



Missouri Department of Health and Senior Services

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Sarah Willson
Director

Mike Kehoe
Governor

Dear Initial Applicant for Licensure as an Ambulatory Surgical Center (ASC),

In response to your request, the Bureau of Ambulatory Care (BAC) is providing you information relative to the licensing of a new Ambulatory Surgical Center (ASC).

You should begin by reviewing and becoming familiar with all applicable requirements under state licensure rules, which can be found at <https://www.sos.mo.gov/cmsimages/adrules/csr/current/19csr/19c30-30.pdf>.

General steps in the licensure process, all of which must be completed prior to issuing a license: The facility will need to be assigned a project number by contacting HSLCARP@health.mo.gov.

1. The facility must be designed, constructed and equipped from plans that have been reviewed and approved by the Department of Health and Senior Services Engineering Consultation Unit (ECU) as being in compliance with all applicable standards established in 19 CSR 30-30.030 and 19 CSR 30-30.040.

- Contact with the ECU should be one of, if not your very first step in the process. Contact the ECU by phone at 573-526-8524, or you may contact David East or Carrie Schaumburg by email at ECU@health.mo.gov.
- They will do onsite visits for the construction at approximately 50% and 80% completion.

2. Submission of the ASC application, fee, addendum and organizational chart to the Bureau of Ambulatory Care at BAC@health.mo.gov and can be found at <https://health.mo.gov/safety/asc/index.php>.

3. The application must be sent at least 30-60 days before the initial licensure survey and will only be active for a 12-month period. Must reapply at that time. The license application must be completed, signed and notarized, and returned to the Bureau of Ambulatory Care with complete documentation as indicated on the attachments and accompanied by the required annual licensing fee of \$200. Please make checks payable to the Department of Health and Senior Services.

4. If the facility will have controlled substances onsite they may apply for registration from the Bureau of Narcotics and Dangerous Drugs (BNDD) and DEA to order narcotics. The registration will be processed once an ASC license has been issued. BNDD can be contacted at 573-751-6321. For more information about BNDD see <http://health.mo.gov/safety/bndd/>.

5. Ensure the facility has applied for and received a certificate to perform laboratory testing from the Clinical Laboratory Improvement Act (CLIA) program. "Laboratory services shall be under the direction of a physician member of the medical staff" as described at 19 CSR 30-30.020 (I)(4). The CLIA lab program can be contacted at 573-751-6318. For more information see <http://www.health.mo.gov/safety/outpatienthealthcare/index.php>.

6. Onsite initial licensure survey to obtain a license to operate as an ASC must be successfully completed before patient care may be offered. The facility must ensure all components to provide patient care are in place and ready to deliver patient care, including but not limited to medications (non-controlled substances), policies, orientation of staff and all equipment are in place to schedule an onsite licensure survey. Again, an onsite initial state licensure survey to ensure compliance with all applicable licensure regulations must occur prior to providing services to any patient.

The application is to be accompanied by:

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The Missouri Department of Health and Senior Services' vision is optimal health and safety for all Missourians, in all communities, for life.

- Appropriate documentation to establish that the applicant is legally entitled to do business in this state and has filed with the Office of Secretary of State. A current business license should also be available for review at the facility and the facility must be in compliance with all local ordinances:
- An Organizational Chart and list of key staff persons for the facility with email and phone for the administrator: • Governing board meeting minutes that show when permission to establish an ASC was given:
- List of the intended surgical specialty types and the projected average length of time for the typical surgical procedure to include recovery from anesthesia.

Facilities planning on participating in the Medicare program as an ASC must first be licensed as an ASC.

Please note: Centers for Medicare and Medicaid (CMS) considers initial federal ASC certification surveys a low priority for the State Agency's workload. This means it is unlikely that the state agency will be able to perform the initial federal certification. For this reason, an ASC seeking certification is strongly urged to contact an approved Accreditation Organization (AO). <https://www.cms.gov/> will detail which AO's are authorized to accredit ASC's

In order to facilitate an orderly opening, please keep our office up to date on when the facility will be nearing completion and have all supplies, medications (non-controlled substances), and equipment in place to be fully operational to schedule the initial licensure survey. Notify our office when construction starts with an anticipated completion date. When the facility is nearing completion routine updates are requested to notify us of any change in the projected completion date. If there are significant changes to any of the dates, please inform our office. Contact by email is adequate for these updates.

If you have any questions regarding the Medicare or state regulations, please contact our office at (573) 751-1588 or via email at BAC@health.mo.gov