Ambulatory Surgical Facility

WASHINGTON STATE LICENSURE:

State Regulations
Overview and Checklists

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About the Author

A founder of Studebaker Nault, PLLC, Emily R. Studebaker practices exclusively in the area of health law. She provides counsel on healthcare transactional and regulatory matters ambulatory surgery centers, single and multi-specialty medical and dental practices and other health care providers and entrepreneurs on compliance and transactional matters.

Ms. Studebaker counsels clients on federal and state fraud and abuse laws, including the federal Anti-kickback Law and the Physician Self-Referral Law (commonly referred to as the "Stark Law") as well as state anti-rebating and fee-splitting prohibitions.

Ms. Studebaker also advises clients regarding corporate practice of medicine and corporate practice of dentistry laws and assist clients to structure medical and dental service organizations to comply with or properly avoid these laws.

Ms. Studebaker represents clients in mergers and acquisitions, divestitures, private equity transactions and joint ventures, and she drafts and negotiates asset purchase agreements, operating agreements, management agreements, employment agreements and medical director agreements.

Representing the Washington Ambulatory Surgery Center Association for nearly 15 years, Ms. Studebaker has a thorough understanding of the issues affecting the ambulatory surgery industry. She regularly assists ambulatory surgery centers with state licensing, Medicare certification and accreditation by Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities, and The Joint Commission. In addition, Ms. Studebaker counsels ambulatory surgery centers on the Washington certificate of need law, prepare certificate of need applications, and represents ambulatory surgery centers in the certificate of need review process and related litigation.

Ms. Studebaker has prepared briefs *amici curiae* to the Washington State Supreme Court and the Washington Court of Appeals regarding issues affecting the ambulatory surgery industry. In 2015, she prepared briefs *amicus curiae* to the Washington Court of Appeals on behalf of the Washington Ambulatory Surgery Center Association in *The Polyclinic, et al. v. Department of Health of the State of Washington*, No. 46937-5-II (2nd Div. 2015), a case involving the applicability of Washington's certificate of need law to expansions and relocations of already certificate of need approved ambulatory surgery centers. In 2009, Ms. Studebaker prepared a brief *amicus curiae* to the Washington Supreme Court on behalf of the Washington Ambulatory Surgery Center Association in *Columbia Physical Therapy, Inc., P.S. v. Benton Franklin Orthopedic Associates, P.L.L.C., et al.*, 168 Wash.2d 421 (2010). This case considered whether physician-owned physical therapy services violate Washington's corporate practice of medicine doctrine and the state's anti-rebating statute.

In addition, Ms. Studebaker represented the Washington Ambulatory Surgery Center Association before the Washington State Legislature on House Bill 1414, the bill introduced in 2014 to require state licensure of ambulatory surgery centers. She also represented the association in connection with the development of the regulations implementing the licensing law. This provides Ms. Studebaker with unique insight on the ambulatory surgery center licensing law and regulations, including the interpretation of both by the Washington State Department of Health.

Ms. Studebaker works with several medical specialty societies and currently serves as outside counsel to the Washington Ambulatory Surgery Center Association and Washington State Dental Association.

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BACKGROUND

The Washington State Department of Health adopted chapter 246-330 WAC to implement the ambulatory surgical facility ("ASF") Licensing Law, chapter 70.230 RCW, and establish minimum health and safety requirements for the licensing, inspection, operation, maintenance, and construction of ambulatory surgical facilities (the "ASF Licensing Regulations").[1]

The Department of Health conducts an on-site survey of each ASF every 18 months using the health and safety standards in chapter 70.230 RCW and the ASF Licensing Regulations.[2,3] In addition to conducting regular on-site surveys, the Department conducts an investigation of every complaint against an ASF that concerns patient well-being.[4]

Following each on-site survey and investigation, the Department notifies the ASF in writing of the survey findings.[5] The ASF then is required to submit to the Department a corrective action plan addressing each deficient practice identified in the survey findings.[6] The Department, in turn, is required to notify the ASF when its submitted plan of correction adequately addresses the survey findings.[7]

The Department may exempt an ASF from complying with portions of the ASF Licensing Regulations when: (i) the exemption will not change the purpose and intent of chapter 70.230 RCW or its implementing regulations; (ii) patient safety, health or well-

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[1]WAC 246-330-001.

[2]WAC 246-330-025(1)(a).

[3]As a substitute for the Department's 18-months on-site survey, on-site surveys conducted by The Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities or the Centers for Medicare and Medicaid Services may substitute for the state licensing survey requirement once every three years. WAC 246-330 -025(1)(b).

being is not threatened; (iii) fire and life safety regulations, infection control standards or other codes or regulations would not be reduced; and (iv) structural integrity of the building is not compromised.[8]

The Department may approve an ASF to use alternative materials, designs, and methods if the documentation and supporting information meets the intent and purpose of, and is equivalent to the methods prescribed in, the ASF Licensing Regulations.[9]

[4] WAC 246-330-025(2).
[5] WAC 246-330-025(1)(c); WAC 246-330-025(2)(b).
[6] WAC 246-330-025(1)(d); WAC 246-330-025(2)(c).
[7] WAC 246-330-025(1)(e); WAC 246-330-025(2)(d).
[8] WAC 246-330-035(1).
[9] WAC 246-330-035(3).

GOVERNANCE

The ASF Licensing Regulations outline the organizational guidance and oversight responsibilities of ASF resources and staff to support safe patient care.[10]

An ASF must have a governing authority that is responsible for determining, implementing, monitoring and revising policies and procedures covering the operation of the facility.[11] The policies and procedures must include:

- Selecting and periodically evaluating a chief executive officer or administrator;
- Appointing and periodically reviewing a medical staff;
- Approving the medical staff bylaws;
- Reporting practitioners according to RCW 70.230.120;
- Informing patients of any unanticipated outcomes according to RCW 70.230.150;
- Establishing and approving a coordinated quality performance improvement plan according to RCW 70.230.080;
- Establishing and approving a facility safety and emergency training program according to RCW 70.230.060;
- Reporting adverse events and conducting root cause analyses according to chapter 246-302 WAC;
- Providing a patient and family grievance process including a time frame for resolving each grievance according to RCW 70.230.080(1)(d);

[10] WAC 246-330-115.

[11] *Id.*

- Defining who can give and receive patient care orders that are consistent with professional licensing laws; and
- Defining who can authenticate written or electronic orders for all drugs, intravenous solutions, blood, and medical treatments that are consistent with professional licensing laws.[12]

Reporting Practitioners

The chief administrator or executive officer of an ASF must report to the Department of Health when the practice of a health care provider licensed by a disciplining authority under RCW 18.130.040 is restricted, suspended, limited, or terminated based upon a conviction, determination, or finding by the ASF that the provider has committed an action defined as unprofessional conduct under RCW 18.130.180.[13] The chief administrator or executive officer must also report any voluntary restriction or termination of the practice of a health care provider while the provider is under investigation or the subject of a proceeding by the ASF regarding unprofessional conduct, or in return for the ASF not conducting such an investigation or proceeding or not taking action.[14]

Reports must be made within 15 days of the date of: (a) a conviction, determination, or finding by the ASF that the health care provider has committed an action defined as unprofessional conduct; or (b) acceptance by the ASF of the voluntary restriction or termination of the practice of a health care provider, including his or her voluntary resignation, while under investigation or the subject of proceedings regarding unprofessional conduct.[15]

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[12] WAC 246-330-115.
[13] RCW 70.230.120(1).
[14] *Id*.
[15] RCW 70.230.120(2).

Failure of an ASF to comply with RCW 70.230.120 is punishable by a civil penalty up to $250.[16]

An ASF, its chief administrator, or its executive officer who files a report is immune from suit, whether direct or derivative, in any civil action related to the filing or contents of the report, unless the conviction, determination, or finding on which the report and its content are based is proven to not have been made in good faith.[17] The prevailing party in any action brought alleging that the conviction, determination, finding, or report was not made in good faith is entitled to recover the costs of litigation, including reasonable attorneys' fees.[18]

The Department must forward reports to the appropriate disciplining authority within 15 days of the date the report is received by the Department.[19] The Department must notify the ASF of the results of the disciplining authority's case disposition – the decision whether to issue a statement of charges, take informal action, or close the complaint without action against a provider – decision within 15 days after the case disposition.

Informing Patients of Unanticipated Outcomes

An ASF must have in place policies to assure that, when appropriate, information about unanticipated outcomes is provided to patients or their families or any surrogate decision makers identified pursuant to RCW 7.70.065.[20] Notifications of unanticipated outcomes under RCW 70.230.150 do not constitute an acknowledgment or admission of liability.[21] The fact of notification, the content disclosed, or any and all statements, affirmations, gestures, or

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[16] RCW 70.230.120(3).
[17] RCW 70.230.120(4).
[18] *Id.*
[19] RCW 70.230.120(5).
[20] RCW 70.230.150.
[21] *Id.*

conduct expressing apology may not be introduced as evidence in a civil action.[22]

Establishing and Approving a Coordinated Quality Performance Improvement Plan

An ASF must maintain a coordinated quality improvement program ("CQIP") for the improvement of the quality of health care services rendered to patients and the identification and prevention of medical malpractice.[23]

The program must include at least the following:

- The establishment of one or more quality improvement committees with the responsibility to review the services rendered in the ASF, both retrospectively and prospectively, in order to improve the quality of medical care of patients and to prevent medical malpractice. Different quality improvement committees may be established as a part of the CQIP to review different health care services. The committees must oversee and coordinate the quality improvement and medical malpractice prevention program and must ensure that information gathered pursuant to the program is used to review and to revise the policies and procedures of the ASF;

- A process, including a medical staff privileges sanction procedure which must be conducted substantially in accordance with medical staff bylaws and applicable rules, regulations, or policies of the medical staff through which credentials, physical and mental capacity, professional conduct, and competence in delivering health care services are periodically reviewed as part of an evaluation of staff privileges;

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[22] RCW 70.230.150.
[23] RCW 70.230.080(1).

- The periodic review of the credentials, physical and mental capacity, and competence in delivering health care services of all persons who are employed or associated with the ASF;

- A procedure for the prompt resolution of grievances by patients or their representatives related to accidents, injuries, treatment, and other events that may result in claims of medical malpractice;

- The maintenance and continuous collection of information concerning the ASF's experience with negative health care outcomes and incidents injurious to patients, patient grievances, professional liability premiums, settlements, awards, costs incurred by the ASF for patient injury prevention, and safety improvement activities;

- The maintenance of relevant and appropriate information concerning individual practitioners within the practitioner's personnel or credential file maintained by the ASF;

- Education programs dealing with quality improvement, patient safety, medication errors, injury prevention, staff responsibility to report professional misconduct, the legal aspects of patient care, improved communication with patients, and causes of malpractice claims for staff personnel engaged in patient care activities; and

- Policies to ensure compliance with the reporting requirements.[24]

Each quality improvement committee must, on at least a semiannual basis, report to the management of the ASF, as identified in the facility's application, in which the committee is located.[25] The

[24] RCW 70.230.080(1).
[25] RCW 70.230.080(4).

report must review the quality improvement activities conducted by the committee, and any actions taken as a result of those activities.[26]

Establishing and Approving a Facility Safety and Emergency Training Program

An ASF must have a facility safety and emergency training program.[27] The program must include on-site equipment, medication, and trained personnel to facilitate handling of services sought or provided and to facilitate the management of any medical emergency that may arise in connection with services sought or provided.[28] It also must include written transfer agreements with local hospitals licensed under chapter 70.41 RCW, approved by the ASF's medical staff.[29] In addition, the program must a procedural plan for handling medical emergencies that must be available for review during surveys and inspections.[30]

Reporting Adverse Events and Conducting Root Cause Analyses

An ASF must report confirmed adverse health events to the Department.

The ASF must notify the Department that an adverse health event has occurred within 48 hours of confirmation of the adverse health event.[31] The notification must include the name of the ASF, the date the adverse event was confirmed, the type of adverse health event, and any additional contextual information the ASF chooses to provide.[32]

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[26] RCW 70.230.080(4).
[27] RCW 70.230.060.
[28] RCW 70.230.060(1).
[29] RCW 70.230.060(2).
[30] RCW 70.230.060(3).
[31] WAC 246-302-020(1).
[32] *Id.*

The ASF must submit a report to the Department within 45 days of the confirmation of the adverse health event.[33] The report must include a root cause analysis and corrective action plan.[34] The root cause analysis must follow the procedures and methods of The Joint Commission or another nationally recognized root cause analysis methodology the Department has found acceptable for ASFs.[35]

The root cause analysis must include the following information:

- The findings regarding the root cause of the adverse health event;
- The number of patients, registered nurses, licensed practical nurses, and unlicensed assistive personnel present in the relevant patient care unit at the time the reported adverse health event occurred;
- The number of nursing personnel present at the time of the adverse health event who have been supplied by temporary staffing agencies, including traveling nurses; and
- The number of nursing personnel, if any, on the patient care unit working beyond their regularly scheduled number of consecutive hours worked by each such nursing personnel at the time of the adverse health event.[36]

The corrective action plan must be consistent with the findings of the root cause analysis and include:

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[33] RWAC 246-302-020(2).
[34] *Id.*
[35] WAC 246-302-020(2)(a).
[36] WAC 246-302-020(2)(b).

- How each finding will be addressed and corrected;
- When each correction will be completed;
- Who is responsible to make the corrections;
- What action will be taken to prevent the adverse health event from reoccurring; and
- A monitoring schedule to assess the effectiveness of the corrective action plan, including who is responsible for the monitoring schedule.[37]

If the ASF determines there is no need to create a corrective action plan for a particular adverse health event, the ASF must provide to the Department a written explanation of the reasons for not creating a corrective action plan.[38]

The ASF may amend the notification or report within sixty days of the submission.[39]

Providing a Patient and Family Grievance Process

An ASF must maintain a coordinated quality improvement program for the improvement of the quality of health care services rendered to patients and the identification and prevention of medical malpractice.[40] The program must include a procedure for the prompt resolution of grievances by patients or their representatives related to accidents, injuries, treatment, and other events that may result in claims of medical malpractice.[41]

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[37] WAC 246-302-020(2)(c).
[38] WAC 246-302-020(3).
[39] WAC 246-302-020(4).
[40] RCW 70.230.080(1).
[41] RCW 70.230.080(1)(d).

LEADERSHIP

The ASF Licensing Regulations describe an ASF leaderships' role in assuring care is provided consistently throughout the ASF according to patient needs.[42]

The ASF leaders must:

- Identify patient care responsibilities for all nursing personnel;
- Assure nursing services are provided in accordance with state nurse licensing law and recognized standards of practice;
- Assure a registered nurse is available for emergency treatment at all times a patient is present in the ASF;
- Establish and implement a facility-wide procedure for double-checking drugs, biologicals, and agents as designated by the ASF;
- Ensure immediate staff access to and appropriate dosages for emergency drugs;
- Require individuals conducting business in the ASF comply with facility policies and procedures;
- Post the complaint hotline notice according to RCW 70.230.160; and

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[42] WAC 246-330-120.

[43] "Abuse" is defined as an "injury or sexual abuse of a patient indicating the health, welfare, and safety of the patient is harmed". WAC 246-330-010(1). "Physical abuse" means "acts or incidents which may result in bodily injury or death." WAC 246-330-010(1)(a). "Emotional abuse" means "to impose willful or reckless mental or emotional anguish by threat, verbal behavior, harassment, or other verbal or nonverbal actions

- Adopt and implement policies and procedures to report suspected abuse[43] within 48 hours to local police or appropriate law enforcement agency according to RCW 26.44.030.[44]

Post Complaint Hotline Notice

An ASF must post in conspicuous locations a notice of the Department's ASF complaint toll-free telephone number.[45] The form of the notice shall be approved by the Department.[46]

Adopt and Implement Policies and Procedures to Report Suspected Abuse

When any practitioner has reasonable cause to believe that a child has suffered abuse or neglect, he or she shall report such incident, or cause a report to be made, to the proper law enforcement agency or to the Department.[47]

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which may result in emotional or behavioral stress or injury." WAC 246-330-010(1)(b).

[44] WAC 246-330-120.

[45] RCW 70.230.160.

[46] *Id.*

[47] RCW 26.44.030(1)(a).

PATIENT RIGHTS AND ORGANIZATIONAL ETHICS

The ASF Licensing Regulations require an ASF to respecting every patient and maintain ethical relationships with the public.[48]

An ASF must:

- Adopt and implement policies and procedures that define each patient's right to:
  - Be treated and cared for with dignity and respect;
  - Confidentiality, privacy, security, complaint resolution, spiritual care, and communication[49];
  - Be protected from abuse and neglect[50];
  - Access protective services;
  - Complain about their care and treatment without fear of retribution or denial of care;
  - Timely complaint resolution;
  - Be involved in all aspects of their care including:
    - Refusing care and treatment; and
    - Resolving problems with care decisions.
  - Be informed of unanticipated outcomes according to RCW 70.230.150;

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[48] WAC 246-330-125.

[49] If communication restrictions are necessary for patient care and safety, the facility must document and explain the restrictions to the patient and family.

[50] Under the ASF Licensing Regulations, "neglect" is defined as "mistreatment or maltreatment, a disregard of consequences constituting a clear and present danger to an individual patient's health, welfare, and safety." WAC 246-330-010(26). It includes "physical neglect", which means "physical or material deprivation, such as lack of medical care,

- Be informed and agree to their care; and
- Family input in care decisions, in compliance with existing legal directives of the patient or existing court-issued legal orders.

- Provide each patient a written statement of patient rights.
- Adopt and implement policies and procedures to address research, investigation, and clinical trials including:
  - How to authorize research;
  - Require staff to follow informed consent laws; and
  - Not hindering a patient's access to care if a patient refuses to participate.[51]

Informing Patients of Unanticipated Outcomes

An ASF must have in place policies to assure that, when appropriate, information about unanticipated outcomes is provided to patients or their families or any surrogate decision makers.[52] Notifications of unanticipated outcomes do not constitute an acknowledgment or admission of liability, nor may the fact of notification, the content disclosed, or any and all statements, affirmations, gestures, or conduct expressing apology be introduced as evidence in a civil action.[53]

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lack of supervision, inadequate food, clothing, or cleanliness." WAC 246-330-010(26)(b). It also includes "emotional neglect", which means "acts such as rejection, lack of stimulation, or other acts that may result in emotional or behavioral problems, physical manifestations, and disorders." WAC 246-330-010(26)(b).

[51] WAC 246-330-125.

[52] RCW 70.230.150.

[53] *Id*.

ADVERSE HEALTH EVENTS REPORTING REQUIREMENTS

The ASF Licensing Regulations require an ASF to report adverse health events to the Department and to comply with the requirements under chapter 246-302 WAC.[54]

An "adverse health event" is defined as the list of 29 serious reportable events updated and adopted by the National Quality Forum in 2011, in its consensus report on serious reportable events in health care including all appendices.[55] Among the adverse events are certain surgical or invasive procedure events, including the following:

- Surgery or other invasive procedure performed on the wrong site;
- Surgery or other invasive procedure performed on the wrong patient;
- Wrong surgical or other invasive procedure performed on a patient; and
- Unintended retention of a foreign object in a patient after surgery or other invasive procedure.[56]

The ASF must notify the Department that an adverse health event has occurred within 48 hours of confirmation of the adverse health event.[57] The notification must include the name of the ASF, the date the adverse event was confirmed, the type of adverse health event, and any additional contextual information the ASF chooses to provide.[58]

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[54] WAC 246-330-130.

[55] WAC 246-302-010(1).

[56] WAC 246-302-030(1).

[57] WAC 246-302-020(1).

[58] *Id*.

The ASF must submit a report to the Department within 45 days of the confirmation of the adverse health event.[59] The report must include a root cause analysis and corrective action plan.[60] The root cause analysis must follow the procedures and methods of The Joint Commission or another nationally recognized root cause analysis methodology the Department has found acceptable for ASFs.[61]

The root cause analysis must include the following information:

- The findings regarding the root cause of the adverse health event;
- The number of patients, registered nurses, licensed practical nurses, and unlicensed assistive personnel present in the relevant patient care unit at the time the reported adverse health event occurred;
- The number of nursing personnel present at the time of the adverse health event who have been supplied by temporary staffing agencies, including traveling nurses; and
- The number of nursing personnel, if any, on the patient care unit working beyond their regularly scheduled number of consecutive hours worked by each such nursing personnel at the time of the adverse health event.[62]

The corrective action plan must be consistent with the findings of the root cause analysis and include:

- How each finding will be addressed and corrected;
- When each correction will be completed;

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[59] WAC 246-302-020(2).
[60] *Id*.
[61] WAC 246-302-020(2)(a).
[62] WAC 246-302-020(2)(b).

- Who is responsible to make the corrections;
- What action will be taken to prevent the adverse health event from reoccurring; and
- A monitoring schedule to assess the effectiveness of the corrective action plan, including who is responsible for the monitoring schedule.[63]

If the ASF determines there is no need to create a corrective action plan for a particular adverse health event, the ASF must provide to the Department a written explanation of the reasons for not creating a corrective action plan.[64]

The ASF may amend the notification or report within sixty days of the submission.[65]

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[63] WAC 246-302-020(2)(c).

[64] WAC 246-302-020(3).

[65] WAC 246-302-020(4).

MANAGEMENT OF HUMAN RESOURCES

The ASF Licensing Regulations ensure that an ASF provides competent staff consistent with scope of services.[66]

An ASF must:

- Create and periodically review job descriptions for all staff;
- Supervise staff performance to assure competency;
- Verify and document licensure, certification, or registration of staff;
- Complete tuberculosis screening for new and current employees consistent with the *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Healthcare Facilities, 2005. Morbidity Mortality Weekly Report (MMWR) Volume 54*, December 30, 2005;
- Provide infection control information to staff upon hire and annually which includes:
- Education on general infection control according to chapter 296-823 WAC blood borne pathogens exposure control; and
- General and specific infection control measures related to patient care.
- Establish and implement an education plan that verifies staff training on prevention, transmission, and treatment of human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) consistent with RCW 70.24.310.[67]

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[66] WAC 246-330-140.

[67] *Id*.

MEDICAL STAFF

The ASF Licensing Regulations require development of a medical staff structure, consistent with clinical competence, to ensure a safe patient care environment.[68]

The medical staff must:

- Be accountable to the governing body;
- Adopt bylaws, rules, regulations, and organizational structure including an appointment and reappointment process;
- Be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges in accordance with recommendations from qualified medical personnel;
- Periodically review and reappraise medical staff privileges using peer review data;
- Periodically review and amend the scope of procedures performed in the ASF;
- If the ASF assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities; and
- Report practitioners for discipline of unprofessional conduct according to RCW 70.230.120.[69]

The chief administrator or executive officer of an ASF must report to the Department of Health when the practice of a health care provider licensed by a disciplining authority under RCW 18.130.040 is restricted, suspended, limited, or terminated based upon a con-

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[68] WAC 246-330-145.

[69] *Id.*

viction, determination, or finding by the ASF that the provider has committed an action defined as unprofessional conduct under RCW 18.130.180.[70] The chief administrator or executive officer must also report any voluntary restriction or termination of the practice of a health care provider while the provider is under investigation or the subject of a proceeding by the ASF regarding unprofessional conduct, or in return for the ASF not conducting such an investigation or proceeding or not taking action.[71]

Reports must be made within 15 days of the date of: (a) a conviction, determination, or finding by the ASF that the health care provider has committed an action defined as unprofessional conduct; or (b) acceptance by the ASF of the voluntary restriction or termination of the practice of a health care provider, including his or her voluntary resignation, while under investigation or the subject of proceedings regarding unprofessional conduct.[72]

Failure of an ASF to comply with RCW 70.230.120 is punishable by a civil penalty up to $250.[73]

An ASF, its chief administrator, or its executive officer who files a report is immune from suit, whether direct or derivative, in any civil action related to the filing or contents of the report, unless the conviction, determination, or finding on which the report and its content are based is proven to not have been made in good faith.[74] The prevailing party in any action brought alleging that the conviction, determination, finding, or report was not made in good faith is entitled to recover the costs of litigation, including reasonable attorneys' fees.[75]

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[70] RCW 70.230.120(1).
[71] *Id*.
[72] RCW 70.230.120(2).
[73] RCW 70.230.120(3).
[74] RCW 70.230.120(4).
[75] *Id*.

The Department must forward reports to the appropriate disciplining authority within 15 days of the date the report is received by the Department.[76] The Department must notify the ASF of the results of the disciplining authority's case disposition – the decision whether to issue a statement of charges, take informal action, or close the complaint without action against a provider – decision within 15 days after the case disposition.

[76] RCW 70.230.120(5).

MANAGEMENT OF INFORMATION

The ASF Licensing Regulations are designed to improve patient outcomes and ASF performance through obtaining, managing, and use of information.[77]

An ASF must:

- Provide medical staff, employees and other authorized persons with access to patient information systems, resources, and services;
- Maintain confidentiality, security, and integrity of information;
- Initiate and maintain a medical record for every patient assessed or treated including a process to review records for completeness, accuracy, and timeliness;
- Create medical records that:
  - Identify the patient;
  - Have clinical data to support the diagnosis, course and results of treatment for the patient;
  - Have signed consent documents;
  - Promote continuity of care;
  - Have accurately written, signed, dated, and timed entries;
  - Indicates authentication after the record is transcribed;
  - Are promptly filed, accessible, and retained according to facility policy; and
  - Include verbal orders that are accepted and transcribed

[77] WAC 246-330-150.

by qualified personnel.

- Establish a systematic method for identifying each medical record, identification of service area, filing, and retrieval of all patient's records; and
- Adopt and implement policies and procedures that address:
  - Who has access to and release of confidential medical records according to the Uniform Health Care Information Act, chapter 70.02 RCW;
  - Retention and preservation of medical records;
  - Transmittal of medical data to ensure continuity of care; and
  - Exclusion of clinical evidence[78] from the medical record.[79]

[78] "Clinical evidence" means evidence used in diagnosing a patient's condition or assessing a clinical course and includes, but is not limited to X-ray films, digital records, laboratory slides, tissue specimens, or medical photographs. WAC 246-330-010(9).

[79] WAC 246-330-150.

COORDINATED QUALITY IMPROVEMENT PROGRAM

The ASF Licensing Regulations are designed to ensure the establishment and on-going maintenance of a coordinated quality improvement program.[80] The intent is to improve the quality of health care services provided to patients and to identify and prevent medical malpractice.

An ASF must have a facility-wide approach to process design and performance measurement, assessment, and improving patient care services according to RCW 70.230.080 including:

- A written performance improvement plan that is periodically evaluated;
- Performance improvement activities that are interdisciplinary and include at least one member of the governing authority;
- Prioritization of performance improvement activities;
- Implementation and monitoring of actions taken to improve performance;
- Education programs dealing with performance improvement, patient safety, medication errors, injury prevention; and
- Review of serious or unanticipated patient outcomes in a timely manner.[81]

The ASF must systematically collect, measure and assess data on processes and outcomes related to patient care and organization functions.[82] It must collect, measure and assess data including, but not limited to:

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[80] WAC 246-330-155.

[81] WAC 246-330-155(1).

[82] WAC 246-330-155(2).

- Operative, other invasive, and noninvasive procedures that place patients at risk;
- Infection rates, pathogen distributions and antimicrobial susceptibility profiles;
- Death;
- Medication management or administration related to wrong medication, wrong dose, wrong time, near misses and any other medication errors and incidents;
- Injuries, falls, restraint use, negative health outcomes and incidents injurious to patients in the ASF;
- Adverse events according to chapter 246-302 WAC;
- Discrepancies or patterns between preoperative and post-operative (including pathologic) diagnosis, including pathologic review of specimens removed during surgical or invasive procedures;
- Adverse drug reactions, as defined by the ASF;
- Confirmed transfusion reactions;
- Patient grievances, needs, expectations, and satisfaction; and
- Quality control and risk management activities.[83]

[83] WAC 246-330-155(2).

INFECTION CONTROL PROGRAM

The ASF Licensing Regulations identify and reduce the risk of acquiring and transmitting infections and communicable diseases between patients, staff, medical staff, and visitors.[84]

An ASF must develop, implement and maintain a written infection control and surveillance program.[85]

It must designate staff to manage the activities of the infection control program, assure the program conforms with patient care and safety policies and procedures, and provide consultation on the program, policies and procedures throughout the entire facility.[86] The ASF must also ensure staff managing the infection control program have a minimum of two years' experience in a health -related field and training in the principles and practices of infection control.[87]

The ASF develop and implement infection control policies and procedures consistent with the guidelines of the centers for disease control and prevention (CDC).[88] It must assure the infection control policies and procedures address, but are not limited to the following:

- Routine surveillance, outbreak investigations and interventions including pathogen distributions and antimicrobial susceptibility profiles consistent with the 2006 CDC health care infection control practices advisory committee guideline, Management of Multidrug-Resistant Organisms in Healthcare Settings;

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[84] WAC 246-330-176.
[85] WAC 246-330-176(1).
[86] WAC 246-330-176(2).
[87] WAC 246-330-176(3).
[88] WAC 246-330-176(4).

- Patient care practices in all clinical care areas;
- Receipt, use, disposal, sterilizing, processing, or reuse of equipment to prevent disease transmission;
- Preventing cross contamination of soiled and clean items during sorting, processing, transporting, and storage;
- Environmental management and housekeeping functions;
- Approving and properly using disinfectants, equipment, and sanitation procedures;
- Cleaning areas used for surgical procedures before, between, and after use;
- Facility-wide daily and periodic cleaning;
- Occupational health consistent with current practice;
- Clothing;
- Traffic patterns;
- Antisepsis;
- Handwashing;
- Scrub technique and surgical preparation;
- Biohazardous waste management according to applicable federal, state, and local regulations;
- Barrier, transmission and isolation precautions; and
- Pharmacy and therapeutics.[89]

In addition, the ASF must stablish and implement a plan for reporting communicable diseases including cluster or outbreaks of

[89] WAC 246-330-176(5).

postoperative infections according to chapter 246-100 WAC.[90] The plan must also provide for surveying and investigating communicable disease occurrences in the ASF consistent with chapter 246-100 WAC.[91] Finally, it must provide for collecting, measuring and assessing data on infection rates, pathogen distributions and antimicrobial susceptibility profiles.[92]

[90] WAC 246-330-176(6)(a).

[91] WAC 246-330-176(6)(b).

[92] WAC 246-330-176(6)(c).

PHARMACEUTICAL SERVICES

The ASF Licensing Regulations assures patient pharmaceutical needs are met in a planned and organized manner.[93]

An ASF must only administer, dispense or deliver legend drugs and controlled substances to patients receiving care in the facility.[94] It must assure drugs dispensed to patients are dispensed and labeled consistent with the requirements of RCW 18.64.246, and chapters 69.41 and 69.50 RCW.[95]

The ASF must also establish a process for selecting medications based on evaluating their relative therapeutic merits, safety, and cost.[96]

The ASF must designate a pharmacist consultant who is licensed in Washington state. The pharmacist consultant can be either employed or contracted by the facility.[97] The pharmacist consultant is responsible for:

- Establishing policy and procedures related to:
  - Purchasing, ordering, storing, compounding, delivering, dispensing and administering of controlled substances or legend drugs;
  - Assuring drugs are stored, compounded, delivered or dispensed according to all applicable state and federal rules and regulations;

[93] WAC 246-330-200.
[94] WAC 246-330-200(1).
[95] WAC 246-330-200(2).
[96] WAC 246-330-200(3).
[97] WAC 246-330-200(4).

- Maintaining accurate inventory records and patient medical records related to the administration of controlled substances and legend drugs;
- Maintaining any other records required by state and federal regulations;
- Security of legend drugs and controlled substances; and
- Controlling access to controlled substances and legend drugs.

- Establishing a process for completing all forms for the purchase and order of legend drugs and controlled substances; and
- Establishing a method for verifying receipt of all legend drugs and controlled substances purchased and ordered by the ASF.[98]

[98] WAC 246-330-200(4).

PATIENT CARE SERVICES

The ASF Licensing Regulations guide the development of a plan for patient care.[99] The ASF accomplishes this by supervising staff and by establishing, monitoring, and enforcing policies and procedures that define and outline the use of materials, resources, and promote the delivery of care.

An ASF must provide personnel, space, equipment, reference materials, training, and supplies for the appropriate care and treatment of patients.[100]

It also must have a registered nurse available for consultation in the ASF at all times patients are present.[101]

The ASF also must adopt, implement, review and revise patient care policies and procedures designed to guide staff that address:

- Criteria for patient admission;
- Reliable method for personal identification of each patient;
- Conditions that require patient transfer to outside facilities;
- Patient safety measures;
- Staff access to patient care areas;
- Use of physical and chemical restraints or seclusion consistent with C.F.R. 42.482;

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[99] WAC 246-330-205.

[100] WAC 246-330-205(1).

[101] WAC 246-330-205(2).

- Use of preestablished patient care guidelines or protocols.[102] When used, these must be documented in the medical record and be preapproved or authenticated by an authorized practitioner or advanced registered nurse practitioner;
- Care and handling of patients whose condition require special medical consideration;
- Preparation and administration of blood and blood products; and
- Discharge planning.[103]

The ASF must have a system to plan and document care in an interdisciplinary manner.[104] This must include development of an individualized patient plan of care, based on an initial assessment.[105] In addition, it must include an assessment for risk of falls, skin condition, pressure ulcers, pain, medication use, therapeutic effects and side or adverse effects.[106]

The ASF must complete and document an initial assessment of each patient's physical condition, emotional, and social needs in the medical record.[107] The initial assessment includes:

- Dependent upon the procedure and the risk of harm or injury, a patient history and physical assessment including but not limited to falls, mental status and skin condition;
- Current needs;
- Need for discharge planning;

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[102] "Protocols" means "a written or electronically recorded descriptions of actions and interventions for implementation by designated ambulatory surgical facility staff under defined circumstances recorded in policy and procedure." WAC 246-330-010(38).

[103] WAC 246-330-205(3).

[104] WAC 246-330-205(4).

- When treating pediatric patients, the immunization status;
- Physical examination, if within thirty days prior to admission, and updated as needed if patient status has changed; and
- Discharge plans when appropriate, coordinated with patient, family or caregiver and receiving agency, when necessary.[108]

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[105] *Id*. "Assessment" means (i) the systematic collection and review of patient-specific data; (ii) A process for obtaining appropriate and necessary information about individuals seeking entry into the ambulatory surgical facility or service; and (iii) information used to match an individual with an appropriate setting or intervention. WAC 246-330-010(6). The assessment is based on the patient's diagnosis, care setting, desire for care, response to any previous treatment, consent to treatment, and education needs. *Id*. .

[106] *Id*.

[107] WAC 246-330-205(5).

[108] *Id*.

SURGICAL SERVICES

The ASF Licensing Regulations guide the development and management of surgical services.[109]

An ASF must adopt and implement policies and procedures that:

- Identify areas where surgery and invasive procedures may be performed;
- Define staff access to areas where surgery and invasive procedures are performed;
- Identify practitioner and advanced registered nurse practitioner's privileges for operating room staff; and
- Define staff qualifications and oversight.[110]

The ASF must use facility policies and procedures which define standards of care.[111] Among these, the ASF must implement a system to identify and indicate the correct surgical site prior to beginning a surgical procedure.[112]

The ASF must provide emergency equipment, supplies, and services to surgical and invasive areas.[113] It also must provide separate refrigerated storage equipment with temperature alarms, when blood is stored in the surgical department.[114]

The ASF must assure a registered nurse qualified by training and experience functions as the circulating nurse in every operating room whenever deep sedation or general anesthesia are used during surgical procedures.[115]

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[109] WAC 246-330-210.

[110] WAC 246-330-210(1).

[111] WAC 246-330-210(2).

[112] WAC 246-330-210(3).

[113] WAC 246-330-210(4).

[114] WAC 246-330-210(5).

[115] WAC 246-330-210(6).

ANESTHESIA SERVICES

The ASF Licensing Regulations guide the management and care of patients receiving anesthesia and sedation.[116]

An ASF must adopt and implement policies and procedures that:

- Identify the types of anesthesia and sedation that may be used;
- Identify areas where each type of anesthesia and sedation may be used; and
- Define the staff qualifications and oversight for administering each type of anesthesia and sedation used in the facility.[117]

The ASF use facility policies and procedures which define standards of care.[118]

The ASF assure emergency equipment, supplies and services are immediately available in all areas where anesthesia is used.[119]

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[116] WAC 246-330-215.
[117] WAC 246-330-215(1).
[118] WAC 246-330-215(2).
[119] WAC 246-330-215(3).

RECOVERY CARE

The ASF Licensing Regulations guide the management of patients recovering from anesthesia and sedation.[120]

An ASF must adopt and implement policies and procedures that define the qualifications and oversight of staff delivering recovery services.[121]

The ASF must assure a physician or advanced registered nurse practitioner capable of managing complications and providing cardiopulmonary resuscitation is immediately available for patients recovering from anesthesia.[122] It must also assure a registered nurse trained and current in advanced cardiac life support measures is immediately available for patients recovering from anesthesia.[123]

[120] WAC 246-330-220.
[121] WAC 246-330-220(1).
[122] WAC 246-330-220(2).
[123] WAC 246-330-220(3).

EMERGENCY SERVICES

The ASF Licensing Regulations guide the management and care of patients receiving emergency services.[124]

An ASF must develop, implement and maintain a facility safety and emergency training program that includes:

- On-site equipment, medication and trained personnel to manage any medical emergency that may arise from the services provided or sought;
- A written and signed transfer agreement[125] with one or more local hospitals that has been approved by the ASF's medical staff;
- Policies and a procedural plan for handling medical emergencies; and
- Define the qualifications and oversight of staff delivering emergency care services.[126]

The ASF must assure at least one registered nurse skilled and trained in emergency care services on duty and in the ASF at all times a patient is present, who is immediately available to provide care and trained and current in advanced cardiac life support.[127]

The ASF must assure communication with agencies and health care providers as indicated by patient condition.[128]

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[124] WAC 246-330-225.

[125] "Transfer agreement" means a written agreement providing an effective process for the transfer of a patient requiring emergency services to a hospital providing emergency services and for continuity of care for that patient. WAC 246-330-010(49).

[126] WAC 246-330-225(1).

[127] WAC 246-330-225(2).

[128] WAC 246-330-225(3).

It also must assure emergency equipment, supplies and services necessary to meet the needs of patients are immediately available.[129]

[129] WAC 246-330-225(4).

MANAGEMENT OF ENVIRONMENT FOR CARE

The ASF Licensing Regulations set forth requirements to manage environmental hazards and risks, prevent accidents and injuries, and maintain safe conditions for patients, visitors, and staff.[130]

An ASF must create and follow an environment of care management plan that addresses safety, security, hazardous materials and waste, emergency preparedness, fire safety, medical equipment, utility systems and physical environment.[131]

An ASF must assure the environment of care management plan contains the following items:

Safety

- Policies and procedures on safety-related issues such as but not limited to physical hazards and injury prevention;
- Method to educate and periodically review with staff the safety policies and procedures;
- Process to investigate, correct and report safety-related incidents; and
- Process to keep the physical environment free of hazards.

Security

- Policies and procedures to protect patients, visitors, and staff while in the facility including preventing patient abduction;
- Method to educate and periodically review security policies and procedures with staff; and
- When the facility has security staff, train the security staff

[130] WAC 246-330-230.

[131] WAC 246-330-230(1).

to a level of skill and competency for their assigned responsibility.

Hazardous Materials and Waste

- Establish and implement a program to safely control hazardous materials and waste according to federal, state, and local regulations;
- Provide space and equipment for safe handling and storage of hazardous materials and waste;
- Process to investigate all hazardous material or waste spills, exposures, and other incidents, and report as required to appropriate authority; and
- Method to educate staff on hazardous materials and waste policies and procedures.

Emergency Preparedness

- Establish, implement and periodically review a disaster plan for internal and external disasters that is specific to the facility and community;
- Process to educate and train staff on the disaster plan;
- Process to periodically conduct drills to test the plan.

Fire Safety

- Policies and procedures on fire prevention and emergencies including an evacuation plan; and
- Process to orient, educate, and conduct drills with staff fire prevention, emergency and evacuation policies and procedures.

Medical Equipment

- Method to operate and maintain medical equipment properly, safely and according to manufacturer's recommendations;

- Perform and document preventive maintenance; and
- Process to investigate, report, and evaluate procedures in response to equipment failures.

Utility Systems

- Policies and procedures to operate and maintain a safe and comfortable environment; and
- Process to investigate and evaluate utility systems problems, failures, or user errors and report incidents.

Physical Environment

- Process to keep the physical environment clean including cleaning the operating room between surgical procedures;
- Provide hot and cold running water under pressure;
- Assure hot water for handwashing does not exceed 120°F;
- Assure cross connection controls meet the requirements of the state plumbing code; and
- Operate and maintain ventilation to prevent objectionable odors and excessive condensation.[132]

[132] WAC 246-330-230(2).