial, on-site inspection prior to licensure and every three
years thereafter or at such other times as the Division deems necessary. In lieu of an on-site
inspection, the Division may accept:

- CMS certification by a federal agency or accrediting organization; or
- A survey conducted within the previous three years by an accrediting organization
  approved by the Division, if:
  - The certification or accreditation is recognized by the Division as addressing the
    standards and condition of participation requirements of the CMS and other
    standards set by the Division and an ASC provides the Division with a letter
    from CMS indicating its deemed status;
  - The ASC notifies the Division of any exit interview conducted by the federal
    agency or accrediting body and permits the Division to participate; and
  - The ASC provides copies of all documentation concerning the certification or
    accreditation requested by the Division.

Complaints
An ASC must post a notice in the facility, in a prominent place and size, that includes but is
not limited to the following information: "If you have concerns about this ambulatory
surgical center and the services provided here, contact the Public Health Division, Health
Care Regulation and Quality Improvement Program: 800 NE Oregon Street, Suite 305,
Portland OR 97232; 971-673-0540."
If the Division receives a complaint about an ASC facility, information obtained by the Division during the course of an investigation is confidential and not subject to public disclosure. The Division may publicly release a report of its findings but may not include information in the report that could be used to identify the complainant or any patient at the ASC.

The Division may use any information obtained during an investigation in an administrative or judicial proceeding concerning the licensing of an ASC, and may report information obtained during an investigation to a health professional regulatory board as defined in ORS 675.160 as that information pertains to a licensee of the board.

**Governing Body Responsibility**

The governing body of each ASC shall insure that a physician is not denied medical staff membership or privileges at the facility *solely* on the basis that the physician holds medical staff membership or privileges at another ASC.

**Personnel**

Rules have been updated with respect to tuberculosis transmission in accordance with CDC and other state guidelines.

**Policies and Procedures**

ASCs are required to adopt new policies and procedures for the following:

- Notifying patients orally and in writing of any financial interest that a health care practitioner (HCP) or the HCPs immediate family member has with a facility where the HCP has referred the patient for treatment;
- Requirements for informed consent signed by the patient or legal representative of the patient for diagnostic and treatment procedures; and
- Requirements for identifying persons responsible for obtaining informed consent and other appropriate disclosures and ensuring that the information provided is accurate.

**Care of Patients**

All of a patient’s risk factors must be evaluated before permitting a surgical procedure to be performed and at the time of discharge from an ASC, each patient must be evaluated by a physician, or by an anesthetist as defined by 45 CFR 410.69(b) for proper anesthesia recovery.

**Medical Records**

Verbal orders must now be countersigned or authenticated within two business days by the ordering health care practitioner or another health care practitioner who is responsible for the care of the patient.
Medical records shall include informed consent forms that document:

- The name of the ASC where the procedure or treatment was undertaken;
- The specific procedure or treatment for which consent was given;
- The name of the health care practitioner performing the procedure or administering the treatment;
- That the procedure or treatment, including the anticipated benefits, material risks, and alternatives was explained to the patient or the patient’s representative or why it would have been materially detrimental to the patient to do so, giving due consideration to the appropriate standards of practice of reasonable health care practitioners in the same or a similar community under the same or similar circumstances;
- The manner in which care will be provided in the event that complications occur that require health services beyond what the ASC has the capability to provide. If the ASC has entered into agreements with more than one hospital, the patient must be provided with the most likely possible option, but that the transfer hospital may be dependent on the type of problem encountered;
- The signature of the patient or the patient’s legal representative; and
- The date and time the informed consent was signed by the patient or the patient’s legal representative.

Medical records must also include documentation of financial interest disclosures as described in policies and procedures section.

**Quality Assessment and Performance Improvement**

In accordance with revised CMS federal regulations, the following changes were made to this section. An ASC already in operation and *NOT* certified by CMS on December 15, 2010 has until June 15, 2011 to be in compliance with these changes.

- The governing body of an ASC must ensure that there is an effective, facility-wide quality assessment and performance improvement program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors;
- The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC. Written documentation of quality assessment and performance improvement activities shall be recorded at least quarterly;
- After an analysis of the causes for adverse events, the ASC must develop and implement facility-wide preventive strategies and ensure that staff are trained in and familiar with these strategies;
- The ASC must set priorities for its performance improvement activities that:
  - Focus on high risk, high volume and problem prone areas,
  - Consider incidence, prevalence and severity of problems in those areas; and
  - Affect health outcomes, patient safety and quality of care;
Infection Control
Minor changes to this section have occurred. Medical staff and health care practitioners with ASC privileges must now be included in policies pertaining to potential infections.

Violations, Enforcement and Civil Penalties
Four new sections have been added that outline what is considered a violation, actions that must be taken if a statement of deficiency is issued, proposed suspension or revocation of a license, and issuing civil penalties. These sections align with rules for other facility types.

Approval of Accrediting Organizations
Accrediting organizations wishing to certify that state licensing standards have been met in ASCs must request approval by the Division. Requests must be in writing and the organization must provide:

- Evidence that it is recognized as a deemed accrediting organization by CMS or if not a deemed organization under CMS provide:
  - Documentation of program policies and procedures that its accreditation process meets state licensing standards;
  - Accreditation history; and
  - References from a minimum of two health care facilities currently receiving services from the organization.

Questions? Contact the HCRQI program at (971) 673-0540 or by e-mail at mailbox.hclc@state.or.us.